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Chapter 1: Overview of medical and mechanical devices in modern healthcare systems

1.1. Introduction to Medical and Mechanical Devices

The current practice of medicine incorporates the use of many different kinds of medical and mechanical devices, which might fall under the broad categories of diagnostics, therapeutics, surveillance, rehabilitation, and care. These devices are designed to facilitate the evaluation of the body and its responses to insults of any sort, and these devices may also circumvent illness or injury by repairing the damage done or by taking over, temporarily or permanently, some of the functions of the damaged body (Dubey et al., 2017; Rehman et al., 2022; Badawy et al., 2023). There are mechanical devices to absorb secretions, to monitor heart rhythms, and to make flow measurements such as the volume of blood perfusing a body part. There are devices to deliver drugs, medications, and nutrients to achieve various therapeutic goals. There are devices to withstand joint musculoskeletal loads. There are devices to stimulate muscle contractions or nerve responses. There are prosthetic and orthotic devices to return people to the world of normal living. These devices may be as simple as splints and ambulatory aids or as complex as computer-driven bionic devices. Such is the cornucopia of mechanical devices available for use in a modern healthcare system. The introduction of these devices has enabled physicians to work more efficiently and has given patients greater flexibility of care and a more normal lifestyle (Tuli et al., 2019; Shaik et al., 2023).

1.1.1 Background and Significance

In the past few decades, advances in technology enabled several remarkable developments in the area of medical device design and manufacturing, as well as the applications of these devices. The emergence of minimally invasive, non-invasive,

remote and real-time diagnostic and treatment options, which provide easy handling, improved efficiency at lower cost and great convincing power, all lead to fast growing and widespread technology use. In addition, the ever-increasing popularity of mobile phones with built-in sensors and cloud connectivity changed the whole context of design and use of medical devices as well. Recent years have seen the exciting advent of wireless and battery-free sensors for body physiology measurements, 'smart' optical and electrochemical sensors for various in-depth diagnosis and materials identification applications, and photopneumatic energy systems, for example, for photoconductive-needle-assisted thrombolysis. At the same time, great promises are also made by the fast-developing machine learning, artificial intelligence and big data techniques for doing pattern recognition and intelligent system developments, including accurate biomarker detection and complex network failure diagnosis. However, new challenges have also arisen. Healthcare costs are skyrocketing. The aging society is creating a growing number of chronic patients. The healthcare systems worldwide are rapidly running out of financial sustainability.

Fig 1.1: Medical and Mechanical Devices in Modern Healthcare Systems.

With the rise of encouragement by the new technology policies, both the academic and industrial communities are charged to redirect their innovations towards cost-effective medical devices for boosting efficiency and lowering the life cycle costs of the healthcare systems. Yet it is extremely challenging, indicating the urgent need for robust theoretical

frameworks and practical approaches to spearhead the ultralight and ultraminiature, low-cost, and highly intelligent medical device development initiatives. This book presents the current research and development in the area of mechanical and medical devices that can potentially impact the design, operation, and performance of innovative, efficient, and exemplary medical devices. As such, the significance of the research works is twofold. First, it aims to demonstrate the concurrent design of mechanical devices and the introduction of new mechanical principles or techniques for addressing the novel needs in the advancement of medical devices. Secondly, it aims to discuss the unique combinations of the design process or mechanical principles together with the design of mechanical devices for meeting the design requirements and specifications or the new opportunities for the research and development of advanced medical devices.

1.2. Historical Development of Medical Devices

Medical and mechanical devices are in common and constant use in modern health care systems. Medical devices are used for: Diagnosis, prevention, monitoring, treatment or alleviation of disease Diagnosis, monitoring, treatment, alleviation of or compensation for an injury Investigation, replacement or modification of the anatomy or any physiological or pathological process or state Control of contraception Support or sustain life Disinfection of medical devices or in vitro medical devices, and equipment for preparation for the above. Mechanical medical devices support physical characteristics of the patient. The widespread use of medical devices raises the question as to when the first medical device appeared. Device use has been with humankind since pre-historic ages. Some scripts elaborate on the use of medicine by means of bleeding, cautery, butchery, magic, surgery, or examination and others by obliteration and supplementary tissues describing various medical device uses. Surgery with scalpels and bandages are part of a surgical moral in ancient writing.

