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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – I - PRINCIPLES OF BIOMEDICAL ENGINEERING – SBMA1102

I. INTRODUCTION

Evolution of modern health care system, Engineering in modern medicine, Role of Biomedical Engineering, Roles played by Biomedical Engineers, Professional status of Biomedical Engineering, History of Biomedical Devices.

1.1 EVOLUTION OF THE MODERN HEALTH CARE SYSTEM

Primitive humans considered diseases to be ‘‘visitations,’’ the whimsical acts of affronted gods or spirits. As a result, medical practice was the domain of the witch doctor and the medicine man and medicine woman. Yet even as magic became an integral part of the healing process, the cult and the art of these early practitioners were never entirely limited to the supernatural. These individuals, by using their natural instincts and learning from experience, developed a primitive science based on empirical laws. For example, through acquisition and coding of certain reliable practices, the arts of herb doctoring, bone setting, surgery, and midwifery were advanced. Just as primitive humans learned from observation that certain plants and grains were good to eat and could be cultivated, so the healers and shamans observed the nature of certain illnesses and then passed on their experiences to other generations. Evidence indicates that the primitive healer took an active, rather than a simply intuitive interest in the curative arts, acting as a surgeon and a user of tools. For instance, skulls with holes made in them by trephiners have been collected in various parts of Europe, Asia, and South America. These holes were cut out of the bone with flint instruments to gain access to the brain. Although one can only speculate the purpose of these early surgical operations, magic and religious beliefs seem to be the most likely reasons. Perhaps this procedure liberated from the skull the malicious demons that were thought to be the cause of extreme pain (as in the case of migraine) or attacks of falling to the ground (as in epilepsy). That this procedure was carried outon living patients, some of whom actually survived, is evident from the rounded edges on the bone surrounding the hole which indicate that the bone had grown again after the operation. These survivors also achieved a special status of sanctity so that, after their death, pieces of their skull were used as amulets to ward off convulsive attacks. From these beginnings, the practice of medicine has become integral to all human societies and cultures. It is interesting to note the fate of some of the most successful of these early practitioners.

The Egyptians, for example, have held Imhotep, the architect of the first pyramid (3000 BC), in great esteem through the centuries, not as a pyramid

builder, but as a doctor. Imhotep's name signified ''he who cometh in peace'' because he visited the sick to give them ''peaceful sleep.'' This early physician practiced his art so well that he was deified in the Egyptian culture as the god of healing. Egyptian mythology, like primitive religion, emphasized the interrelationships between the supernatural and one's health. For example, consider the mystic sign Rx, which still adorns all prescriptions today. It has a mythical origin in the legend of the Eye of Horus. It appears that as a child Horus lost his vision after being viciously attacked by Seth, the demon of evil. Then Isis, the mother of Horus, called for assistance to Thoth, the most important god of health, who promptly restored the eye and its powers. Because of this intervention, the Eye of Horus became the Egyptian symbol of godly protection and recovery, and its descendant, Rx, serves as the most visible link between ancient and modern medicine.

The concepts and practices of Imhotep and the medical cult he fostered were duly recorded on papyri and stored in ancient tombs. One scroll (dated c. 1500 BC), acquired by George Elbers in 1873, contains hundreds of remedies for numerous afflictions ranging from crocodile bite to constipation. A second famous papyrus (dated c. 1700 BC), discovered by Edwin Smith in 1862, is considered to be the most important and complete treatise on surgery of all antiquity. These writings outline proper diagnoses, prognoses, and treatment in a series of surgical cases. These two papyri are certainly among the outstanding writings in medical history. As the influence of ancient Egypt spread, Imhotep was identified by the Greeks with their own god of healing, Aesculapius. According to legend, the god Apollo fathered Aesculapius during one of his many earthly visits. Apparently Apollo was a concerned parent, and, as is the case for many modern parents, he wanted his son to be a physician. He made Chiron, the centaur, tutor Aesculapius in the ways of healing. Chiron's student became so proficient as a healer that he soon surpassed his tutor and kept people so healthy that he began to decrease the population of Hades. Pluto, the god of the underworld, complained so violently about this course of events that Zeus killed Aesculapius with a thunderbolt and in the process promoted Aesculapius to Olympus as a god. Inevitably, mythology has become entangled with historical facts, and it is not certain whether Aesculapius was in fact an earthly physician like Imhotep, the Egyptian. However, one thing is clear; by 1000 BC, medicine was already a highly respected profession. In Greece, the Aesculapia were temples of the healing cult and may be considered among the first hospitals (Fig.

1.1). In modern terms, these temples were essentially sanatoriums that had strong religious overtones.

In them, patients.

Fig: 1.1-Illustration of sick child brought into the temple of Aesculapius

were received and psychologically prepared, through prayer and sacrifice, to appreciate the past achievements of Aesculapius and his physician priests. After the appropriate rituals, they were allowed to enjoy ‘‘temple sleep.’’ During the night, ‘‘healers’’ visited their patients, administering medical advice to clients who were awake or interpreting dreams of those who had slept. In this way, patients became convinced that they would be cured by following the prescribed regimen of diet, drugs, or bloodletting. On the other hand, if they remained ill, it would be attributed to their lack of faith. With this approach, patients, not treatments, were at fault if they did not get well. This early use of the power of suggestion was effective then and is still important in medical treatment today. The notion of ‘‘healthy mind, healthy body’’ is still in vogue today. One of the most celebrated of these ‘‘healing’’ temples was on the island of Cos, the birthplace of Hippocrates, who as a youth became acquainted with the curative arts through his father, also a physician. Hippocrates was not so much an

innovative physician as a collector of all the remedies and techniques that existed up to that time. Since he viewed the physician as a scientist instead of a priest, Hippocrates also injected an essential ingredient into medicine: its scientific spirit. For him, diagnostic observation and clinical treatment began to replace superstition. Instead of blaming disease on the gods, Hippocrates taught that disease was a natural process, one that developed in logical steps, and that symptoms were reactions of the body to disease. The body itself, he emphasized, possessed its own means of recovery, and the function of the physician was to aid these natural forces. Hippocrates treated each patient as an original case to be studied and documented. His shrewd descriptions of diseases are models for physicians even today. Hippocrates and the school of Cos trained a number of individuals who then migrated to the corners of the Mediterranean world to practice medicine and spread the philosophies of their preceptor. The work of Hippocrates and the school and tradition that stem from him constitute the first real break from magic and mysticism and the foundation of the rational art of medicine. However, as a practitioner, Hippocrates represented the spirit, not the science, of medicine, embodying the good physician: the friend of the patient and the humane expert.

As the Roman Empire reached its zenith and its influence expanded across half the world, it became heir to the great cultures it absorbed, including their medical advances. Although the Romans themselves did little to advance clinical medicine (the treatment of the individual patient), they did make outstanding contributions to public health. For example, they had a well-organized army medical service, which not only accompanied the legions on their various campaigns to provide ‘‘first aid’’ on the battlefield but also established ‘‘base hospitals’’ for convalescents at strategic points throughout the empire. The construction of sewer systems and aqueducts were truly remarkable Roman accomplishments that provided their empire with the medical and social advantages of sanitary living. Insistence on clean drinking water and unadulterated foods affected the control and prevention of epidemics, and however primitive, made urban existence possible. Unfortunately, without adequate scientific knowledge about diseases, all the preoccupation of the Romans with public health could not avert the periodic medical disasters, particularly the plague, that mercilessly befell its citizens.

1.2 Engineering in modern medicine

Modern medical practice actually began at the turn of the twentieth century. Before 1900, medicine had little to offer the average citizen since its resources were mainly physicians, their education, and their little black bags. At this time physicians were in short supply, but for different reasons than exist today. Costs were minimal, demand small, and many of the services provided by the physician also could be obtained from experienced amateurs residing in the community. The individual's dwelling was the major site for treatment and recuperation, and relatives and neighbors constituted an able and willing nursing staff. Midwives delivered babies, and those illnesses not cured by home remedies were left to run their fatal course. Only in the twentieth century did the tremendous explosion in scientific knowledge and technology lead to the development of the American health care system with the hospital as its focal point and the specialist physician and nurse as its most visible operatives.

In the twentieth century, advances in the basic sciences (chemistry, physiology, pharmacology, and so on) began to occur much more rapidly. It was an era of intense interdisciplinary cross-fertilization. Discoveries in the physical sciences enabled medical researchers to take giant strides forward. For example, in 1903 William Einthoven devised the first electrocardiograph and measured the electrical changes that occurred during the beating of the heart. In the process, Einthoven initiated a new age for both cardiovascular medicine and electrical measurement techniques.

Of all the new discoveries that followed one another like intermediates in a chain reaction, the most significant for clinical medicine was the development of x-rays. When W.K. Roentgen described his ''new kinds of rays,'' the human body was opened to medical inspection. Initially these x-rays were used in the diagnosis of bone fractures and dislocations. In the United States, x-ray machines brought this modern technology to most urban hospitals. In the process, separate departments of radiology were established, and the influence of their activities spread, with almost every department of medicine (surgery, gynecology, and so forth) advancing with the aid of this new tool. By the 1930s, x-ray visualization of practically all the organ systems of the body was possible by the use of barium salts and a wide variety of radiopaque materials.

The power this technological innovation gave physicians was enormous. The x-ray permitted them to diagnose a wide variety of diseases and injuries accurately.

In addition, being within the hospital, it helped trigger the transformation of the hospital from a passive receptacle for the sick poor to an active curative institution for all citizens of the American society

The introduction of sulfanilamide in the mid-1930s and penicillin in the early 1940s significantly reduced the main danger of hospitalization: cross infection among patients. With these new drugs in their arsenals, surgeons were able to perform their operations without prohibitive morbidity and mortality due to infection. Also consider that, even though the different blood groups and their incompatibility were discovered in 1900 and sodium citrate was used in 1913 to prevent clotting, the full development of blood banks was not practical until the 1930s when technology provided adequate refrigeration. Until that time, ‘‘fresh’’ donors were bled, and the blood was transfused while it was still warm.

As technology in the United States blossomed so did the prestige of American medicine. From 1900 to 1929 Nobel Prize winners in physiology or medicine came primarily from Europe, with no American among them. In the period 1930 to 1944, just before the end of World War II, seven Americans were honored with this award. During the post-war period of 1945 to 1975, 37 American life scientists earned similar honors, and from 1975–2003, the number was 40. Thus, since 1930 a total of 79 American scientists have performed research significant enough to warrant the distinction of a Nobel Prize. Most of these efforts were made possible by the technology (Fig. 1.2) available to these clinical scientists.

The employment of the available technology assisted in advancing the development of complex surgical procedures (Fig. 1.4). The Drinker respirator was introduced in 1927 and the first heart–lung bypass in 1939. In the 1940s, cardiac catheterization and angiography (the use of a cannula threaded through an arm vein

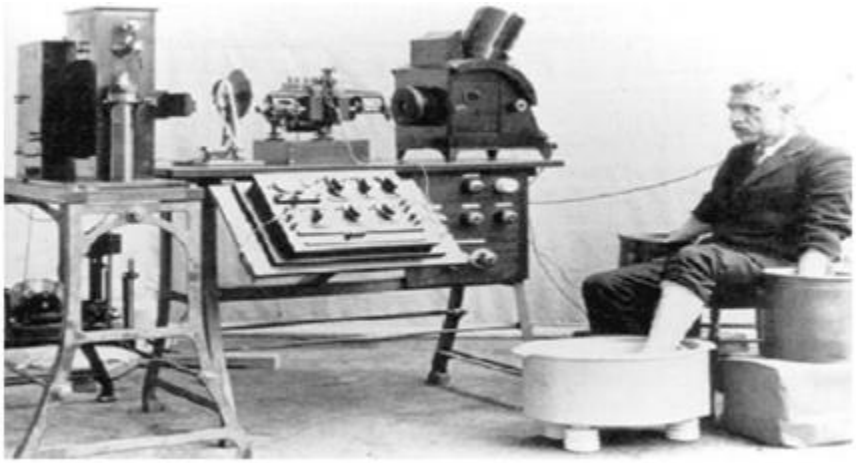

Fig: 1.2-Photograph depicting an early electrocardiograph machine

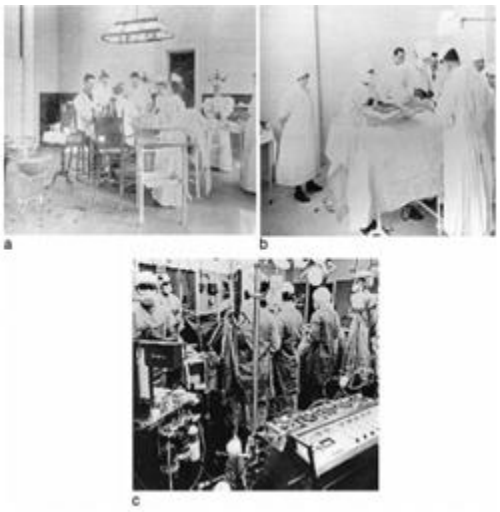

Fig:1.3- Changes in the operating room(a)the surgical scene at the turm of the century, (b) the surgical scene in the late 1920s and early 1930s, (c)the surgical scene today

and into the heart with the injection of radiopaque dye for the x-ray visualization of lung and heart vessels and valves) were developed. Accurate diagnoses of congenital and acquired heart disease (mainly valve disorders due to rheumatic fever) also became possible, and a new era of cardiac and vascular surgery began.

Another child of this modern technology, the electron microscope, entered the medical scene in the 1950s and provided significant advances in visualizing relatively small cells. Body scanners to detect tumors arose from the same science that brought societies reluctantly into the atomic age. These ‘‘tumor detectives’’ used radioactive material and became commonplace in newly established departments of nuclear medicine in all hospitals. The impact of these discoveries and many others was profound. The health care system that consisted primarily of the ‘‘horse and buggy’’ physician was gone forever, replaced by the doctor backed by and centered around the hospital, as medicine began to change to accommodate the new technology. Following World War II, the evolution of comprehensive care greatly accelerated. The advanced technology that had been developed in the pursuit of military objectives now became available for peaceful applications with the medical profession benefiting greatly from this rapid surge of technological finds. For instance, the realm of electronics came into prominence. The techniques for following enemy ships and planes, as well as providing aviators with information concerning altitude, air speed, and the like, were now used extensively in medicine to follow the subtle electrical behavior of the fundamental unit of the central nervous system, the neuron, or to monitor the beating heart of a patient.

Science and technology have leap-frogged past one another throughout recorded history. Anyone seeking a causal relation between the two was just as likely to find technology the cause and science the effect as to find science the cause and technology the effect. As gunnery led to ballistics, and the steam engine to thermodynamics, so powered flight led to aerodynamics. However, with the advent of electronics this causal relation between technology and science changed to a systematic exploitation of scientific research and the pursuit of knowledge that was undertaken with technical uses in mind.

The list becomes endless when one reflects upon the devices produced by the same technology that permitted humans to stand on the moon. What was considered science fiction in the 1930s and the 1940s became reality. Devices continually changed to incorporate the latest innovations, which in many cases became outmoded in a very short period of time. Telemetry devices used to monitor the activity of a patient’s heart freed both the physician and the patient from the wires that previously restricted them to the four walls of the hospital room. Computers, similar to those that controlled the flight plans of the Apollo capsules, now completely inundate our society. Since the 1970s, medical

researchers have put these electronic brains to work performing complex calculations, keeping records (via artificial intelligence), and even controlling the very instrumentation that sustains life. The development of new medical imaging techniques (Fig. 1.5) such as computerized tomography (CT) and magnetic resonance imaging (MRI) totally depended on a continually advancing computer technology. The citations and technological discoveries are so myriad it is impossible to mention them all.

‘‘Spare parts’’ surgery is now routine. With the first successful transplantation of a kidney in 1954, the concept of artificial organs gained acceptance and officially came into vogue in the medical arena (Fig. 1.6). Technology to provide prosthetic devices such as artificial heart valves and artificial blood vessels developed. Even an artificial heart program to develop a replacement for a defective or diseased human heart began. Although, to date, the results have not been satisfactory, this program has provided ‘‘ventricular assistance’’ for those who need it. These technological innovations radically altered surgical organization and utilization. The comparison of a hospital in which surgery was a relatively minor activity as it was a century ago to the contemporary hospital in which surgery plays a prominent role dramatically suggests the manner in which this technological effort has revolutionized the health profession and the institution of the hospital.

Through this evolutionary process, the hospital became the central institution that provided medical care. Because of the complex and expensive technology that could be based only in the hospital and the education of doctors oriented both as clinicians and investigators toward highly technological norms, both the patient And the physician were pushed even closer to this center of attraction. In addition, the effects of the increasing maldistribution and apparent shortage of physicians during the 1950s and 1960s also forced the patient and the physician to turn increasingly to the ambulatory clinic and the emergency ward of the urban hospital in time of need.

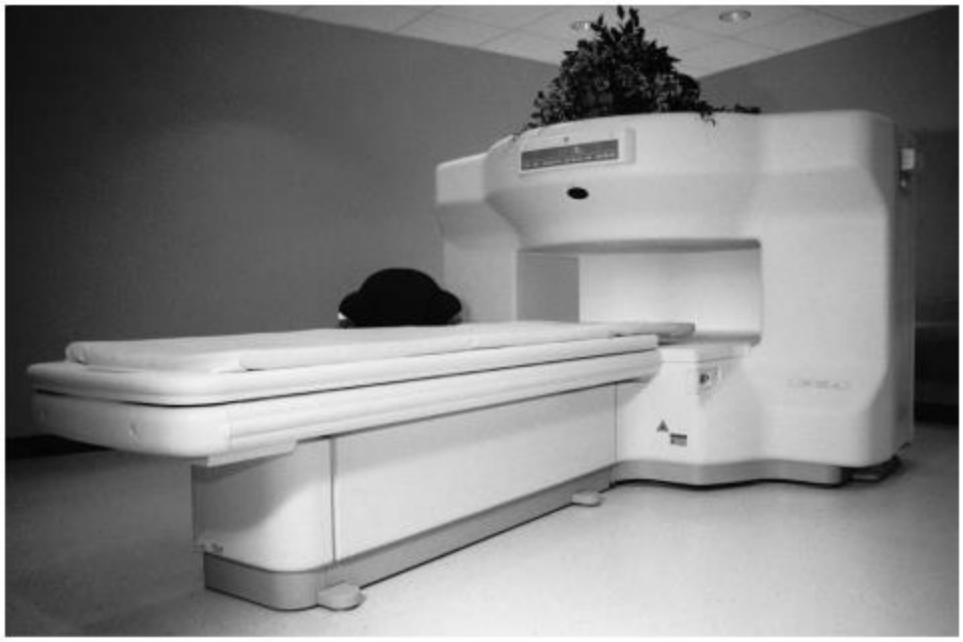

Fig:1.4 Photograph of a modern medical imaging facility

Emergency wards today handle not only an ever-increasing number of accidents (largely related to alcohol and the automobile) and somatic crises such as heart attacks and strokes, but also problems resulting from the social environments that surround the local hospital. Respiratory complaints, cuts, bumps, and minor trauma constitute a significant number of the cases seen in a given day. Added to these individuals are those who live in the neighborhood of the hospital and simply cannot afford their own physician. Often such individuals enter the emergency ward for routine care of colds, hangovers, and even marital problems. Because of these developments, the hospital has evolved as the focal point of the present system of health care delivery. The hospital, as presently organized, specializes in highly technical and complex medical procedures. This evolutionary process became inevitable as technology produced increasingly sophisticated equipment that private practitioners or even large group practices were economically unequipped to acquire and maintain. Only the hospital could provide this type of service. The steady expansion of scientific and technological innovations has not only necessitated specialization for all health professionals (physicians, nurses, and technicians) but has also required the housing of advanced technology within the walls of the modern hospital.

1.3 ROLE OF BIOMEDICAL ENGINEERING

Many of the problems confronting health professionals today are of extreme importance to the engineer because they involve the fundamental aspects of device and systems analysis, design, and practical application—all of which lie at the heart of processes that are fundamental to engineering practice. These medically relevant design problems can range from very complex large-scale constructs, such as the design and implementation of automated clinical laboratories, multiphasic screening facilities (i.e., centers that permit many tests to be conducted), and hospital information systems, to the creation of relatively small and simple devices, such as recording electrodes and transducers that may be used to monitor the activity of specific physiological processes in either a research or clinical setting. They encompass the many complexities of remote monitoring and telemetry and include the requirements of emergency vehicles, operating rooms, and intensive care units. The American health care system, therefore, encompasses many problems that represent challenges to certain members of the engineering profession called biomedical engineers. Since biomedical engineering involves applying the concepts, knowledge, and approaches of virtually all engineering disciplines (e.g., electrical, mechanical, and chemical engineering) to solve specific health care related problems, the opportunities for interaction between engineers and health care professionals are many and varied. Biomedical engineers may become involved, for example, in the design of a new medical imaging modality or development of new medical prosthetic devices to aid people with disabilities. Although what is included in the field of biomedical engineering is considered by many to be quite clear, many conflicting opinions concerning the field can be traced to disagreements about its definition. For example, consider the terms biomedical engineering, bioengineering, biological engineering, and clinical (or medical) engineer, which are defined in the Bioengineering Education Directory. Although Pacela defined bioengineering as the broad umbrella term used to describe this entire field, bioengineering is usually defined as a basic-research-oriented activity closely related to biotechnology and genetic engineering, that is, the modification of animal or plant cells or parts of cells to improve plants or animals or to develop new microorganisms for beneficial ends. In the food industry, for example, this has meant the improvement of strains of yeast for fermentation. In agriculture, bioengineers may be concerned with the improvement of crop yields by treating plants with organisms to reduce frost damage. It is clear that bioengineers for the future will have tremendous impact on the quality of human life. The full

potential of this specialty is difficult to imagine. Typical pursuits include the following:

- Development of improved species of plants and animals for food production
- Invention of new medical diagnostic tests for diseases
- Production of synthetic vaccines from clone cells
- Bioenvironmental engineering to protect human, animal, and plant life from toxicants and pollutants
- Study of protein-surface interactions
- Modeling of the growth kinetics of yeast and hybridoma cells
- Research in immobilized enzyme technology
- Development of therapeutic proteins and monoclonal antibodies

The term biomedical engineering appears to have the most comprehensive meaning. Biomedical engineers apply electrical, chemical, optical, mechanical, and other engineering principles to understand, modify, or control biological (i.e., human and animal) systems. Biomedical engineers working within a hospital or clinic are more properly called clinical engineers, but this theoretical distinction is not always observed in practice, and many professionals working within U.S. hospitals today continue to be called biomedical engineers.

The breadth of activity of biomedical engineers is significant. The field has moved from being concerned primarily with the development of medical devices in the 1950s and 1960s to include a more wide-ranging set of activities

These areas include

- Application of engineering system analysis (physiologic modeling, simulation, and control to biological problems
- Detection, measurement, and monitoring of physiologic signals (i.e., biosensors and biomedical instrumentation)
- Diagnostic interpretation via signal-processing techniques of bioelectric data
- Therapeutic and rehabilitation procedures and devices (rehabilitation engineering)
- Devices for replacement or augmentation of bodily functions (artificial organs) & Computer analysis of patient-related data and clinical decision making (i.e., medical informatics and artificial intelligence)
- Medical imaging; that is, the graphical display of anatomic detail or physiologic function

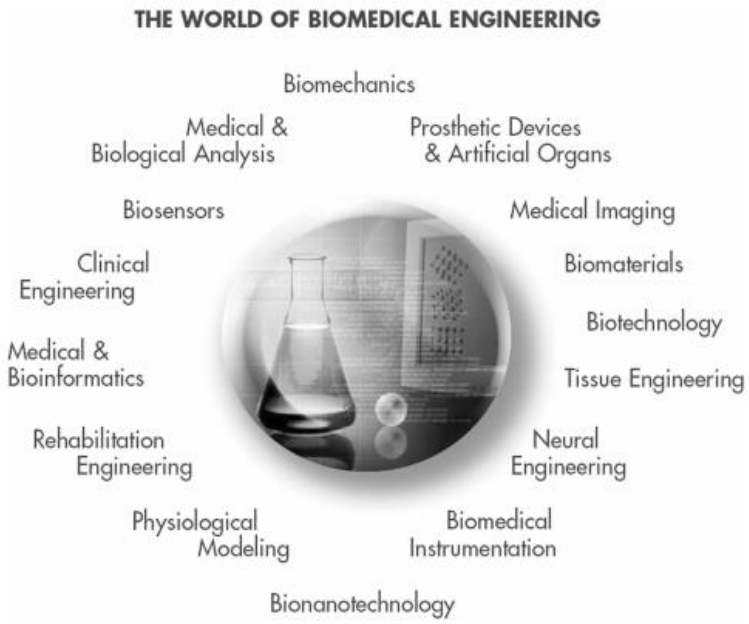

Fig:1.5: The world of biomedical engineering.

Typical pursuits of biomedical engineers include

- Research in new materials for implanted artificial organs
- Development of new diagnostic instruments for blood analysis
- Writing software for analysis of medical research data
- Analysis of medical device hazards for safety and efficacy
- Development of new diagnostic imaging systems
- Design of telemetry systems for patient monitoring
- Design of biomedical sensors
- Development of expert systems for diagnosis and treatment of diseases
- Design of closed-loop control systems for drug administration
- Modelling of the physiologic systems of the human body
- Design of instrumentation for sports medicine
- Development of new dental materials
- Design of communication aids for individuals with disabilities
- Study of pulmonary fluid dynamics
- Study of biomechanics of the human body
- Development of material to be used as replacement for human skin

The preceding list is not intended to be all-inclusive. Many other applications use the talents and skills of the biomedical engineer. In fact, the list of biomedical engineers' activities depends on the medical environment in which they work. This is especially true for clinical engineers, biomedical engineers employed in hospitals or clinical settings. Clinical engineers are essentially responsible for all the high-technology instruments and systems used in hospitals today; for the training of medical personnel in equipment safety; and for the design, selection, and use of technology to deliver safe and effective health care.

Engineers were first encouraged to enter the clinical scene during the late 1960s in response to concerns about the electrical safety of hospital patients. This safety scare reached its peak when consumer activists, most notably Ralph Nader, claimed that ''at the very least, 1,200 Americans are electrocuted annually during routine diagnostic and therapeutic procedures in hospitals.'' This concern was based primarily on the supposition that catheterized patients with a low-resistance conducting pathway from outside the body into blood vessels near the heart could be electrocuted by voltage differences well below the normal level of sensation. Despite the lack of statistical evidence to substantiate these claims, this outcry served to raise the level of consciousness of health care professionals with respect to the safe use of medical devices.

In response to this concern, a new industry—hospital electrical safety—arose almost overnight. Organizations such as the National Fire Protection Association (NFPA) wrote standards addressing electrical safety in hospitals. Electrical safety analyzer manufacturers and equipment safety consultants became eager to serve the needs of various hospitals that wanted to provide a ''safety fix,'' and some companies developed new products to ensure patient safety, particularly those specializing in power distribution systems (most notably isolation transformers). To alleviate these fears, the Joint Commission on the Accreditation of Healthcare Organizations (then known as the Joint Commission on Accreditation of Hospitals) turned to NFPA codes as the standard for electrical safety and further specified that hospitals must inspect all equipment used on or near a patient for electrical safety at least every six months. To meet this new requirement hospital administrators considered a number of options, including: (1) paying medical device manufacturers to perform these electrical safety inspections, (2) contracting for the services of shared-services organizations, or (3) providing these services with in-house staff. When faced with this decision, most large hospitals opted for in-house service and created whole departments to provide the technological support necessary to address these electrical safety concerns.

As a result, a new engineering discipline—clinical engineering—was born. Many hospitals established centralized clinical engineering departments. Once these departments were in place, however, it soon became obvious that electrical safety failures represented only a small part of the overall problem posed by the presence of medical equipment in the clinical environment. At the time, this equipment was neither totally understood nor properly maintained. Simple visual inspections often revealed broken knobs, frayed wires, and even evidence of liquid spills. Many devices did not perform in accordance with manufacturers' specifications and were not maintained in accordance with manufacturers' recommendations. In short, electrical safety problems were only the tip of the iceberg. By the mid-1970s, complete performance inspections before and after equipment use became the norm and sensible inspection procedures were developed. In the process, these clinical engineering pioneers began to play a more substantial role within the hospital. As new members of the hospital team, they

- Became actively involved in developing cost-effective approaches for using medical technology
- Provided advice to hospital administrators regarding the purchase of medical equipment based on its ability to meet specific technical specifications
- Started utilizing modern scientific methods and working with standards-writing organizations
- Became involved in the training of health care personnel regarding the safe and efficient use of medical equipment.
- Then, during the 1970s and 1980s, a major expansion of clinical engineering occurred, primarily due to the following events:
- The Veterans' Administration (VA), convinced that clinical engineers were vital to the overall operation of the VA hospital system, divided the country into biomedical engineering districts, with a chief biomedical engineer overseeing all engineering activities in the hospitals in that district.
- Throughout the United States, clinical engineering departments were established in most large medical centres and hospitals and in some smaller clinical facilities with at least 300 beds.
- Health care professionals (i.e., physicians and nurses) needed assistance in utilizing existing technology and incorporating new innovations.
- Certification of clinical engineers became a reality to ensure the continued competence of practicing clinical engineers.

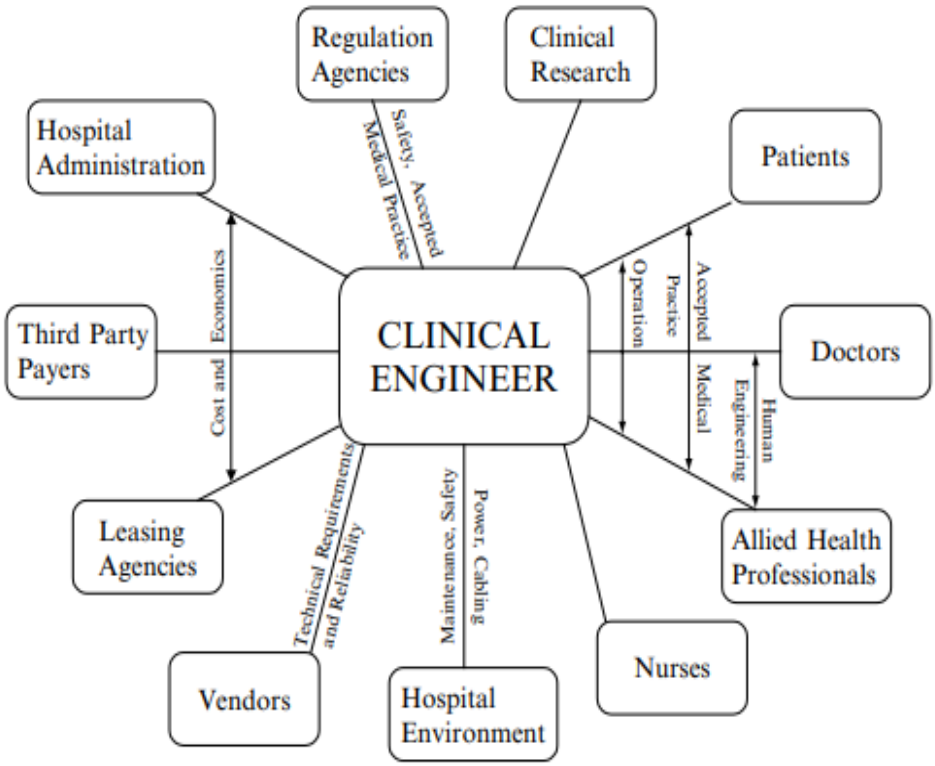

Fig: 1.6-The range of interactions with clinical engineers in a hospital setting

encompasses the entire field. As a result, there has been an explosion of biomedical engineering specialists to cover this broad spectrum of activity. Yet, because of the interdisciplinary nature of this activity, there is considerable interplay and overlapping of interest and effort between them. For example, biomedical engineers engaged in the development of biosensors may interact with those interested in prosthetic devices to develop a means to detect and use the same bioelectric signal to power a prosthetic device. Those engaged in automating the clinical chemistry laboratory may collaborate with those developing expert systems to assist clinicians in making clinical decisions based on specific laboratory data. The possibilities are endless.

Perhaps a greater potential benefit occurring from the utilization of biomedical engineers is the identification of problems and needs of our present health care

delivery system that can be solved using existing engineering technology and systems methodology. Consequently, the field of biomedical engineering offers hope in the continuing battle to provide high-quality health care at a reasonable cost. If properly directed towards solving problems related to preventive medical approaches, ambulatory care services, and the like, biomedical engineers can provide the tools and techniques to make our health care system more effective and efficient.

1.4 ROLES PLAYED BY BIOMEDICAL ENGINEERS

In its broadest sense, biomedical engineering involves training essentially three types of individuals: (1) the clinical engineer in health care, (2) the biomedical design engineer for industry, and (3) the research scientist. Currently, one might also distinguish among three specific roles these biomedical engineers can play. Each is different enough to merit a separate description. The first type, the most common, might be called the ‘‘problem solver.’’ This biomedical engineer (most likely the clinical engineer or biomedical design engineer) maintains the traditional service relationship with the life scientists who originate a problem that can be solved by applying the specific expertise of the engineer. For this problem-solving process to be efficient and successful, however, some knowledge of each other’s language and a ready interchange of information must exist. Biomedical engineers must understand the biological situation to apply their judgment and contribute their knowledge toward the solution of the given problem as well as to defend their methods in terms that the life scientist can understand. If they are unable to do these things, they do not merit the ‘‘biomedical’’ appellation.