In the Greek Age centuries preceding Christ, Asclepius was the God of Medicine, and Hippocrates is known as the Father of Medicine. The existing texts elaborate on how to heal people and at the same time are a critique of the practices of that period. They describe the preparation of patients, the knowledge of anatomy, the description of instruments, such as knives, or cure methods with the aid of devices, usually involving some type of adjuvant or mixture for cauterization. Likewise, Roman, Jewish, and Arabic writings describe procedures and devices for surgical procedures and the cure of diseases, mostly related to obstetrics through the use of obstetrician devices, catheters, clamps, and re-roots, some borrowed by the Greeks from the Egyptians. The Middle Ages even include the use of devices in medicine. However, the detailed description of all types of surgical instruments only appears with the Renaissance, when a museum with surgical instruments was created.

1.2.1. Research Design

Geographically, the research is confined to the first civilization – Mesopotamia. Since the first records of medical devices date back to the third millennium B.C.E., the research covers a time span from that millennium until the first centuries of the Common Era. The research uses textual and archaeological data for the analysis of the objects in the subfields of mechanical medicine, i.e., prosthetics, surgery, and physical therapy, as well as a limitation of the approach to the applied natural sciences. Textual data includes Sumerian and Akkadian medicinal texts, for which a catalogue of devices and substance medicines is also being created. Further textual data come from Mesopotamian myth texts, royal inscriptions, hymns and prayers, law codes, literature, and lexical texts. Archaeological data are drawn from the excavations throughout the territory of Mesopotamia. The research design also addresses problems with textual transmission in the textual data and dating of archaeological data.

In order to further the understanding of the applied natural sciences in ancient Mesopotamia, the research provides specific data and insight in its three parts, which address devices in the respective subfields of mechanical medicine. The first part collects lists of devices with instructions and remedies from several medicinal texts in order to show what devices were in use and how they were used in ancient Mesopotamia. The second part gathers and describes archaeological examples of the devices used in explanations of surgical and dental operations in the first part. The analysis of the methods, devices, and physicians through textual and archaeological data provides border data for the refinement of research in the understanding of the applied natural sciences in ancient Mesopotamia and in the field of Mesopotamian medicine.

1.3. Classification of Medical Devices

Medical devices can be and are classified in many ways, the most common should be presented in the following sections. Devices are first divided in groups according to their representative purpose in health-care systems, so broadly as to have a simple overview. General aspects of the larger groups are then introduced before discussing particular devices in more depth. Finally, devices are considered in a simple functional classification, going from the simplest to the most complex devices, and the particular groups are again compared to this outline.

About 90 % of all devices fall in four main groups. The first group is made up of devices for diagnosis, mostly disease description and identification, using non-invasive or, at least, minimally invasive techniques. The second group is found in therapeutics, including devices for damage or disease correction and physical or chemical prevention of future events. A third, large, more or less equal group encompasses devices for

monitoring, or measuring, bodily or organ systems' health and for controlling support functions, enhancing deficient organ or system function or relieving their incapacity. Finally, a less frequent but large fourth group is related to support. These devices support medical functions not summarized in the first three objects, as administration organization systems, health-care worker and patient culture and training and education.

Diagnostic Devices

Diagnostic medical devices investigate a desired effect or property of the human body or of a body fluid or excreted product. Their purpose is to identify and describe a malady. Most, the larger fraction, and more important use non-invasive or at least minimally invasive techniques to carry out the measurements. They also need to comply with a set of required properties outlining the representative set of possibilities for a specific diagnostic task. Among these properties, analytical sensitivity and specificity are essential.

Fig 1.2 : Classification of Medical Devices.