The second type, which is more rare, might be called the ‘‘technological entrepreneur’’ (most likely a biomedical design engineer in industry). This individual assumes that the gap between the technological education of the life scientist or physician and present technological capability has become so great that the life scientist cannot pose a problem that will incorporate the application of existing technology. Therefore, technological entrepreneurs examine some portion of the biological or medical front and identify areas in which advanced technology might be advantageous. Thus, they pose their own problem and then proceed to provide the solution, at first conceptually and then in the form of hardware or software. Finally, these individuals must convince the medical community that they can provide a useful tool because, contrary to the situation in which problem solvers find themselves, the entrepreneur’s activity is speculative at best and has no ready-made customer for the results. If the venture is

successful, however, whether scientifically or commercially, then an advance has been made much earlier than it would have been through the conventional arrangement. Because of the nature of their work, technological entrepreneurs should have a great deal of engineering and medical knowledge as well as experience in numerous medical systems.

The third type of biomedical engineer, the ‘‘engineer–scientist’’ (most likely found in academic institutions and industrial research labs), is primarily interested in applying engineering concepts and techniques to the investigation and exploration of biological processes. The most powerful tool at their disposal is the construction of an appropriate physical or mathematical model of the specific biological system under study. Through simulation techniques and available computing machinery, they can use this model to understand features that are too complex for either analytical computation or intuitive recognition. In addition, this process of simulation facilitates the design of appropriate experiments that can be performed on the actual biological system. The results of these experiments can, in turn, be used to amend the model.

Thus, increased understanding of a biological mechanism results from this iterative process. This mathematical model can also predict the effect of these changes on a biological system in cases where the actual experiments may be tedious, very difficult, or dangerous. The researchers are thus rewarded with a better understanding of the biological system, and the mathematical description forms a compact, precise language that is easily communicated to others. The activities of the engineer–scientist inevitably involve instrument development because the exploitation of sophisticated measurement techniques is often necessary to perform the biological side of the experimental work. It is essential that engineer–scientists work in a biological environment, particularly when their work may ultimately have a clinical application. It is not enough to emphasize the niceties of mathematical analysis while losing the clinical relevance in the process. This biomedical engineer is a true partner of the biological scientist and has become an integral part of the research teams being formed in many institutes to develop techniques and experiments that will unfold the mysteries of the human organism. Each of these roles envisioned for the biomedical engineer requires a different attitude, as well as a specific degree of knowledge about the biological environment. However, each engineer must be a skilled professional with a significant expertise in engineering technology. Therefore, in preparing new professionals to enter this field at these various levels, biomedical

engineering educational programs are continually being challenged to develop curricula that will provide an adequate exposure to and knowledge about the environment, without sacrificing essential engineering skills. As we continue to move into a period characterized by a rapidly growing aging population, rising social and economic expectations, and a need for the development of more adequate techniques for the prevention, diagnosis, and treatment of disease, development and employment of biomedical engineers have become a necessity. This is true not only because they may provide an opportunity to increase our knowledge of living systems, but also because they constitute promising vehicles for expediting the conversion of knowledge to effective action.

The ultimate role of the biomedical engineer, like that of the nurse and physician, is to serve society. This is a profession, not just a skilled technical service. To use this new breed effectively, health care practitioners and administrators should be aware of the needs for these new professionals and the roles for which they are being trained. The great potential, challenge, and promise in this endeavor offer not only significant technological benefits but also humanitarian benefits.

1.5 PROFESSIONAL STATUS OF BIOMEDICAL ENGINEERING

Biomedical engineers are professionals. Professionals have been defined as an aggregate of people finding identity in sharing values and skills absorbed during a common course of intensive training. Whether individuals are professionals is determined by examining whether or not they have internalized certain given professional values. Furthermore, a professional is someone who has internalized professional values and is licensed on the basis of his or her technical competence. Professionals generally

accept scientific standards in their work, restrict their work activities to areas in which they are technically competent, avoid emotional involvement, cultivate objectivity in their work, and put their clients' interests before their own. The concept of a profession that is involved in the design, development, and management of medical technology encompasses three primary occupational models: science, business, and profession. Consider initially the contrast between science and profession. Science is seen as the pursuit of knowledge, its value hinging on providing evidence and communicating with colleagues. Profession, on the other hand, is viewed as providing a service to clients who have problems

they cannot handle themselves. Scientists and professionals have in common the exercise of some knowledge, skill, or expertise. However, while scientists practice their skills and report their results to knowledgeable colleagues, professionals such as lawyers, physicians, and engineers serve lay clients. To protect both the professional and the client from the consequences of the layperson's lack of knowledge, the practice of the profession is often regulated through such formal institutions as state licensing. Both professionals and scientists must persuade their clients to accept their findings. Professionals endorse and follow a specific code of ethics to serve society. On the other hand, scientists move their colleagues to accept their findings through persuasion.

Consider, for example, the medical profession. Its members are trained in caring for the sick, with the primary goal of healing them. These professionals not only have a responsibility for the creation, development, and implementation of that tradition, but they are also expected to provide a service to the public, within limits, without regard to self-interest. To ensure proper service, the profession closely monitors the licensing and certification process. Thus, medical professionals themselves may be regarded as a mechanism of social control. However, this does not mean that other facets of society are not involved in exercising oversight and control of physicians in their practice of medicine.

A final attribute of professionals is that of integrity. Physicians tend to be both permissive and supportive in relationships with patients and yet are often confronted with moral dilemmas involving the desires of their patients and social interest. For example, how to honor the wishes of terminally ill patients while not facilitating the patients' deaths is a moral question that health professionals are forced to confront

One can determine the status of professionalization by noting the occurrence of six crucial events: (1) the first training school; (2) the first university school; (3) the first local professional association; (4) the first national professional association; (5) the first state license law; and (6) the first formal code of ethics.

The early appearances of the training school and the university affiliation underscore the importance of the cultivation of a knowledge base. The strategic innovative role of the universities and early teachers lies in linking knowledge to practice and creating a rationale for exclusive jurisdiction. Those practitioners

pushing for prescribed training then form a professional association. The association defines the tasks of the profession: raising the quality of recruits; redefining their function to permit the use of less technically skilled people to perform the more routine, less involved tasks; and managing internal and external conflicts. In the process, internal conflict may arise between those committed to previously established procedures and newcomers committed to change and innovation. At this stage, some form of professional regulation, such as licensing or certification, surfaces because of a belief that it will ensure minimum standards for the profession, enhance status, and protect the layperson in the process.

The last area of professional development is the establishment of a formal code of ethics, which usually includes rules to exclude unqualified and unscrupulous practitioners, rules to reduce internal competition, and rules to protect clients and emphasize the ideal service to society. A code of ethics usually comes at the end of the professionalization process.

In biomedical engineering, all six of these critical steps have been taken. The field of biomedical engineering, which originated as a professional group interested primarily in medical electronics in the late 1950s, has grown from a few scattered individuals to a very well-established organization. There are approximately 48 international societies throughout the world serving an increasingly expanding community of biomedical engineers. Today, the scope of biomedical engineering is enormously diverse. Over the years, many new disciplines such as tissue engineering and artificial intelligence, which were once considered alien to the field, are now an integral part of the profession.

Professional societies play a major role in bringing together members of this diverse community to share their knowledge and experience in pursuit of new technological applications that will improve the health and quality of life of human beings. Intersocietal cooperation and collaborations, both at national and international levels, are more actively fostered today through professional organizations such as the Biomedical Engineering Society (BMES), the American Institute of Medical and Biological Engineers (AIMBE), and the Engineering in Medicine and Biology Society (EMBS) of the Institute of Electrical and Electronic Engineers (IEEE).

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – 2 - PRINCIPLES OF BIOMEDICAL ENGINEERING – SBMA1102

II-BIOLOGY AND ENGINEERING

BIOLOGY AND ENGINEERING

Characteristics of human anatomy and physiology related to biomedical devices, Engineering of immunity and pathology, Communication systems in the body and its connection to biomedical engineering**.**

2.1 CHARACTERISTICS OF HUMAN ANATOMY AND PHYSIOLOGY RELATED TO BIOMEDICAL DEVICES

Introduction:

- Medical instrumentation is a subdivision of biomedical engineering. It emphasizes the measurement of all the variables in the body for the use of diagnosis and all the devices that perform therapy.
- It is a cross-disciplinary field of study comprising

  Engineering

  Biology

  Chemistry

  Medicine
- Biomedical Instrumentation is used to take measurements for

  Monitoring

  Diagnostic means

  Therapy
- Biomedical instrumentation is generally classified into two major types:
- Clinical Instrumentation is devoted to diagnosis, care and treatment of patients.
- Research Instrumentation is used primarily in search for new knowledge pertaining to various systems composing the human organism.

Studying of Biomedical Instrumentation helps in the following manners:

1. To understand mechanisms, efficiencies & physical changes of various subsystems of the body.

2. To evolve an instrumentation system for diagnosis, therapy and supplementation of body function.

3**.** To obtain qualitative & quantitative knowledge through different instruments which can help for analysis of disorders, and further the Biomechanics of the cure process.

4. To understand Bio-Chemico- Electro – Thermo- Hydraulico- Pneumatico- Physico Magnato-Mechano – Dynamic actions and changes of various sub systems of the body in normal states.

5. To understand above actions & changes in various sub systems of the body in the abnormal states i.e. in Pathology.

6. To obtain qualitative & quantitative knowledge of what drug does to the body (Pharmacodynamics) and what body does to the drug.

Basic Objectives of the Biomedical Instrumentation

Under mentioned are the principal objectives of a biomedical instrumentation system

1. Information Gathering: Instruments used to measure natural phenomena to aid man in the quest of knowledge about himself.

2. Diagnosis: Measurements are made to help detect and correct malfunction of the system being measured.

3. Evaluation: It is used to determine the ability of a system to meet its functional requirements.

4. Monitoring: It is used to monitor certain situation for continuous or periodic information.

5. Control: It is used to automatically control the operation of a system based on changes in multiple internal parameters.

2.2 ANATOMY AND PHYSIOLOGY:

- The science of structure of the body is known as Anatomy and that of its functioning is known as Physiology.

Anatomy is further classified as

1.Gross Anatomy: It deals with the study of structure of the organs with naked eyes on dissection.

2. Topographical Anatomy: It deals with the position of the organs in relation to each other.

3. Microscopic Anatomy (Histology): It is the study of the minute structures of the organs by means of microscopy. Cytology is a special field where structure, function and development of the cells are studied.

Physiology is classified into

1. Cell Physiology: The study of the functions of the cells.

2. Pathophysiology: It relates to the pathological (symptoms of diseases) functions of the organs.

3. Circulatory Physiology: The study of blood circulation relating to the functioning of the heart.

4. Respiratory Physiology: It deals with the functioning of the breathing organs.

Physiological Systems of the Human Body:

There are several systems working parallel to each other in our body. They are as mentioned below.

1. Cardiovascular System.

2. Respiratory System.

3. Nervous System.

4. Skeletal System.

5. Muscular System.

6. Digestive System.

7. Endocrine System.

8. Exocrine System.

9. Lymphatic System.

10. Urinary System.

11. Reproductive System.

Cardiovascular System:

The circulatory system, also called the cardiovascular system or the vascular system, is an organ system that permits blood to circulate and transport nutrients (such as amino acids and electrolytes), oxygen, carbon dioxide, hormones, and blood cells to and from the cells in the body to provide nourishment and help in fighting diseases, stabilize temperature and pH, and maintain homeostasis.

Respiratory System:

The respiratory system (called also respiratory apparatus, ventilator system) is a biological system consisting of specific organs and structures used for the process of respiration in an organism. The respiratory system is involved in the intake and exchange of oxygen and carbon dioxide between an organism and the environment. In air-breathing vertebrates like human beings, respiration takes place in the respiratory organs called lungs.

Nervous System:

The network of nerve cells and fibers which transmits nerve impulses between parts of the body. It consists of two main parts, the central nervous system (CNS) and the peripheral nervous

system (PNS). The CNS contains the brain and spinal cord. The PNS consists mainly of nerves, which are enclosed bundles of the long fibers or axons that connect the CNS to every other part of the body.

Skeletal System:

The skeletal system includes all of the bones and joints in the body. Each bone is a complex living organ that is made up of many cells, protein fibers, and minerals. The skeleton acts as a scaffold by providing support and protection for the soft tissues that make up the rest of the body. The skeletal system also provides attachment points for muscles to allow movements at the joints.

Muscular System:

The muscular system is an organ system consisting of skeletal, smooth and cardiac muscles. It permits movement of the body, maintains posture, and circulates blood throughout the body. The muscular system in vertebrates is controlled through the nervous system, although some muscles (such as the cardiac muscle) can be completely autonomous. Together with the skeletal system it forms the musculoskeletal system, which is responsible for movement of the human body.

Digestive System:

The digestive system is a group of organs working together to convert food into energy and basic nutrients to feed the entire body. Food passes through a long tube inside the body known as the alimentary canal or the gastrointestinal tract (GI tract). The alimentary canal is made up of the oral cavity, pharynx, esophagus, stomach, small intestines, and large intestines.

Endocrine System:

The endocrine system includes all of the glands of the body and the hormones produced by those glands. The glands are controlled directly by stimulation from the nervous system as well as by chemical receptors in the blood and hormones produced by other glands. By regulating the functions of organs in the body, these glands help to maintain the body's homeostasis.

Exocrine System:

The exocrine system is an organ system consisting of the skin, hair, nails, and exocrine glands. The skin is only a few millimeters thick yet is by far the largest organ in the body. The average person's skin weighs 10 pounds and has a surface area of almost 20 square feet. Skin forms the body's outer covering and forms a barrier to protect the body from chemicals, disease, UV light, and physical damage.

Lymphatic System:

The immune and lymphatic systems are two closely related organ systems that share several organs and physiological functions. The immune system is our body's defense system against infectious pathogenic viruses, bacteria, and fungi as well as parasitic animals and protists. The immune system works to keep these harmful agents out of the body and attacks those that manage to enter.

Urinary System:

The urinary system consists of the kidneys, ureters, urinary bladder, and urethra. The kidneys filter the blood to remove wastes and produce urine. The ureters, urinary bladder, and urethra together form the urinary tract, which acts as a plumbing system to drain urine from the kidneys, store it, and then release it during urination. Besides filtering and eliminating wastes from the body, the urinary system also maintains the homeostasis of water, ions, pH, blood pressure, calcium and red blood cells.

Reproductive System:

The male reproductive system includes the scrotum, testes, spermatic ducts, sex glands, and penis. These organs work together to produce sperm, the male gamete, and the other components of semen. These organs also work together to deliver semen out of the body and into the vagina where it can fertilize egg cells to produce offspring. The female reproductive system includes the ovaries, fallopian tubes, uterus, vagina, vulva, mammary glands and breasts. These organs are involved in the production and transportation of gametes and the production of sex hormones. The female reproductive system also facilitates the fertilization of ova by sperm and supports the development of offspring during pregnancy and infancy.

Classification of Biomedical Instruments:

Table: 2.1: Classification of Biomedical Instruments

BLOOD INSTRUMENTS	HEART INSTRUMENT
Blood Pressure meter	ECG
Blood PH meter	Pace Maker
Blood flow meter	Defibrillator
Blood cell counter	Heart Lung Machine
Calorimeter	Bed side Monitor
Spectra – Photometer	Plethysmograph

Flame photometer	**Electronic stethoscope**
Digital BP meter	**Phonocardiograph**

BRAIN INSTRUMENTS	**MUSCLE INSTRUMENTS**
EEG	**EMG**
Tomograph	**Muscle Stimulator**

KIDNEY INSTRUMENTS	
Dialysis Instrument	**Audiometer**
Lithotripsy	**Hearing aid**

2.3 ENGINEERING OF IMMUNITY AND PATHOLOGY

First – Early detection of unwelcome factor of change and activation of response systems.

Second – Setting the stage for an effective, least interfering, response with normal body function and activation of systemic responses.

Third – Activation of long-term survival and adaptation signals, and natural repair systems.

Fourth – Timely termination of the response and learning from the experience if need be!

The advent of molecular genetics, molecular pathophysiology, utilization of new imaging techniques, and advances in bioinformatics and health data, have shed light over novel etiologic factors of disorders and opened eyes to more pieces of the puzzle of diseases of the human body. Researchers in clinical medicine and basic science are deciphering the complex trails by which our immune response is both regulated by and controls many functions of a living creature, from

fundamentals of a local response at the site of injury to the neuro developmental function of immune pathways in the developing brain, and to the inclusive mechanisms by which immunity regulates one's longevity and survival. It is not at all a daring claim that our immune system is the executive element in almost every defense mechanism of the human body to counteract threats. Whether it be invading microorganisms into the guts, an abnormally proliferating cell in the lining of our lungs, a blood clot in one of the cerebral arteries, aberrant aggregation of cholesterol in endothelium lining of the coronary artery, or an aging cell in the macula of the eye. Immune aspects of physiology and pathology of the human being are now the prevailing notion in research, therapeutic modalities, and day-to-day practice of clinicians.