1.3.1. Diagnostic Devices

Diagnostic devices assist caregivers in determining the status of a medical condition and include both active and passive sensors. They may detect a presence, absence, or level of biochemical agents in a biological sample. Examples of passive sensors used for diagnostics are the immunoassays in laboratory tests. Such assays have been traditionally conducted with test tubes and pipettes. Usually, in a clinical lab, hundreds of samples are processed at the same time by specialized staff. Moreover, automated analysis machines work on the samples for the longest time and deliver results, providing compensation for their lack of specificity and sensitivity. Advances in MEMS and microfacturing technology pave the way for having lab-on-a-chip devices for point-of-care diagnostic devices that are becoming smaller and faster than at a traditional lab.

Point-of-care diagnostic devices avoid incurring additional costs in clinical tests by sending a patient sample to a clinical lab if the point-of-care test is positive. The target groups of point-of-care devices may be non-medical professionals, such as patients or parents. Thus, tests have a very low technical barrier, meaning that they need to be simple and intuitive. Tests should not jeopardize safety. Rapid new tests have reduced the reliance on traditional tests for bacterial and viral infections, such as throat swabs, that require laboratory analysis and long sample processing times. These require trained practitioners as do sample collection and preparation for sample testing and quantification in molecular biology. Other tests for infection detection detect analyzed indicators from a patient urine sample, so can have a low barrier for use.

1.3.2. Therapeutic Devices

Therapeutic devices that are used to affect some change in a biological system often exert their action via the production of some energy, such as heat, light, or ice. Other devices modify the exchange of another physical phenomenon with the environment, such as an electric current passing through tissues to produce some therapeutic effect. Another type of therapeutic device involves the implantation or transplantation of a solid mass, which may be composed of solid biological tissue. The most commonly used therapeutic devices are thermic devices, which transfer heat into tissues to affect a change in a local biological reaction. Such devices are also known as diathermies.

Thermic therapy is an ancient practice. Natural hot springs were used by mankind millennia ago to relieve painful symptoms and treat diseases of various origins. In modern medicine, the principles of thermic therapy found different applications, ranging from direct heat application to the use of external heating, such as infrared light or ultrasound, to the local or systemic application of local antipyretic drugs. A learned and careful use of accessible thermic therapeutic devices will convert the heat into an

effective healing method; no other natural force can act on the human body so locally or for such a long period of time.

1.3.3. Monitoring Devices

Prevention, through regular and frequent monitoring of a patient's health outcomes, can greatly reduce the volume and severity of diseases. Monitoring devices offer the capability to do this at home or at the doctor's office or hospital. Traditionally, these were invasive and non-invasive cables, sensors and probes for collecting data on ECG, EEG, EMG, EOG, blood sugar, blood pressure, temperature, lipids, hydration, oxygen saturation, inadequate linking response frequency ranges, breath frequency, and many other parameters. Collecting these measurements continuously over long periods, or short durations very frequently was limited to the clinical environment. Monitoring once a day was then the best that was possible at home from devices that utilized manual human patient inputs or samples. In-house monitoring systems, on the other hand, are now becoming obsolete with the advent of non-invasive RF-enabled wearable devices.

These non-invasive wearable biosensor systems can now sample ECG, blood pressure in response to stress, temperature gradients, hydration, oxygen saturation, respiration and possibly several other parameters, possibly even blood sugar and lipids using novel methods, for frequent and long-term continuous use without inflicting pain to the patient, and also without the risk of any infection to the patient. Such long-term measurements are of invaluable importance, as most diseases are either environmental dependent, triggered by stress conditions that occur but for a short duration, or are due to the gradual breaking down of the various physiological processes, or continuous low-grade infections, and are very difficult to detect at the human workspace. Also, repeated or continuous monitoring is of great value in alleviating pain or psychological stress on the patient by predicting an alarming condition ahead of time for preemptive actions.