This book is presented as the result of an effort to provide basics to this vast area of growing knowledge, on the basic actions of the immune system in health and disease. Uncertain nature of the "change", temporally and regionally, necessitates a 24-hour alert system to summon immune effectors and exert the proper scenario of action. The effectors cells of the immune system are therefore distributed in a tightly regulated manner all throughout the body and over time. The mucosal-associated lymphoid tissue comprises the largest pool of immune effectors, followed by bone marrow and spleen, which are the primary training and regulation sites of immunity. Most interesting is that each and every organ system and each cell in the body is conferred with the intrinsic ability to respond to change, injury, or an adverse event, and set off a cascade of adaptation or maladaptation**.**

This makes us to the important crosstalk of immunity with three major regulatory bodies in human body. Immunity acts in consort with hemostatic response, neuroendocrine system, and circulatory/lymphatic system to exert potent internal regulatory signals. Later on, in this section, we look briefly at the fundamentals of the function of the human immune system to be able to move on to the exciting new dimensions of the role of immunity in cancer immunology, immunology of transplantation, autoimmunity, and immune deficiencies.

Conventionally, there has been a trend to define the immune system, first by introducing the immune mediators, cells and organs involved in various responses, and then by dividing the responses into "innate" and "adaptive or acquired" response.

The innate immunity is as diverse and ancient as the structures of different parts of the human body. Each organ system has developed over time, barriers to minimize the scope of pathogen invasion, or better neutralize the attack at the site of entry. We believe that the evolution of human immune system is the product of and currently shaped by, an everlasting struggle with rapidly reproducing and frequently changing microbial pathogens. The various mechanisms of innate immunity are developed in order to quickly identify the stereotypes in pathogen structures [i.e., pathogen-associated molecular patterns (PAMPs)] and provide either mechanical barriers or respond by secretion or cell surface expression of antagonizing molecules, most importantly known as antimicrobial peptides. Pattern recognition in innate immunity is based on, but not confined to, identification of peptides, as well as carbohydrates and pathogen-associated nucleic acid segments . Inflammation is a transitory and ongoing nonspecific mechanism of innate immunity. A full-armed activation of defense and repair mechanisms, and involvement of the pathogen-specific, acquired immune responses follow the initial inflammatory response. Inflammation could be defined as a harmonic array of activation of plasma proteins (complement system, antimicrobial peptides such as defensins and cathelicidins, cytokines, and vasoactive mediators), circulating and infiltrating leukocytes **(**polymorphonuclear leukocytes, lymphocytes, macrophages/monocytes etc.). Endothelial lining of the vessels and indolent cells of the parenchyma are known as non-specified, yet highly active players of inflammation.

The primary goal of the inflammatory response is to recruit immune cells to the site of invasion. Yet, failure to remove the pathogen from the site of entry, as happens following the invasion of *Mycobacterium tuberculosis* to a hilar lymph node of the lung, failure to terminate the response, such as when antigen: antibody complex deposits in glomerular basement membrane a few weeks after streptococcal pharyngitis, excessive response to a benign pathogen, when resident alveolar macrophages, eosinophils, and neutrophils are drawn to the site where Aspergillus spores penetrate the respiratory system, each underlie formation of different types of immune diseases.

Before we move to describe the common scenarios by which the immune system operates its actions and the distinct disciplines in emerging fundamental of cancer immunology, immunology of transplants, systemic and organ-specific autoimmune disorders, and immuno deficiencies, let us move to the building blocks of immunity, tissue/cellular components of the immunity.

2.4 COMMUNICATION SYSTEMS IN THE BODY AND ITS CONNECTION TO BIOMEDICAL ENGINEERING.

The central nervous system is divided into two major parts: the brain and the spinal cord.

The Brain

The brain lies within the skull and is shaped like a mushroom. The brain consists of four principal parts:

- the brain stem
- the cerebrum
- the cerebellum
- the diencephalon

The brain weighs approximately 1.3 to 1.4 kg. It has nerve cells called the neurons and supporting cells called the glia.

There are two types of matter in the brain: grey matter and white matter. Grey matter receives and stores impulses. Cell bodies of neurons and neuroglia are in the grey matter. White matter in the brain carries impulses to and from grey matter. It consists of the nerve fibers (axons).

The Brain Stem

The brain stem is also known as the Medulla oblongata. It is located between the pons and the spinal cord and is only about one inch long.

The Cerebrum

The cerebrum forms the bulk of the brain and is supported on the brain stem. The cerebrum is divided into two hemispheres. Each hemisphere controls the activities of the side of the body opposite that hemisphere.

The hemispheres are further divided into four lobes:

- Frontal lobe
- Temporal lobes
- Parietal lobe
- Occipital lobe

The Cerebellum

This is located behind and below the cerebrum.

The Diencephalon

The diencephalon is also known as the fore brain stem. It includes the thalamus and hypothalamus. The thalamus is where sensory and other impulses go and coalesce.

The hypothalamus is a smaller part of the diencephalon

Other Parts of the Brain

Other parts of the brain include the midbrain and the pons:

- The midbrain provides conduction pathways to and from higher and lower centers
- the pons acts as a pathway to higher structures; it contains conduction pathways between the medulla and higher brain centers

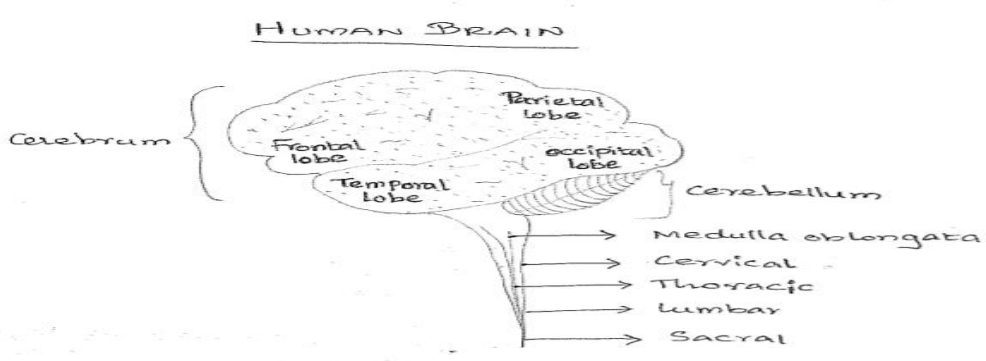

Fig:2.1: Human Brain

The Spinal Cord

The spinal cord is along tube like structure which extends from the brain. The spinal cord is composed of a series of 31 segments. A pair of spinal nerves comes out of each segment. The region of the spinal cord from which a pair of spinal nerves originates is called the spinal segment. Both motor and sensory nerves are located in the spinal cord.

The spinal cord is about 43 cm long in adult women and 45 cm long in adult men and weighs about 35-40 grams. It lies within the vertebral column, the collection of bones (back bone).

Other Parts of the Central Nervous System

The meninges are three layers or membranes that cover the brain and the spinal cord. The outermost layer is the dura mater. The middle layer is the arachnoid, and the innermost layer is the pia mater. The meninges offer protection to the brain and the spinal cord by acting as a barrier against bacteria and other microorganisms.

The Cerebrospinal Fluid (CSF) circulates around the brain and spinal cord. It protects and nourishes the brain and spinal cord.

The Peripheral Nervous System

The Peripheral nervous system is made up of two parts:

- Somatic nervous system
- Autonomic nervous system

Somatic Nervous System

The somatic nervous system consists of peripheral nerve fibers that pick up sensory information or sensations from the peripheral or distant organs (those away from the brain like limbs) and carry them to the central nervous system.

These also consist of motor nerve fibers that come out of the brain and take the messages for movement and necessary action to the skeletal muscles. For example, on touching a hot object the sensory nerves carry information about the heat to the brain, which in turn, via the motor nerves, tells the muscles of the hand to withdraw it immediately.

The whole process takes less than a second to happen. The cell body of the neuron that carries the information often lies within the brain or spinal cord and projects directly to a skeletal muscle.

Autonomic Nervous System

Another part of the nervous system is the Autonomic Nervous System. It has three parts:

- the sympathetic nervous system
- the parasympathetic nervous system

- the enteric nervous system

This nervous system controls the nerves of the inner organs of the body on which humans have no conscious control. This includes the heartbeat, digestion, breathing (except conscious breathing) etc.

The nerves of the autonomic nervous system enervate the smooth involuntary muscles of the (internal organs) and glands and cause them to function and secrete their enzymes etc.

The Enteric nervous system is the third part of the autonomic nervous system. The enteric nervous system is a complex network of nerve fibers that innervate the organs within the abdomen like the gastrointestinal tract, pancreas, gall bladder etc. It contains nearly 100 million nerves.

EEG (Electroencephalography)

EEG measures electrical activity of the brain

The brain consists of billions of cells, half of which are neurons, half of which help and facilitate the activity of neurons. These neurons are densely interconnected via synapses, which act as gateways of inhibitory or excitatory activity.

Any synaptic activity generates a subtle electrical impulse referred to as a *postsynaptic* potential. Of course, the burst of a single neuron is difficult to reliably detect without direct contact with it. However, whenever thousands of neurons fire in sync, they generate an electrical field which is strong enough to spread through tissue, bone, and skull. Eventually, it can be measured on the head surface.

Think of this as a constant rumble of subtle earthquakes. Taken by itself, each burst might be too small to notice, but if several of them occur at the same time, in the same location, and in the same rhythm, they all add up to a mega-quake that will be noticeable even hundreds of miles away.

EEG, is the physiological method of choice to record the electrical activity generated by the brain via electrodes placed on the scalp surface. For faster application, electrodes are mounted in elastic caps similar to bathing caps, ensuring that the data can be collected from identical scalp positions across all respondents.

(EEG) Definition:

- measures electrical activity generated by the synchronized activity of thousands of neurons (in volts)

- provides excellent time resolution, allowing you to detect activity within cortical areas - even at sub-second timescales

As the voltage fluctuations measured at the electrodes are very small, the recorded data is digitized and sent to an amplifier. The amplified data can then be displayed as a sequence of voltage values.

Price differences in EEG systems are typically due to the number of electrodes, the quality of the

digitization, the quality of the amplifier, and the number of snapshots the device can take per second (this is the sampling rate in Hz).

1. **Occipital cortex**

The occipital cortex is the visual processing center of our brain, located in the rearmost portion of the skull. All the things that we see are processed here (although some processing does also occur before and after the signal arrives). EEG experiments with visual stimuli (videos, images) often focus on effects in occipital regions.

2. **Parietal cortex**

The parietal cortex is all about integrating information stemming from external sources and internal sensory feedback from our body. The parietal cortex is responsible for merging all of these information sources into a coherent representation of how our body relates to the environment, and how all things (objects, people) in the environment spatially relate to us. Tasks requiring eye or hand movements as well as eye-hand coordination would be impossible without parietal cortex, which also processes, stores and retrieves the shape, size and orientation of objects to be grasped.

3. **Temporal cortex**

The temporal cortex is associated with processing sensory input to derived, or higher, meanings using visual memories, language and emotional associations. The left temporal cortex is involved in the comprehension of written and spoken language. Medial (inner) regions are more active during spatial navigation.

4. **Frontal cortex**

The frontal part of the human brain is enlarged compared to most other mammals. Basically, the frontal cortex is all about executive function: it helps us maintain control, plan for the future, and monitor our behavior. Apart from the regional characteristics of where certain electrical activity originates, you can also analyze which frequencies primarily drive the ongoing activity.

EEG Frequency ranges

Delta (1 – 4 Hz)

- Delta in sleep labs, delta waves are examined to assess the depth of sleep. The stronger the delta rhythm, the deeper the sleep. Increased delta power (an increased quantity of delta wave recordings) has also been found to be associated with increased concentration on internal working memory tasks

Theta (4 – 7 Hz)

- Theta is associated with a wide range of cognitive processing such as memory encoding and retrieval as well as cognitive workload. Whenever we're confronted with difficult

tasks (counting backwards from 100 in steps of 7, or when recalling the way home from work, for example), theta waves become more prominent. Theta is also associated with increased fatigue levels

Alpha (7 – 12 Hz)

- Alpha whenever we close our eyes and bring ourselves into a calm state, alpha waves take over. Alpha levels are increased when in a state of relaxed wakefulness. Biofeedback training often uses alpha waves to monitor relaxation. They are also linked to inhibition and attention

Beta (12 – 30 Hz)

- Beta over motor regions, beta frequencies become stronger as we plan or execute movements of any body part . Interestingly, this increase in beta is also noticeable as we observe bodily movements of other people . Our brain seemingly mimics their limb movements, indicating that there is an intricate "mirror neuron system" in our brain which is potentially coordinated by beta frequencies.

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – 3 - PRINCIPLES OF BIOMEDICAL ENGINEERING – SBMA1102

III- BIOPOTENTIAL ELECTRODES

Medical Electronics, Basis of Bioelectric potential Bio potential electrodes, biomedical amplifiers, Characteristics of recording systems, Computer applications in medicine, Design of electro medical equipment.

3.1 BASIS OF BIOELECTRIC POTENTIAL

Electrode – Electrolyte Interface

General Ionic Equations

C<->Cn+ +ne-

A m-<->A +me -

- If electrode has same material as cation, then this material gets oxidized and enters the electrolyte as a cation and electrons remain at the electrode and flow in the external circuit.
- If anion can be oxidized at the electrode to form a neutral atom, one or two electrons are given to the electrode The dominating reaction can be inferred from the following :
- Current flow from electrode to electrolyte : Oxidation (Loss of e-)
- Current flow from electrolyte to electrode : Reduction (Gain of e-)

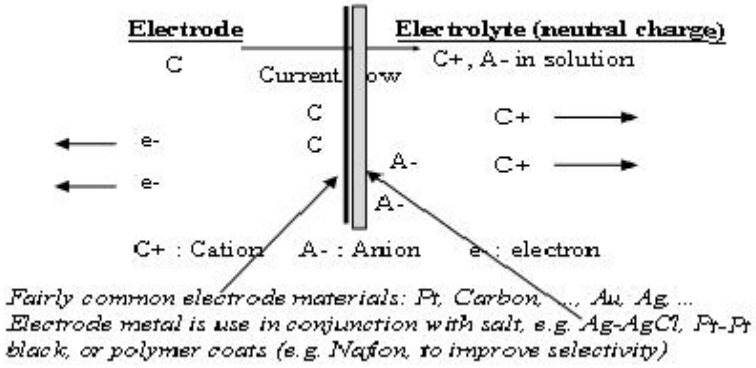

Figure 3.1: Electrolyte Interface

Half Cell Potential

Half cell potential cannot be measured without a second electrode.

The half cell potential of the standard hydrogen electrode has been arbitrarily set to zero. Other half cell potentials are expressed as a potential difference with this electrode

Reason for Half Cell Potential : Charge Separation at Interface

- Oxidation or reduction reactions at the electrode-electrolyte interface lead to a double-charge layer, similar to that which exists along electrically active biological cell membranes.

Reason for Half Cell Potential : Charge Separation at Interface

- Oxidation or reduction reactions at the electrode-electrolyte interface lead to a double charge layer, similar to that which exists along electrically active biological cell membranes.

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Measuring Half Cell Potential

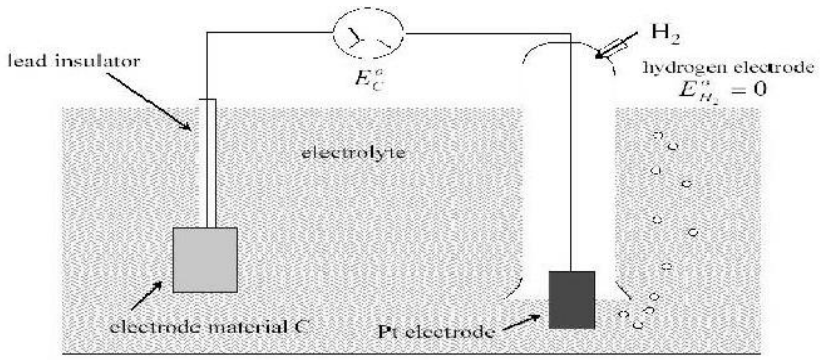


Figure:3.2: Half Cell Potential

Polarization

If there is a current between the electrode and electrolyte, the observed half cell potential is often altered due to polarization.

Polarizable and Non-Polarizable Electrodes

1. Perfectly Polarizable Electrodes: These are electrodes in which no actual charge crosses the electrode-electrolyte interface when a current is applied. The current across the interface is a displacement current and the electrode behaves like a capacitor.