1.3.4. Supportive Devices

Currently, the global market offers a plethora of devices whose goal is to help and provide support to patients and their caregivers in the development of daily routines. These supportive medical devices remind or provide help in the execution of a function that otherwise would not be possible, either due to age limitations or some type of disability, or that would be too cumbersome. With the increasing life expectancy in all regions, a considerable part of the population will face the limitations caused by senescence. Such limitations, especially in the functional and psychological spheres, impose on the elderly's life a gradual withdrawal from community activities, from their relatives, and even from their own country's economy.

These impairments and consequent feelings of inadequacy can be overcome through the use of assistive devices, designed to promote or even substitute the action of individuals with limitations, and thus reduce the secondary impacts of senescence. Also, patients with different disabilities or chronic diseases, who live with difficulties due to their disease, also require the use of these devices. Many of these patients will need assistance for the rest of their life, but some present possibilities of recovery if the hospital discharge is well planned, with adequate support. Understanding that there are various levels of disability, these devices may provide from independence to the support of caregivers, although some exceptions necessarily require a unique approach.

Some of the devices useful for older adults are communication devices, which help elderly people communicate with their caregivers or family members. Another type is called environment devices; they promote autonomy through modifications of the environment. Examples are: furniture and equipment adapted to the elderly and/or with reduced mobility and/or disabilities; home automation; adapted means of transport; wheeled chair lifts; stairlifts; lifts; elevators. There are also devices called exercises devices, which help in the rehabilitation of motor and/or cognitive disabilities and/or provide exercise, as: physiotherapy devices; recreational games; social games. Lastly, the devices called organ aids promote the replacement of lost or deteriorated functions. Examples are: adapted utensils; various means of transport; suspensory; eyeglasses; denture.

1.4. Regulatory Framework for Medical Devices

Regulatory status of medical devices is related to many aspects, i.e. technology implementation, user safety and efficacy, intellectual property rights and commercial laws, and is defined by a regulatory body. Implemented within local jurisdictions, regulations provide a general framework that governs the use of technologies, whilst the corresponding regulatory body dictates procedural requirements for each category of devices. Regulation of medical devices' design, manufacturing, and marketing is done within different jurisdictional levels located at country, state, or province levels depending on the governmental structure. As such, the regulation on medical devices varies from region to region, and country to country.

Among those, the U.S. FDA is one of the most influential organizations regarding medical device regulatory policies, due to the increased adoption of medical technologies across the world, and its early foundation which has been followed by many countries. Other notable bodies that influence medical device regulation are the UK MHRA, the Japanese PMDA and other regional medical technology regulatory organizations. However, despite this multitude of regulatory entities, it is still difficult to predefined regulatory pathways for new devices. International standards such as the

ISO 13485 Quality Management System and ISO 14971 Risk Management explain minimum requirements that should facilitate the process along the entire product value chain, from design to use.

Establishing a regulatory pathway that provides competent authorities the assurance that devices in use, regardless of where they are marketed to, ensures user safety and effectiveness and increases patient trust in innovative technologies. Technology companies that create novel devices must provide adequate cure, maintenance, and aftersales service to achieve the highest level of confidence possible. The framework continues to evolve to accommodate the introduction of new product classes and explorative validation methods.

1.4.1. FDA Regulations

Over the last 30 or so years the FDA has developed extensive documentation addressing safety and effectiveness of medical devices. Legally, the FDA is charged with ensuring that medical devices are safe and effective, and that they are manufactured, labeled, and marketed properly. To achieve this goal, the FDA regulates devices of the medical, dental, and veterinary fields. More specifically, all medical devices made in the US, or imported, must be manufactured in accordance with current Good Manufacturing Practices. The types of products that fall into this category are diverse - anything from bedpans to kitty litter to bone cement to drugs for use in humans to implanted devices. The facilities that manufacture these types of products must be inspected routinely by the FDA and comply with the regulations.