Example : Ag/AgCl Electrode.

Perfectly Non-Polarizable Electrode:

These are electrodes where current passes freely across the electrode-electrolyte interface, requiring no energy to make the transition.

Over potentials. Example: Platinum electrode

Example: Ag-AgCl is used in recording while Pt is use in stimulation

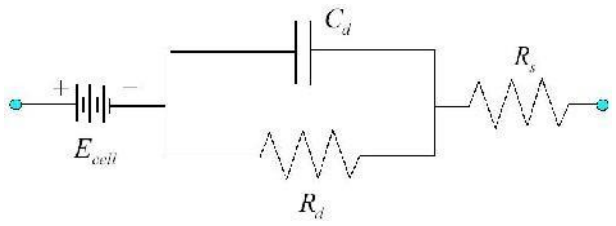


Figure:3.3 Equivalent Circuit

Cd : capacitance of electrode-eletrolyte interface

Rd : resistance of electrode-eletrolyte interface

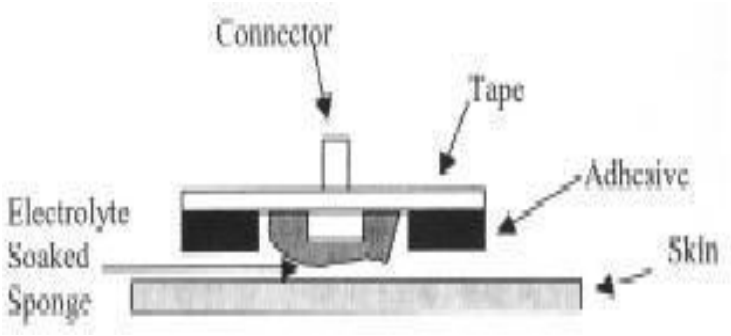
Rs : resistance of electrode lead wire

Ecell : cell potential for electrode

Electrode Skin Interface

Motion Artifact

- When the electrode moves with respect to the electrolyte, the distribution of the double layer of charge on polarizable electrode interface changes. This changes the half cell potential temporarily.
- If a pair of electrodes is in an electrolyte and one moves with respect to the other, a potential difference appears across the electrodes known as the motion artifact. This is a source of noise and interference in biopotential measurements. Motion artifact is minimal for non-polarizable electrodes



- Figure 3.4 Body surface Recording Electrodes

3.2 BIO POTENTIAL ELECTRODES

Commonly Used Biopotential Electrodes Metal Plate Electrodes are

1. Suction Electrodes
2. Floating Electrodes
3. Flexible Electrodes

Large surface: Ancient, therefore still used, ECG

– Metal disk with stainless steel; platinum or gold coated

– EMG, EEG

– smaller diameters

– motion artifacts

– Disposable foam

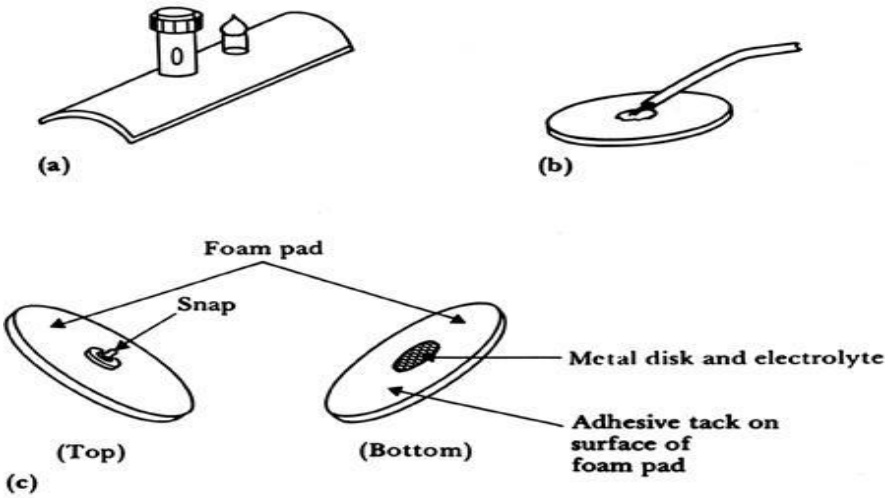


Figure 3.5 Metal plate Electrode

Suction electrodes

- No straps or adhesives required

- precordial (chest) ECG

- can only be used for short periods

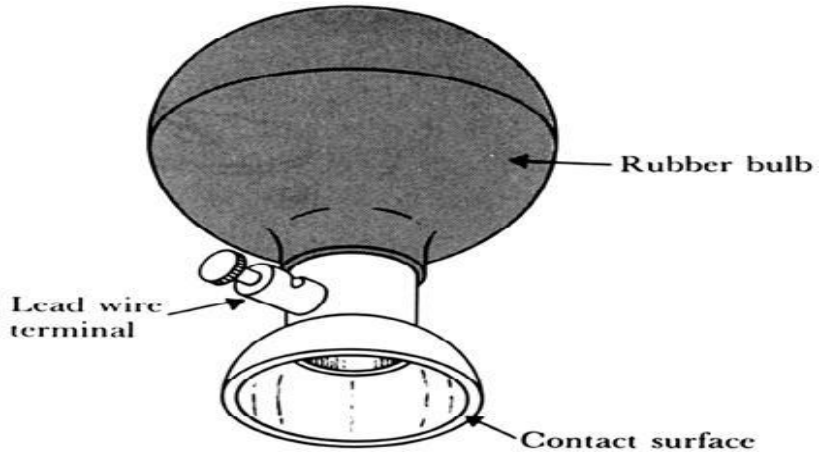


Figure:3.6: Suction Electrode

Floating electrodes

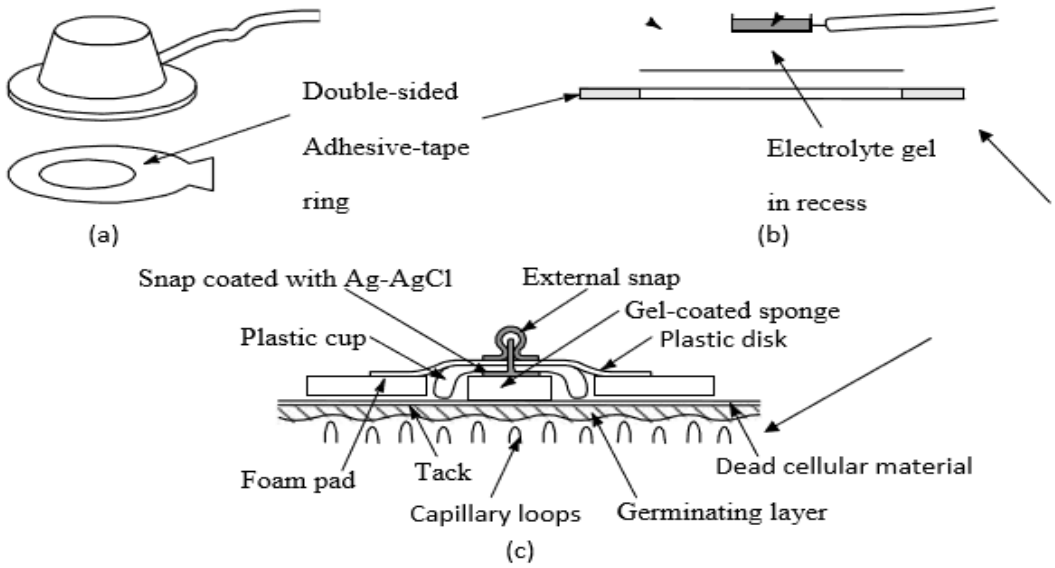


Figure:3.7-Floating Electrodes

Flexible electrodes

- Body contours are often irregular
- Regularly shaped rigid electrodes may not always work
. - Special case : infants
- Material : -

Polymer or nylon with silver

- Carbon filled silicon rubber (Mylar film)

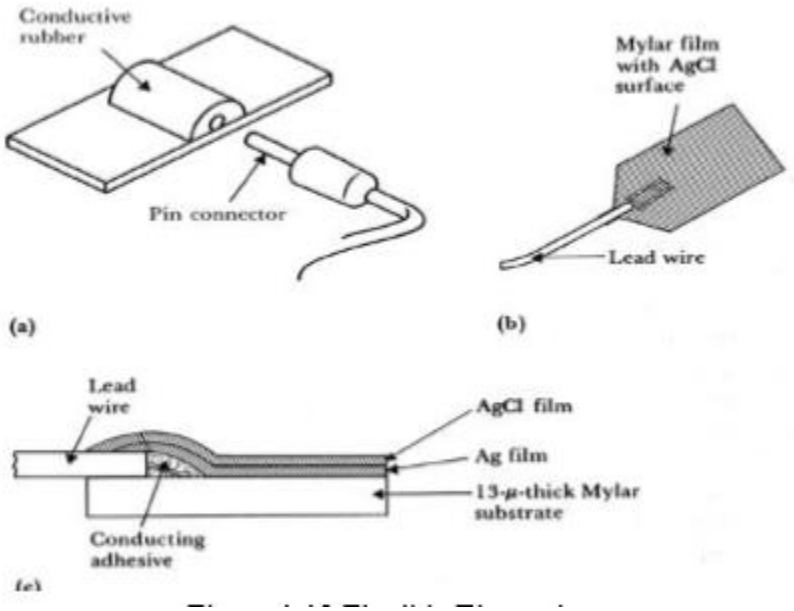


Figure:3.8- Flexible Electrodes

(a)Carbon-filled silicone rubber electrode.

(b)Flexible thin-film electrode.

(c) Cross-sectional view of the thin-film electrode in (b).

Electrodes in Biopotential Measurements

• to make the electrode cheaper

• more suitable for lower noise measurement for EEG

• circumvent patents that are based on plastic/foam electrode body

• attractive to consumers for use with their ECG machines at home

• reduce artifact (minimize the motion of skin/electrode) in ambulatory recording

In a research laboratory, scientists want to record from single cells in a culture dish. They want to record action potentials from single, isolated heart cells. What kind of electrode would they need to use (describe material and design)? Give a simplified schematic (circuit model of the electrode) described in the notes given to you.

Neural electrodes/microelectrodes

It is used to measure potential within asingla cell.It is small in diameter and during insertion of microelectrode into cell will not damage to human cell.

It is classified into

1. Metallic

2. Non metallic (Micropipet)

Metallic Electrode

It is formed by electrolytic ally etching the tip of fine tungsten filament stainless wire into a minute structure.

Potential within the cell can be measured by using two electrodes

1. Micro electrode,

2. Reference electrode.

Non Metallic (Micropipet)

It is used to measure the potential within the single cell using non metallic material is used.

It is filled within an electrolyte ,that is compatible with the cellular fluids.

3.3 BIOPOTENTIAL AMPLIFIERS

- These are very important part of modern medical instrumentation. We need to amplify biopotentials which are generated in the body at low levels with high source impedance.
- Biopotentials amplifiers are required to increase signal strength while maintaining fidelity

Basic Requirements of Biopotential Amplifiers

Essential functions of a bioamplifier are:

• To take a weak biopotential and increase its amplitude so that it can be processed, recorded or displayed

• To amplify voltage, but it could be considered as a power amplifier as well. To amplify current since in some cases a biopotential amplifier is used to isolate the load from the source current gain only.

Input Impedance (Zin)

• All biopotential amplifiers must have high input impedance minimize loading (remember the characteristics of biopotential electrodes resulting into loading and distortion if input impedance of the amplifier is not high enough) – typical values of Zin over the frequency range of the measure and = 10 MΩ (remember the loading rule)

Protection & Isolation

• The input circuit of a biopotential amplifier must provide protection to the live measure

Vbio

• Any potential or current at amplifier's input terminals can affect

Vbio

• Electric currents produced by the biopotential amplifier can result in microshock and macro shock

• The bioamplifier must have isolation and protection circuitry so that the current through the electrodes can be kept at safe levels and any artifact generated by such current can be minimized

Output Impedance (Zout)

- The output circuit does not present any critical problems, all it needs to do is to drive the load
- Output impedance must be low with respect to the load impedance and it must be capable of satisfying the power requirements of the load

Bandwidth (BW)

Frequency response

• The bio potential amplifier must be sensitive to important frequency components of the bio signal

• Since biopotentials are low level signals, it is important to limit bandwidth optimize signal-to-noise ratio.

Gain (G)

• Biopotential amplifiers have a gain of 1000 or greater

Mode of Operation

- Very frequently biosignals are obtained from bipolar electrodes
- Electrodes symmetrically located with respect to ground need differential amplification

• High CMRR required because:

1. Common mode signals much greater than the biosignal appear on bipolar electrodes 2. Symmetry with respect to ground is not perfect (mismatch between electrode impedances) – more on this later.

Calibration Signal

- Medical and clinical equipment require quick calibration. The gain of the biopotential amplifier must be calibrated to provide us with an accurate indication of the signal's amplitude
- Push button to apply standard signal to the input of the biopotential amplifier
- Adjustable gain switch carefully selects calibrated fixed gains.

3.4 CHARACTERISTICS OF RECORDING SYSTEM

Characteristics	The records system should...
Reliable	• routinely capture records within the scope of the business activity it supports • routinely create process metadata • provide adequate information about the records within them • have controls that will ensure accuracy and quality of records created, captured and managed • present records in useable and readable form • provide timely access to records • prevent unauthorised access, use, alteration,

	concealment, deletion, destruction or removal of records • manage and store records for as long as they are needed
Secure	• allow setting up access and permission controls to protect records from unauthorised use, alteration, deletion or removal, such as user registration/deregistration • have security controls that allow logging, monitoring and termination of access and use. The logs should be protected from tampering.
Compliant	• be designed and managed in compliance with legal and regulatory requirements that apply to the business documented within them. Please note that the records system's compliance should be regularly monitored and assessed.
Comprehensive	• create, capture and manage records and associated metadata resulting from the business activities supported by the system
Fixity	• Capture and preserve records as an accurate, unaltered record of the business activity or systems event it documents in a fixed point in time. Records may be captured through the process metadata which shows information on the changes made to the record, when and who changed the records.

Table3.1- Characteristics of recording system

3.5 COMPUTER APPLICATIONS IN MEDICINE

Hospital information system

Medical informatics is a rapidly growing discipline. It seeks to organize and manage information in support of patient care, biomedical research and education through the aid of computer and information networks . A computerized hospital information system can establish consistent standards in the transmission and storage of data and continuously monitor all transactions. It provides easy access to valuable patient care information. The physicians can have direct access to all the information of his/her patient through the use of computer. A hospital information system generally covers areas like registration, admission/transfer/discharge, billing, medical record, index, wards, operation theater scheduling, stores/inventory, pharmacy, diet, CSSD, bio-medical maintenance, payroll, accounts, etc.

To date, several software vendors have developed hospital systems relating to managing hospitals. Generally hospital administrators prefer to buy readymade package and customize the same to suit their needs.

Data Analysis in Medicine

In medical research large number of data is collected. This data is to be compiled, analyzed and interpreted. For this purpose, certain statistical methods are to be applied, these include calculation of standard deviation, standard error, application of tests of statistical significance like Z Test, unpaired and paired t test and chi-square test. Statistical methods are time consuming. With the help of computer, large number of statistical calculations can be performed in a very short time.

Several good quality statistical packages are available, which allow the use of many more methods than is practical using traditional paper calculations . These statistical packages include the following :

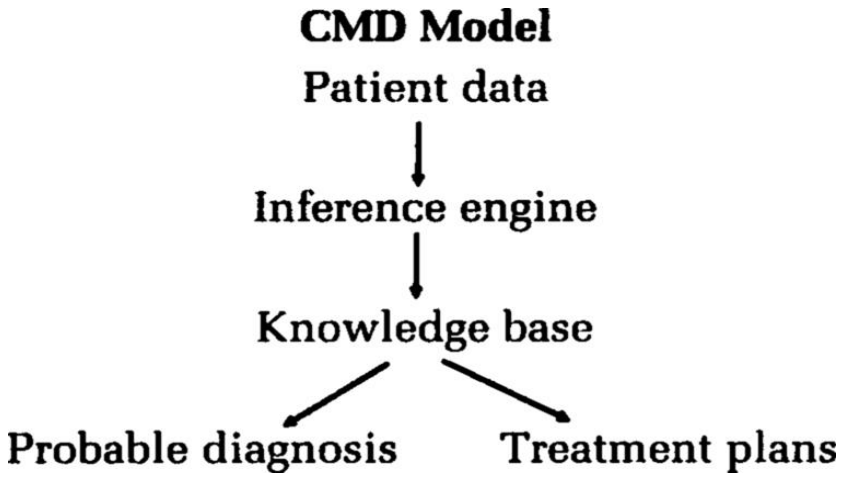
- **1. The biomedical computer package (BMD) :** This was the first package developed and provides a standard set of advanced statistical programs.
- **2. Statistical package for the social sciences (SPSS):** It is used for wide range of medical problems. Many statistical options are available in SPSS varying from simple statistics to multivariate analysis.
- **3. Genstat:** This is a powerful package with special emphasis on analysis of variance.
- **4. Epi-Info :** This package is developed by WHO for epidemiological studies. This package has word processing, data analysis and graphical abilities. Questionnaire can be made directly by text editor. Data analysis is very simple and serves the need of most of investigators. The program is made available by WHO and CDC (Centre for Disease Control) and are not copyrighted. Making copies for others is permitted and encouraged.

Laboratory Computing

The primary objective of a clinical laboratory is to provide accurate results in short time. Laboratory analysis includes blood chemistry, photometry, microbiology, etc. Results must match with patient identification details and should be valid. Quick access to laboratory system can contribute to efficient patient care system.

Computer Assisted Decision making (CMD)

It is an interactive computer system that directly assists doctors with clinical decision making task. The system is intended to support doctors, complementing their natural abilities to make judgment with computer's vast memory, reliability and processing capabilities. A general model of computer assisted medical decision making has been developed



Care of critically ill patients

Critically ill patients require large number of therapeutic interventions to optimize their chances of survival. For this, the variables must be collected frequently and the data derived there from made available to the clinicians and nursing staff. This results in a large quantity of information, which may lose its significance unless the data recorded is presented in a clear manner. In the intensive care unit it is now possible to computerize the total management of data recorded on the patients. Data management includes the entry, integration and reporting of all vital signs, medications, intake and output volumes and laboratory values.

Closed loop system for the direct computer control of the infusions of vasodilator has been developed. An intraarterial canula connected to a suitable cardiovascular monitor provides the input signal to the computer. A pump which infuses the vasodilator drug to the patient is controlled by computer to maintain the arterial pressure within predetermined units.

Computer assisted therapy

Methods for planning, monitoring and adjusting dosages regimens of powerful and potentially toxic drugs, e.g. digitalis and antibiotics like gentamicin have been developed. The physician can plan dosage regimens by selecting a target peak total body concentration of a drug.

Medical imaging

During last decade computers were commonly used for high resolution image generation. Dedicated hardware and software is required to generate such images in

CT scan, MRI, ultrasound, and gamma cameras. It is possible to integrate these workstations to the main hospital information system. Three dimensional images of living human anatomy, regional physiology and biochemistry in health and diseases are in use.

Other applications of computer

In addition computers are being used in primary health care, psychiatry, physiological measurements, medical education, literature search, and as an aid to the handicapped.

3.6 DESIGN OF ELECTRO MEDICAL EQUIPMENT

Designing electronic medical devices requires engineers to walk an extra mile. After all, it's the matter of saving lives! Since accuracy and reliability are crucial for medical equipment, designers have to follow a strict set of regulations for their designs. While this norm has been a constant in this vertical, there have been many changes and up gradations in terms of form factor, usage and technology incorporated in devices. This article reviews all these upgrades and essentials in medical electronics design.

New technologies

Medical devices—both diagnostic and treatment types—have seen a shift in design preferences over the years. The combination of electronics, mechanical engineering, medical science and software engineering governs the progress of these equipment.

Nitesh K. Jangir, co-founder, Coeo Labs, a Bengaluru-based medical equipment manufacturer, says, "Design starts from the hardware. Most of the medical devices use embedded software. So hardware requires more attention. You need to know what kind of sensors, components and MCUs you will be using."

For medical devices, application-specific integrated circuit (ASIC) system-on-chips are preferable over field-programmable gate array (FPGA) chips—the reason being that although FPGA offers more customisation options through simple designs, ASICs provide higher power efficiency, better performance and purpose-specificity. Upgraded image processing technologies have improved different applications such as computed tomography and magnetic resonance imaging scan tests.

Miniaturization and portability is another major trend in medical devices. To ensure easy handling as well as quick diagnosis, many critical equipment like ultrasound machines and electrocardiograms (ECG) are being designed in portable shape. This has made diagnosis of commute-affected patients much easier.

Even ventilators are becoming portable. One of the newest examples is a portable ventilator designed by professor Diwakar Vaish, head of robotics and research, A-SET Training and Research Institute, in collaboration with Dr Deepak Agarwal, professor of neurosurgery at AIIMS, New Delhi. Its main components include pressure sensor monitors and a special microcontroller unit that operates on a program based on machine learning algorithm.

As regards connectivity, Nitesh says, “Almost all medical devices are becoming connected to the Internet. This is giving users the freedom to utilise data from anywhere. For instance, users are adopting ECG devices with Bluetooth connectivity to access ECG data through their phones. We as designers try to ensure that every device at least has the option to connect to the Internet. Wi-Fi, GSM and Bluetooth are the main wireless technologies being utilised. So we integrate the respective modules with the circuit board.”

“Globally, Zigbee is widely used in medical equipment. In India, there are a handful of companies using Zigbee. These companies use Zigbee for medical equipment mainly because their Wi-Fi is occupied for other applications. Once again, keeping this in mind, medical devices are being designed with multiple wireless platform connectivity modes,” he adds.

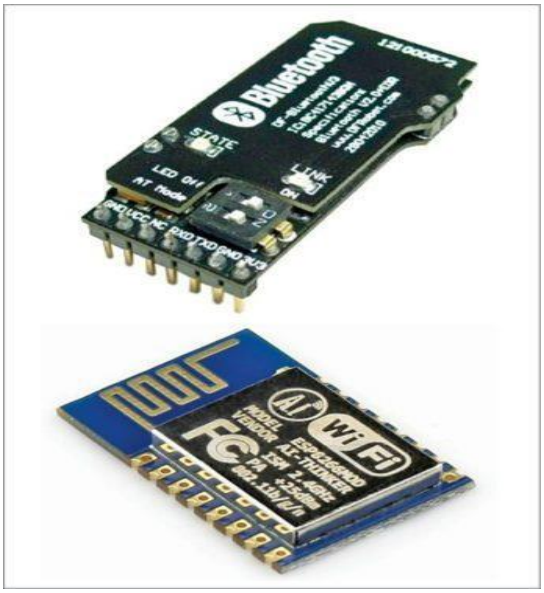


Fig. 3.1: Connectivity modules like Bluetooth and Wi-Fi are increasingly being included in medical device design

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – 4 - PRINCIPLES OF BIOMEDICAL ENGINEERING – SBMA1102

IV-CLINICAL ENGINEERING

Evolution of clinical engineering, Clinical engineer Vs Biomedical engineer, Role of clinical engineers, Good clinical practice, Major functions of a clinical engineering department, Standards for clinical engineering.

4.1 EVOLUTION OF CLINICAL ENGINEERING

In the twentieth century, technological innovation has reshaped the field of medicine and the delivery of health-care services. Although the art of medicine has a long history, advances in medical technology, primarily in this century, have provided a wide range of positive diagnostic, therapeutic, and rehabilitative tools that are now routinely used in the cure of specific diseases and illnesses. In the process, the modern hospital in the United States has evolved as the center of a technologically sophisticated health-care system serviced by a technologically sophisticated staff. With the dramatic role technology has played in shaping medical care, engineering professionals have become intimately involved in many medical ventures. As a result, the discipline of biomedical engineering has emerged as an integrating medium for two dynamic professions: medicine and engineering. Today, biomedical engineers assist in the struggle against illness and disease by providing materials, tools, and techniques (such as biomaterials, medical imaging, and artificial intelligence) that can be utilized for research, diagnosis, and treatment by health-care professionals. In addition, one subset of the biomedical engineering community, namely clinical engineers, has become an integral part of the health-care delivery team by managing the utilization of medical equipment within the hospital environment. The purpose of this chapter is to provide a broad overview of technology's role in shaping our modern health-care system and to review the basic functions performed by clinical engineers within a hospital environment. This chapter also presents the status of the professionalization of clinical engineering (including certification), describes attributes of clinical engineering educational programs, and reflects upon the future of the discipline.

4.2 CLINICAL ENGINEER VS BIOMEDICAL ENGINEER

Biomedical Engineering Biomedical engineering is an interdisciplinary field in which the principles, laws, and techniques of engineering, physics, chemistry, and other physical sciences are applied to facilitate progress in medicine, biology, and other life sciences. Biomedical engineering encompasses both engineering science and applied engineering in order to define and solve problems in medical research and clinical medicine for the improvement of health care. It is the application of engineering principles and techniques to the medical field. It combines the design and problem solving expertise of engineering with the medical expertise of physicians to help improve patient health care and the quality of life of healthy individuals. Therefore many specialty areas are considered to belong to the field of Biomedical Engineering. In this field there is continual change and creation of new areas due to rapid advancement in technology. Some of these specialty areas are:

• Biomedical Sensors and Devices Instrumentation & Engineering

• Biomaterials Engineering

• Molecular, Cellular, Tissue, Genetic & Cloning Engineering

• Medical Imaging & Biomedical Optics

• Orthopedical, Biomechanical & Rehabititational Engineering

• Cardiovascular / Cardiopulmonary System Engineering

• Bioinformatics and Computational Engineering

• Physiological Systems Engineering

• Human Performance and Neuroengineering

• Clinical / Hospital Engineering

Clinical Engineering / Engineer

Clinical Engineering is a branch of biomedical engineering for professionals responsible for the management of medical equipment in a hospital. Or (as per definition of ACCE (American College of Clinical engineering)):"A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology."

Tasks of a clinical engineer

The tasks of a clinical engineer are typically, but not exclusively:

Medical equipment planning and technology assessment.

• Acquisition and management of medical device inventory.

• Supervising biomedical engineering technicians (BMETs) to support and maintain medical devices used at the point of delivery of care.

• Ensuring that safety and regulatory issues are taken into consideration.

• Serving as a technological consultant for any issues in a hospital where medical devices are concerned.

Clinical Engineers and biomedical engineering technicians (BMETs)

Clinical Engineers are often confused with another professional group in the hospital, the Biomedical Equipment Technicians (BMETs). In reality, these two groups perform different but equally valuable functions. The BMET is the person responsible for direct support, service, and repair of the medical equipment in the hospital. BMET education and training is usually of a more directly technical nature, and is supplemented with specific schooling in service to the equipment.

BMETs answer the call when medical equipment fails to function properly and must work closely with nurses and other hospital staff, as well as the equipment vendor, as they service and maintain the equipment. The job of the clinical engineer, however, is somewhat different.

4.3 ROLE OF CLINICAL ENGINEERS.

Clinical Engineering Program In many hospitals, administrators have established clinical engineering departments to manage effectively all the technological resources, especially those relating to medical equipment, that are necessary for providing patient care. The primary objective of these departments is to provide a broad-based engineering program that addresses all aspects of medical instrumentation and systems support.

The organizational chart of the medical support services division of a typical major medical facility. Note that within this organizational structure, the director of clinical engineering reports directly to the vice-president of medical support services. This administrative relationship is extremely important since it recognizes the important role clinical engineering departments play in delivering quality care. It should be noted, however, that in the more common organizational structure, clinical engineering services fall under the category of "facilities," "materials management," or even just "support services." In practice, there is an alternative capacity in which clinical engineers can function. They can work directly with clinical departments, thereby bypassing much of the hospital hierarchy. In this situation, clinical departments can offer the clinical engineer both the chance for intense specialization and, at the same time, the opportunity to develop a personal relationship with specific clinicians based on mutual concerns and interests (Wald, 1989).

Establishment of a Clinical Engineering Department

The establishment of a clinical engineering department requires the following three major administrative steps. First, the hospital administration appoints a qualified individual as director. Directors of clinical engineering usually function at the department-head level in the organizational structure of the institution and are provided with sufficient authority and resources to perform their duties efficiently and in accordance with professional norms. According to the World Health Organization (WHO)(Issakov et al., 1990), the job title for clinical engineering director is as follows.

General Statement.

The clinical engineering director, by his or her education and experience, acts as a manager and technical director of the clinical engineering department. The individual designs or directs the design of equipment modifications that may correct design deficiencies or enhance the clinical performance of medical equipment. The individual may also supervise the implementation of those design modifications. The education and experience that the director possesses enables him or her to analyze complex medical or laboratory equipment for purposes of defining corrective maintenance and developing appropriate preventive maintenance or performance assurance protocols. The clinical engineering director works with nursing and medical staff to analyze new medical equipment needs and participates in both the prepurchase planning process and the

incoming acceptance testing process. This individual also participates in the equipment management process through involvement in the system development, implementation, maintenance and modification processes.

Duties and Responsibilities. The director of clinical engineering has a wide range of duties and responsibilities. For example, this individual:

• Works with medical and nursing staff in the development of technical and performance specifications for equipment required in the medical mission.

Once equipment is specified and the purchase order developed, generates appropriate testing of the new equipment.

• Does complete performance analysis on complex medical or laboratory equipment and summarizes results in brief concise, easy-to-understand terms for the purposes of recommending corrective action or for developing appropriate preventive maintenance and performance assurance protocols.

Designs and implements modifications that permit enhanced operational capability. May supervise the maintenance or modification as it is performed by others.

• Must know the relevant codes and standards related to the hospital environment and the performance assurance activities. (Examples in the U.S. are NFPA 99, UL 544, and JCAHO, and internationally, IEC-TC 62. See Chapter 5 for details of these codes and standards.)

Is responsible for obtaining the engineering specifications (systems definitions) for systems that are considered unusual or one-of-a-kind and are not commercially available.

• Supervises in-service maintenance technicians as they work on codes and standards and on preventive maintenance, performance assurance, corrective maintenance, and modification of new and existing patient care and laboratory equipment. Supervises parts and supply purchase activities and develops program policies and procedures for same.

Sets department goals, develops budgets and policy, prepares and analyzes management reports to monitor department activity, and manages and organizes the department to implement them.

Teaches measurement, calibration, and standardization techniques that promote optimum performance.

In equipment-related duties, works closely with maintenance and medical personnel. Communicates orally and in writing with medical, maintenance, and administrative professionals. Develops written procedures and recommendations for administrative and technical personnel.

Direction Received and Supervisory Responsibility.

The director of clinical engineering functions with a minimum of supervision and often supervises or directs the work of biomédical equipment maintenance technicians and clinical engineers with less seniority.

Working Conditions.

The work site is within the hospital and includes patient areas where the employee may be exposed to sick patients and to research projects.

Minimum Qualifications.

- A bachelor's degree (four years) in an electrical or electronics program or the equivalent is required (preferably with a clinical or biomédical adjunct). A Master's degree is desirable. A minimum of three years experience as a clinical engineer and two years in a progressively responsible supervisory capacity is needed. Additional qualifications are as follows:
- Must have some business knowledge and management skills that enable him or her to participate in budgeting, cost accounting, personnel management, behavioral counseling, job description development, and interviewing for hiring or firing purposes. Knowledge and experience in the use of microcomputers is desirable.
- Must be able to use conventional electronic trouble-shooting instruments such as millimetres, function generators, oscillators, and oscilloscopes. Should be able to use conventional machine shop equipment such as drill presses, grinders, belt sanders, shears, brakes, and standard hand tools.
- Must possess or be able to acquire a knowledge of the techniques, theories, and characteristics of materials, drafting and fabrication techniques in conjunction with chemistry, anatomy, physiology, optics, mechanics, and hospital procedures.

Clinical engineering certification or professional engineering registration are required.

- In the second step in the establishment of a clinical engineering department, the hospital administration, in conjunction with the director of clinical engineering, prepares a mission statement which defines the dimension and scope of responsibility of the clinical engineering department. The mission statement and list of objectives must conform to the overall strategic plan of the hospital. For example, consider the following (Simmons and Wear, 1988).

Mission Statement.

It is the policy of the hospital clinical engineering department to provide technical and management professional clinical engineering support to hospital administration, hospital engineering department, medical, surgical, nursing, and other allied health professional departments, and staff medical professionals. The clinical engineering department will perform a primary role in the assurance of compliance to relevant laws, statutes, regulations, and standards by the establishment and implementation of effective instrumentation control programs. These programs will ensure the efficacious and safe use of medical instrumentation for the benefit of the patients and hospital employees alike. It is the policy of the clinical engineering department to augment this program by the continued development and presentation of educational materials through the use of in-service education and training sessions for clinical personnel.

Objective 1. To define, develop, and implement the hospital clinical engineering program which will provide scientific, technical, and management support to hospital administration, clinical departments, and medical staff.

Objective 2. To develop and issue all necessary programs, technical procedures, and documentation with the concurrence of appropriate personnel.

Objective 3. To determine and provide those professional scientific and technical consultation services that will be provided by the hospital clinical engineering department to the clinical and medical staffs.

Objective 4. To define program education and training needs for clinical department employees, medical staff, and clinical engineering personnel.

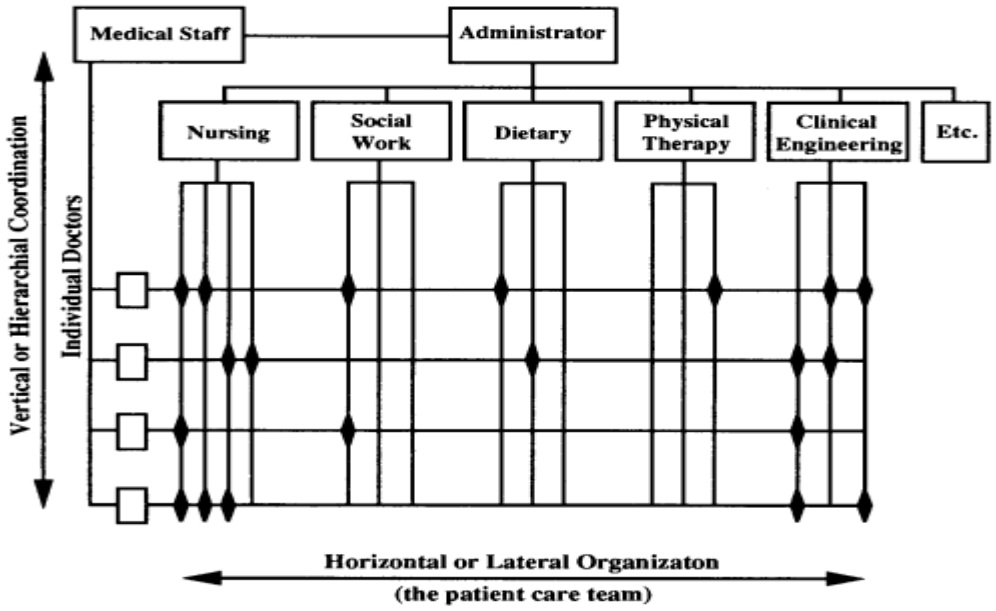
Objective 5. To establish communication methods for status reporting of program implementation both in management and in technical areas.

Objective 6. To optimize program costs in such a way so as to provide maximum improvement in patient care as a result of this program while attempting to minimize costs. No compromise will be made in the area of employee safety, as required by applicable laws, codes, and standards.

Finally, the clinical engineering department determines and requests adequate work space, personnel, test equipment, and supplies to accomplish its specified objectives in compliance with established codes and standards.

4.4 MAJOR FUNCTIONS OF A CLINICAL ENGINEERING DEPARTMENT

The role of the clinical engineer in today's hospital can be both challenging and gratifying because the care of patients requires a partnership between medical staff and modern technology. As previously discussed, this interchange has led to a close working relationship between the clinical engineer and many members of the medical and hospital staff. The team approach is key to the successful operation of any clinical engineering program. Figure 1.6 illustrates the degree of teamwork and interdependence required to maintain constructive interrelationships. In this matrix presentation, it is important to note that the health-care team approach to the delivery of patient care creates both vertical and lateral reporting relationships. Although clinical engineers report hierarchically to their hospital administrator, they also interact with hospital staff to meet patient requirements.



Matrix diagram illustrating the bi-directional interdependence and degree of teamwork required to maintain effective interaction between the members of the health-care delivery team.

As a result of the wide-ranging scope of interrelationships within the medical setting, the duties and responsibilities of clinical engineering directors are extremely diversified. Yet, a common thread is provided by the very nature of the technology they manage. Directors of clinical engineering departments are usually involved in the following areas:

- Developing, implementing, and directing equipment management programs. Specific tasks include evaluating and selecting new technology, accepting and installing new equipment, and managing the inventory of medical instrumentation, all in keeping with the responsibilities and duties defined by the administrator. The director advises the administrator of the budgetary, personnel, space, and test equipment requirements necessary to support this equipment management program.
- Advising administration and medical and nursing staffs in areas such as safety, the purchase of new medical instrumentation and equipment, and the design of new clinical facilities.
- Evaluating and taking appropriate action on incidents attributed to equipment malfunction or misuse. The director summarizes the technological significance of each incident and document the findings of the investigation. He or she submits a report to the appropriate hospital authority and, according to the Safe Medical Devices Act of 1990, to the device manufacturer, the Food and Drug Administration (FDA) or both.
- Selecting departmental staff and training them to perform their functions in a professional manner

- Establishing departmental priorities, developing and enforcing departmental policies and procedures, and supervising and directing departmental activities. The director takes an active role in leading the department to achieve its overall technical goals.

The core functions of clinical engineers are as follows:

1. Technology management.

2. Risk management.

3. Technology assessment.

4. Facilities design and project management.

5. Quality assurance.

6. Training.

4.5 STANDARDS FOR CLINICAL ENGINEERING

Professionals have been defined as an aggregate of people finding identity in sharing values and skills absorbed during a common course of intensive training. Parsons (1954) stated that one determines whether or not individuals are professionals by examining whether or not they have internalized certain given professional values. Friedson (1971) redefined Parsons's definition by noting that a professional is someone who has internalized professional values and is to be recruited and licensed on the basis of his or her technical competence. Furthermore, he pointed out that professionals generally accept scientific standards in their work, restrict their work activities to areas in which they are technically competent, avoid emotional involvement, cultivate objectivity in their work, and put their clients' interests before their own.

The concept of a profession that manages technology encompasses three occupational models; science, business, and profession. Of particular interest is the contrast between science and profession. Science is seen as the pursuit of knowledge, its value hinging on providing evidence and communicating with colleagues. Profession, on the other hand, is viewed as providing a service to clients who have problems they cannot handle themselves. Science and profession have in common the exercise of some knowledge, skill, or expertise. However, while scientists practice their skills and report their results to knowledgeable colleagues, professionals—such as lawyers, physicians, and engineers—serve lay clients. To protect both the professional and the client from the consequences of the layperson's lack of knowledge, the practice of the profession is regulated through such formal institutions as state licensing. Both professionals and scientists must persuade their clients to accept their findings. Professionals endorse and follow a specific code of ethics to serve society. On the other hand, scientists move their colleagues to accept their findings through persuasion (Goodman, 1989).

Consider, for example, the medical profession. Its members are trained in caring for the sick, with the primary goal of healing them. These professionals not only have a responsibility for

the creation, development, and implementation of that tradition, they are expected to provide a service to the public, within limits, without regard to self-interest. To ensure proper service, the profession itself closely monitors licensing and certification. Thus, medical professionals themselves may be regarded as a mechanism of social control. However, this does not mean that other facets of society are not involved in exercising oversight and control of physicians in their practice of medicine.

A final attribute of professionals is that of integrity (Parsons, 1954). Physicians tend to be both permissive and supportive in relationships with patients and yet are often confronted with moral dilemmas involving the desires of their patients and the social interest. For example, how to honor the wishes of terminally ill patients while not facilitating the patients' deaths is a moral question that health professionals are forced to confront.

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – 5 - PRINCIPLES OF BIOMEDICAL ENGINEERING – SBMA1102

V. RESEARCH IN BIOMEDICAL

Medical devices and Robotics, Bio fabrication and Bio manufacturing, Biomedical Imaging, Bio molecular Science and Engineering, Musculoskeletal Biomechanics and Mechano biology, Systems Biology, Tissue Engineering, Rehabilitation Engineering, Biomaterials and Nanotechnology, Neural Engineering- Case Studies.

5.1 MEDICAL DEVICES AND ROBOTICS

Surgical Robots

Major manufacturers are increasing their R&D efforts within robotic surgical systems. The overall market is currently dominated by Intuitive Surgical, but the landscape is rapidly changing. The entrance of major manufacturers such as Johnson & Johnson and Medtronicare is bolstering the medtech surgical robotics market.

There are specific product lines from each company focusing on individual therapeutic areas for minimally invasive robotic surgery. For example, the da Vinci System is a general surgical robot focusing on a myriad of surgical procedures in urological, bariatric, and gynaecological surgical procedures. Additionally, the MAKO System from Stryker specialises in orthopaedic surgery, specifically partial and complete knee replacements.

The key to market domination will be product proliferation, as each company tries to highlight its own features. Specific companies have remarkably distinct operation methods, such as seen with Intuitive Surgical compared to TransEnterix. Both companies offer robotic surgical systems with system specific attachments, but Intuitive has built-in chips to determine the use of their disposable accessories, and TransEnterix's attachments are reusable.

The procedure volumes of robotic surgical procedures within the healthcare industry are growing rapidly as well. This growth can be attributed to the increase in the adoption rates of robotic surgical systems globally.

Exoskeletons

Robots can aid recovery and assist with surgery. For example, Cyberdyne's Hybrid Assistive Limb (HAL) exoskeleton, which uses sensors placed on the skin to detect small electrical signals in the patient's body and respond with movement at the joint, are designed to assist patients rehabilitate from conditions leading to lower limb disorders, including spinal cord injuries and strokes.

Such devices are not cheap—the monthly rental for a HAL suit is expected to be $1,000—and the price will need to come down as output scales up and component costs of items including sensors, electronics, and electrical engineering decrease.

The exoskeleton market is one of the fastest growing segments in robotics. It includes bio-feedback waistband lumbar support for airport and warehouse workers, which are already a common sight in Japan. Advances in brain-machine connectivity will impact the evolution of

exoskeletons. The leading companies in the field are Cyberdyne, ReWalk Robotics, and Ekso Bionics.

Care Robots

The number of robots used to provide care and support to elderly and disabled patients is currently very low, but is expected to increase significantly over the next decade, particularly in countries like Japan, which is facing a predicted shortfall in the number of available caregivers. Initial use cases for these products are relatively simple, such as helping people get into and out of bed, but they will increasingly be called upon to perform more complex tasks, from reminding patients when to take medication to providing emotional support and interaction for those lacking regular human contact.

Another expected use case for care robots is to assist nurses with the multitude of tasks that they perform on an hourly basis. Many of these tasks are simple but vital, such as taking blood, recording temperature, or improving patient hygiene. If robots were able to help with these simple repetitive tasks, it would give nurses more time to focus on individualised patient care and devising treatment plans. Products like the Robear Japanese, developed by research institute RIKEN and Sumitomo Riko, are already assisting patients and nurses in Japan.

Toyota and Honda have been developing human support robots (HSRs) for many years. In 2016, Toyota launched a $1bn five-year project to open and run two AI/robotics labs in Palo Alto, California, US under the leadership of former Defense Advanced Research Projects Agency (DARPA) robotics chief Gill Pratt. The facilities were aimed as much at Toyota's HSR division as its automotive operation. Honda is doing something similar, but the project is based in Tokyo.

AIST's Paro is classified as a therapeutic robot. Designed to be cute and elicit an emotional response from patients in hospitals and nursing homes, Paro is a robotic baby harp seal covered in soft white fur and exhibits many of the same behaviours as a real pet.

Hospital Robots

Hospital robots, like Aethon's TUG autonomous mobile robot, can be used to deliver medications, laboratory specimens, or other sensitive material within a hospital environment. TUG can navigate using a built-in map and an array of on-board sensors. Additionally, it uses Wi-Fi to communicate with elevators, automatic doors, and fire alarms.

Among the big medical equipment makers, GE, McKesson, and Siemens are also manufacturing hospital robots. An industry outsider, iRobot, teamed up with InTouch Health to create a robot that is specifically made for hospitals.

Robots have been designed to disinfect hospital devices and equipment. One company that is showing a lot of promise in this market is Xenex, which has created a robot that disinfects using pulsed Xenon light and can disinfect an entire patient room in less than 20 minutes. Currently, more than 400 hospitals are working with Xenex.

5.2 BIOFABRICATION AND BIOMANUFACTURING

Bio fabrication is a revolutionary approach to healthcare that uses manufacturing processes to produce biomaterials, devices, cells, tissues, and organs. The core technology underlying bio fabrication is 3D printing, or additive manufacturing—the same technology that has sparked advances in rapid prototyping through the additive manufacturing of polymer-based constructs. Bio fabrication represents a variation on this theme, often described as 3D bio printing, combining cells, biomaterials, and synthetic materials into biological constructs. Such constructs encompass a vast range of applications, including custom-made biomedical devices; micro fluidic devices that incorporate 3D miniaturized organs called organoids for high-throughput drug and toxicity screening; tissue-engineered skin, cartilage, and bone; blood vessels and hollow organs such as the bladder; and even complex organs such as the kidney, liver, lung, and heart.

This special issue of Trends in Biotechnology reviews many of these envisioned applications or in cases where the translation of the technology remains hypothetical, gives opinions on their future potential. Some Opinion papers presented in this issue include those of Yeong and colleagues, who ask whether skin bio printing is an impending reality or simply a fantasy; Visscher and colleagues, who foresee a bio fabrication-based approach to craniofacial reconstruction using multiple tissue types; and Ozbolat and colleagues, who advocate the potential of bio printing to overcome current limitations in 3D models for pharmaceutical testing. In addition, Rouwkema and Khademhosseini review the current applications of novel fabrication techniques to creating vasculature in engineered tissues.

To realize the potential that bio fabrication holds, manufacturing challenges need to be addressed. These manufacturing challenges are many, but there are central challenges that we believe the field can advance together, which will bring us one step closer to realizing the true benefits that bio fabrication promises. Some of these central manufacturing challenges include (1) consistent, reliable, and multi-sourced starting materials for bio fabrication (e.g., biomaterials, cells, and reagents); (2) coordinated standards and regulatory pathways for biomedical products; (3) advanced, modular, closed, and automated platform technologies for biofabication; and (4) quality-control systems integrated into the manufacturing process to ensure that bio fabricated products are well defined, characterized, and aligned with regulatory standards.

On the theme of manufacturing challenges, short articles by Knowlton and Tasoglu, and by Tamayol and colleagues, highlight some recent progress in bio fabricated organs-on-chips and in bio fabricated textile processing. In an Opinion, Wan poses the question of whether the advent of organoids has made a biomaterial-based approach to tissue engineering obsolete, while a Review by Picollet-D'hahan and colleagues discusses recent advances in fabricating flow-based organ models. Finally, Xu and colleagues describe how bio printed constructs can evolve over time, in a process they term 4D bio printing.

Investments into realizing these diverse applications and overcoming the associated manufacturing challenges will yield tremendous returns in boosting economies across the world. We predict that countries that align funding efforts across private and government sectors to address and solve these manufacturing challenges will enjoy economic benefits of creating more

jobs, as well as providing a new era of personalized medicine where off-the-shelf bioengineered products will become a reality.

5.3 BIOMEDICAL IMAGING

Biomedical imaging concentrates on the capture of images for both diagnostic and therapeutic purposes. Snapshots of in vivo physiology and physiological processes can be garnered through advanced sensors and computer technology. Biomedical imaging technologies utilize either x-rays (CT scans), sound (ultrasound), magnetism (MRI), radioactive pharmaceuticals (nuclear medicine: SPECT, PET) or light (endoscopy, OCT) to assess the current condition of an organ or tissue and can monitor a patient over time over time for diagnostic and treatment evaluation. The science and engineering behind the sensors, instrumentation and software used to obtain biomedical imaging has been evolving continuously since the x-ray was first invented in 1895. Modern x-rays using solid-state electronics require just milliseconds of exposure time, drastically reducing the x-ray dose originally needed for recording to film cassettes. The image quality has also improved, with enhanced resolution and contrast detail providing more reliable and accurate diagnoses.
The limitations of what x-rays could reveal were partially addressed through the introduction of contrast medium to help visualize organs and blood vessels. First introduced as early as 1906, contrast agents, too, have evolved over the years. Today, digital x-rays enable images to more easily be shared and compared.

Digital imaging gave rise to the CT scanner and allows physicians to watch real-time x-rays on a monitor—a technique known as x-ray fluoroscopy—to help guide invasive procedures such as angiograms and biopsies. No longer limited to simple anatomical imaging, current research is focusing on what can be gleaned through functional imaging. Biomedical engineers are using CT and MRI to measure the blood profusion of tissue; especially important after a heart attack or suspected heart attack. Researchers are also using functional MRI (fMRI) to measure different types of brain activity following strokes and traumatic head injuries.
PET scans—which use a radioactive tracer to measure metabolic changes, blood flow and oxygen use—have also improved with technological advancements. PET scans enable researchers to compare, for example, brain activity during periods of depression based on the chemical activity in the brain.

Optical molecular imaging technologies represent a new area of research that can be used to image human cells and molecules without the need for a biopsy or cell culture. Using contrast or imaging agents that attach to specific molecules, disease processes, such as cancer, can be spotted before they render their effects at the level of gross pathology.
Optical coherence tomography (OCT) is a newer form of CT being used in research that constructs images from light that is transmitted and scattered through the body.
The power of ultrasound is being used in conjunction with microbubbles. The microbubbles can be injected directly into a specific location and then burst via ultrasound to emit localized contrast agents for imaging, chemotherapy for cancer treatment, air to help dissolve clots, and genes or drugs which can more easily penetrate cell membranes that are weakened by ultrasound.

New imaging techniques bring new means for peering into the human body, helping to reduce the need for more invasive diagnostic and treatment procedures.

Biomedical Image Processing

Biomedical image processing is similar in concept to biomedical signal processing in multiple dimensions. It includes the analysis, enhancement and display of images captured via x-ray, ultrasound, MRI, nuclear medicine and optical imaging technologies.
Image reconstruction and modeling techniques allow instant processing of 2D signals to create 3D images. When the original CT scanner was invented in 1972, it literally took hours to acquire one slice of image data and more than 24 hours to reconstruct that data into a single image. Today, this acquisition and reconstruction occurs in less than a second.
Rather than simply eyeball an x-ray on a lightbox, image processing software helps to automatically identify and analyze what might not be apparent to the human eye. Computerized algorithms can provide temporal and spatial analysis to detect patterns and characteristics indicative of tumors and other ailments.
Depending on the imaging technique and what diagnosis is being considered, image processing and analysis can be used to determine the diameter, volume and vasculature of a tumor or organ; flow parameters of blood or other fluids and microscopic changes that have yet to raise any otherwise discernible flags.

5.4 MUSCULOSKELETAL BIOMECHANICS AND MECHANOBIOLOGY

Mechanics regulates biological processes at the molecular, cellular, tissue, organ, and organism levels. A goal of this journal is to promote basic and applied research that integrates the expanding knowledge-bases in the allied fields of biomechanics and mechanobiology. Approaches may be experimental, theoretical, or computational; they may address phenomena at the nano, micro, or macrolevels. Of particular interest are investigations that
(1) quantify the mechanical environment in which cells and matrix function in health, disease, or injury,

(2) identify and quantify mechanosensitive responses and their mechanisms,

(3) detail inter-relations between mechanics and biological processes such as growth, remodeling, adaptation, and repair, and

(4) report discoveries that advance therapeutic and diagnostic procedures.

Especially encouraged are analytical and computational models based on solid mechanics, fluid mechanics, or thermomechanics, and their interactions; also encouraged are reports of new experimental methods that expand measurement capabilities and new mathematical methods that facilitate analysis.

- Highlights approaches that are experimental, theoretical, or computational and that address phenomena at the nano, micro, or macro levels
- Integrates knowledge in the allied fields of biomechanics and mechanobiology
- Emphasizes analytical and computational models based on solid mechanics, fluid mechanics, or thermomechanics and their interactions
- Encourages reports on new experimental methods that expand measurement capabilities and new mathematical methods that facilitate analysis.

5.5 SYSTEMS BIOLOGY

Systems biology seeks to study biological systems as a whole, contrary to the reductionist approach that has dominated biology. Such a view of biological systems emanating from strong foundations of molecular level understanding of the individual components in terms of their form, function and interactions is promising to transform the level at which we understand biology. Systems are defined and abstracted at different levels, which are simulated and analysed using different types of mathematical and computational techniques. Insights obtained from systems level studies readily lend to their use in several applications in biotechnology and drug discovery, making it even more important to study systems as a whole.

Biological systems are enormously complex, organised across several levels of hierarchy. At the core of this organisation is the genome that contains information in a digital form to make thousands of different molecules and drive various biological processes. This genomic view of biology has been primarily ushered in by the human genome project. The development of sequencing and other high-throughput technologies that generate vast amounts of biological data has fuelled the development of new ways of hypothesis-driven research. Development of computational techniques for analysis of the large data, as well as for the modelling and simulation of the complex biological systems have followed as a logical consequence.

Simulatable computational models of biological systems and processes form the cornerstone of the emerging science of systems biology. Traditionally, biology has focused on identifying individual genes, proteins and cells, and studying their specific functions. Each of these is indeed extremely important in understanding the individual molecules, but as individual isolated pieces of information, they are insufficient to provide insights about complex phenomena such as human health and disease. As an analogy, to study an aircraft, focused detailed studies on individual components such as the engine, wings and tail, would not be sufficient to understand how an aircraft can fly. More importantly, it would not provide any understanding of what component influences what other component in what manner and to what extent, an understanding which is very important to effectively set things right when something malfunctions. In the same way, since diseases occur when there is some malfunction in the form or function of one or more of the cellular components, we need an understanding how various molecules in a cell influence each other in health, in order to attempt curing or correcting it to the extent possible.

The scale at which various molecular level studies can now be carried out is providing us systematic data on many fronts enabling us to reconstruct holistic models of larger systems.

Systems biology seeks to study biochemical and biological systems from a holistic perspective, promising to transform how biology is done. The goal is for a comprehensive understanding of the system's influence on its individual components, leading to the appearance of complex properties such as robustness, emergence, adaptation, regulation and synchronisation, seen so very often in biological systems. Essentially, systems biology advocates a departure from the reductionist viewpoint, emphasising on the importance of a holistic view of biological systems. It also aims at a departure from the "spherical cow" 1 , in trying to encapsulate the enormous complexity of biological systems in greater detail. Systems biology adopts an integrated approach to study and understand the function of biological systems, particularly, the response of such systems to perturbations such as the inhibition of a reaction in a pathway, or the administration of a drug. It can of course be argued that systems biology is just a new name for the conventional disciplines such as physiology and pharmacology, which are well established for several decades now.

Undoubtedly, these disciplines emphasise the need for considering whole systems. Yet, systems biology emerges as a new discipline, since it differs from the conventional disciplines in a fundamental way: the latter treat much of the whole system as a 'black-box', giving us only an idea of the end picture but not enabling us to ask 'why' or 'how' a particular outcome is seen. Systems biology on the other hand aims to reconstruct systems by a bottom-up approach, with detailed knowledge about the individual components that make up the system and how these components interact with each other. Modelling and simulation of complex biological networks form the cornerstone of systems biology; the coupling of in silico models with in vivo and in vitro experimentation, with modelling guiding experimentation and experimentation aiding in model refinement, can provide impetus to improve the understanding of biological systems. Effects and influences of one component on the other are deciphered, providing a greater understanding of how genotypes relate to phenotypes.

5.6 TISSUE ENGINEERING

TISSUE ENGINEERING IS a set of techniques to produce tissue, primarily for repair or improvement of human body functions. There are also some additional spin-off applications, such as screening of pharmaceutics and artificial meat. Tissue-engineered constructs are different than medical implants, which are technical devices made from man-made materials, without living tissue parts.

Tissue already in clinical use and tissue under development

Today there are several examples of tissue engineering in clinical use, e.g. skin, cartilage, bone, heart valves and bladder. There are many more examples, which still are at the research and animal experiment levels, like artificial liver, pancreas and blood vessels. For most examples, tissue is grown outside the body and then implanted into a patient. There are, however, also parallel attempts and ideas for in-vivo tissue engineering, where e.g. a cell culture is implanted and develops into a desired tissue inside the body.

Key components of a tissue engineering process are a tissue, or *cell sample,* that constitutes the seed and starting point of the process, and secondly a *scaffold* that holds and supports the seed and steers its growth into desired geometrical shape and location. A third important component is an environment of *signal substances and nutrition* etc. that steers the growing cell culture, or tissue seed, towards the desired biological properties, including both geometrical size and shape and bio-functional properties.

A bioreactor steers the shape and functional properties of the tissue

The tissue engineering process is often implemented in a bioreactor designed to steer both the geometrical shape and the bio-functional properties. In addition, the bioreactor also provides pressure and temperature control and specific motional programs like agitation and rotation. To build complex tissue structures it has become increasingly popular to use 2D or 3D-printing to fabricate the structures.

Some tissue requires vascularization

In terms of hurdles and challenges, there is a clear dividing line between target tissues that require vascularization, i.e. blood vessels in the grown tissue, which deliver nutrients and oxygen and remove waste products, and those which do not. For example, tissue engineered heart valves can function without vascularization because they are surrounded by blood, carrying nutrients and oxygen, while an artificial tissue engineered liver or pancreas must have internal vascularization.

5.6 REHABILITATION ENGINEERING

Rehabilitation engineering is the use of engineering principles to 1) develop technological solutions and devices to assist individuals with disabilities and 2) aid the recovery of physical and cognitive functions lost because of disease or injury.

Rehabilitation engineers design and build devices and systems to meet a wide range of needs that can assist individuals with mobility, communication, hearing, vision and cognition. These tools help people with day-to-day activities related to employment, independent living and education.

Rehabilitation engineering may involve relatively simple observations of how individuals perform tasks, and making accommodations to eliminate further injuries and discomfort. On the other end of the spectrum, rehabilitation engineering includes sophisticated brain computer interfaces that allow a severely disabled individual to operate computers and other devices simply by thinking about the task they want to perform.

Rehabilitation engineers also improve upon standard rehabilitation methods to regain functions lost due to congenital disorders, disease (such as stroke or joint replacement) or injury (such as limb loss) to restore mobility.

Ongoing research in rehabilitation engineering involves the design and development of innovative technologies and techniques that can help people regain physical or cognitive functions. For example:

- **Rehabilitation robotics**, to use robots as therapy aids instead of solely as assistive devices. Smart rehabilitation robotics aid mobility training in individuals suffering from impaired movement, such as following a stroke.
- **Virtual rehabilitation**, which uses virtual reality simulation exercises for physical and cognitive rehabilitation. These tools are entertaining, motivate patients to exercise, and provide objective measures such as range of motion. The exercises can be performed at home by a patient and monitored by a therapist over the Internet (known as tele-rehabilitation), which offers convenience as well as reduced costs.
- **Physical prosthetics**, such as smarter artificial legs with powered ankles, exoskeletons, dextrous upper limbs and hands. This is an area where researchers continue to make advances in design and function to better mimic natural limb movement and user intent.
- **Advanced kinematics**, to analyze human motion, muscle electrophysiology and brain activity to more accurately monitor human functions and prevent secondary injuries.
- **Sensory prosthetics**, such as retinal and cochlear implants to restore some lost function to provide navigation and communication, increasing independence and integration into the community.
- **Brain computer interfaces**, to enable severely impaired individuals to communicate and access information. These technologies use the brain's electrical impulses to allow individuals to move a computer cursor or a robotic arm that can reach and grab items, or send text messages.
- **Modulation of organ function**, as interventions for urinary and fecal incontinence and sexual disorders. Recent developments in neuromodulation of the peripheral nervous system offer the promise to treat organ function in the case of a spinal cord injury.
- **Secondary disorder treatment**, such as pain management.

5.7 BIOMATERIALS AND NANOTECHNOLOGY

There have been numerous efforts made to use tissue engineering strategies to treat injuries to the CNS and PNS. The goal of these strategies is to mimic the characteristics of natural tissue. Tissue engineering

strategies include biomaterial-based strategies and cell-based delivery, which are introduced into the body to aid in self-repair. Biomaterial-based strategies use either natural or synthetic materials as scaffolds, which can be a therapeutic drug carrier and a substrate for cells to attach to and proliferate to encourage tissue regrowth, in this case neural regeneration

These scaffolds need to meet a certain criteria such as providing adequate mechanical strength, having certain cues, and facilitating new tissue integration. The nanotechnology aspect of these biomaterials allows close and direct connection to cells that can affect development and cellular response. The scaffolds are molded to a certain shape to conform to the requirements of the injury. For example, injectable hydrogels are a common tissue engineering strategy to treat traumatic brain injury or spinal cord injury.

The hydrogels are introduced in liquid form into the site of injury and provide the opportunity for growth factors and cell delivery to yield a favorable environment for regeneration. Several biomaterials have been studied such as agarose, methylcellulose, poly(N-isopropylacrylamide), and poly(ethylene glycol) (PEG)-poly(lactic acid)-PEG tri-block polymer (Zhong and Bellamkonda, 2008; Kubinová and Syková, 2010). These biomaterials have been observed to encourage cell infiltration, reduce scar tissue infiltration, and aid neurite extension for functional recovery in experimental models. Unlike injectable hydrogel systems, solid polymer-based nerve guidance conduits (NGCs) are used as bioactive scaffolds for peripheral nerve injury. These scaffolds are alternatives to autografts and allografts, and are intended to provide a favorable environment for nerve regeneration. While there are commercial scaffolds available, there is still an ongoing effort to develop new scaffolds that can better mimic the native nerve and further improve recovery.

5.8 NEURAL ENGINEERING

How does the brain instruct us to breathe ten times per minute? What controls this respiratory rhythm? How do neurons communicate and coordinate their activity? Understanding how the brain functions from a quantitative point-of-view is the domain of the neural engineer (a.k.a. neuroengineer).
Neural engineers are interested in understanding, interfacing with and manipulating the nervous system. Computational neuroscientists are creating computer models of neural systems down to the level of single neurons. Scientists are also exploring how neurons communicate with one another by taking recordings from actual neurons and having those recordings “interact” with recordings from other neurons. Using quantitative techniques, the nature of these communications are being measured and analyzed. One benefit of understanding this communication is to provide new ways to interface between neural tissue and manmade technologies. This is known as brain-machine interfacing.

The Bionic Arm

One of the most striking examples of neural engineering—specifically brain-machine interfaces—is the bionic arm. The DEKA Arm, for example, is currently in clinical trials at the VA. With hundreds of US soldiers coming home from Iraq and Afghanistan having had their arms amputated, the VA wanted to provide an artificial limb far more advanced than the basic hook used since World War II. DARPA (the Defense Advanced Research Projects Agency)

challenged Segway inventor, Dean Kamen, to create an arm that would allow amputees to pick up a raisin or grape and know the difference without looking at it. The hand could be no larger than an average human hand and weigh no more than nine pounds.

The DEKA Arm was developed by a team of over 300 scientists—comprised of engineers, neuroscientists and psychologists—from DARPA and Kamen's DEKA Research and Development Corporation.
Control of the fully functioning hand is directed by a patient's nervous system since the nerves that come from the spinal cord are still available in the shoulder. As an amputee simply thinks about moving their missing hand, the brain fires electrical impulses that are detected by electrodes in the prosthesis.
So there is no real learning curve for the amputee. Additional control over the arm is generated by pressing buttons built into the patient's shoes.

Beyond control of the arm and hand, there was still the grape vs. raisin challenge to conquer. The resulting neural interface had to account for position, touch and pressure, with haptic perception achieved using sensors that vibrate according to the intensity of the grip to provide cognitive feedback.
So the DEKA Arm both recognizes signals *from* the brain (efferent) and relays signals back *to* the brain (afferent).

Disrupting Neurocircuitry

By understanding how neurons work, biomedical engineers specializing in neural engineering can look for ways to either stimulate or disrupt this neurocircuitry. Implantable devices similar to the pacemakers used in the cardiac setting could be used to control nervous system disorders such as Parkinson's disease, depression and epilepsy. California-based NeuroPace, Inc., is currently in clinical trials with their responsive neurostimulation (RNS®) system, which monitors and interrupts abnormal electrical activity in the brain before seizures occur.

If we think of nerves as wires, these wires—or neurocircuits—can either be stimulated or blocked. In the not-too-distant future, high frequency electrical stimulation could be used on peripheral nerves in the arms and legs to selectively block some communication—pain, for example—without interfering with other communication. The ability to give highly localized and reversible anesthesia would be one application of this technology. Another is bladder control. Most bladder control problems are actually the result of the inability to control the neurons that indicate to a person whether they need to urinate. High frequency electrical stimulation via an external device could be used to help coordinate activities that the body can no longer control; especially useful for those who are paralyzed.

Visual Prostheses

An artificial retina could soon become reality as many groups are developing devices to replace damaged retinas. A consortium of researchers in Australia, for example, are working on bionic vision technologies to restore sight to people with degenerative vision loss due to either retinitis pigmentosa or age-related macular degeneration. In both conditions, there is a problem in the

part of the eye that senses light but the neural circuitry and visual processing ability of the brain is still intact.

Using a camera attached to a pair of glasses, signals are transmitted to a microchip implanted in the retina. From here, small electrical currents are sent to surviving neurons in the brain. Current technology limits the number of implanted electrodes to about 100, so the resolution captured by the camera is processed and reduced to create rudimentary images. But these images can make a world of difference to someone who otherwise cannot see.

The Australian technology will not be tested in humans until at least 2013 and would take several more years before it reaches the market. Second Sight in California is currently in clinical trials on a similar retinal prosthesis system that offers 60 electrodes. And a German consortium has taken a different approach that offers more electrodes, but they are not encapsulated and, therefore, not long-lasting. The German solution is also being tested in humans. Some of the research in neural engineering sounds like science fiction but is actually science fact. We have seen a robot controlled via cultured neurons in a dish; a fish wired to electrodes dictating the movements of a robot and a remote-controlled rat turning left or right with the press of a button.

Neural engineering incorporates a diverse array of disciplines, including neuroscience, mathematics, engineering, biophysics, computer science and psychology. This important work is providing new insights into our understanding of dementia, Parkinson's, brain injury, strokes and other neurologic deficits.

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