Under Section 210.130, the FDA establishes the clinical trial procedures for medical devices. These devices may be used during investigational studies of products like blood or blood components for delivery in the United States. Devices are classified either Class I, II, or III based on the degree of risk involved in their intended use, their complexity, the technological characteristics, and the purposes for which they are labeled or represented. Generally speaking, Class I devices are the least risky, mostly because they involve generally accepted technologies that have been available for a long time without causing any adverse effects. Class II devices are more complex and pose a somewhat greater risk or potential danger. Class III devices are the most hazardous of all, and are regulated very carefully during the design and manufacturing stages as well as the post-market phase of their life cycle. Use of Class III devices involves higher device risks than other classes, but there are no other types of legally marketed devices.

1.4.2. International Standards

Currently, in development and is established hundreds of international standards describe and regulate various fields of medicine. For example, is published more than 800 standards for traditional recipes, biotechnological and pharmaceutical additives, etc. Furthermore, more than 240 are developed, such as: Medical electrical equipment; Electromagnetic compatibility of medical equipment and medical electrical systems; Medical electrical equipment for diagnostic ultrasound. There are also environmental safety, ergonomic, interface, in vitro diagnostic, radiocommunication, software, sterilizing, transportable, and product specification international standards.

The major advantage of these international standards is the inherent concern for safety and effectiveness issues, such as electromagnetic compatibility, electrical safety, hermetic packing and quality controls. Medical devices which comply with international standards are exempt from the fact that they are sometimes scrutinized by the National Health Medicines Board, responsible for maintaining the country's standards for drug safety, which are stricter than those recommended. With respect to architectural standards, there are two major entities that draft architectural standards at an international level. Well-known examples of standards drafted in such a manner are domestic appliance safety, product safety, and biosafety standards. Such technical standards are developed with respect to a wide range of medical devices and are sometimes adopted as laws and implemented worldwide.

1.5. Technological Innovations in Medical Devices

According to the National Health Expenditure Accounts, the United States spent nearly $3.8 trillion on health care in 2014, or an estimated $11,500 per person. The increase was primarily due to rising prices and demand for healthcare services. Rising costs of healthcare are forcing healthcare providers to search for solutions to improve clinical outcomes while simultaneously lowering costs, a necessity known as the "triple aim" and several key strategic priorities outlined in the report on the National Strategy for Quality Improvement. Technological innovations in medical devices that address the issues of access, cost, and quality of healthcare may in fact provide a fourth aim for those in the medical technology field developing these products.

The development of telemedicine technologies that allow healthcare providers to assess and advise patients whenever and wherever they are medically necessary removes barriers to access of quality healthcare. Devices such as remote microchip implant and GPS active tracking devices to monitor physiological behavior can notify providers in advance of deteriorating conditions, allowing for proactive interventions and the avoidance of excessive costs associated with deteriorated conditions. Wearable devices

and other devices such as low-cost electrocardiogram, stethoscope, defibrillator, ultrasound, and optical monitor devices allow patients to monitor health conditions throughout their daily activities, while transmitting data to physicians, assisting with the early detection of conditions requiring further medical intervention.

Demographic trends indicate that we are moving toward an aging population, which will require significant levels of medical care over time. This growing older population is expected to create higher demand for skilled surgeons and operating theater access. Robotic surgical systems can increase the efficiency with which surgical procedures are performed, reducing the number of personnel required to assist in these procedures, while enabling the surgeons to perform interventions with unparalleled capabilities.

1.5.1. Telemedicine Technologies

Introduction to Telemedicine Telemedicine is the use of advanced telecommunications technology which include two-way video, email, smartphones, and wireless tools to provide health care services over long distances. Telemedicine technology includes any technology that allows for the delivery of health care services over distances, without an in-person visit. It has been utilized in providing specialty consultations, routine follow-up care, pre-operative assessments, emergency department treatment for minor injuries, and post-operative visits. Additionally, telemedicine is critical when the patient is in short supply of healthcare resources due to chronic disease, trauma, or war. It has significant potential in emergency, intensive care, and geographical distant areas. In those committed to long-distance initiatives, it can be vital in seeking to establish health facility programs and afterwards build the skills of the local health care team. Tele-studies and tele-training can significantly enhance the knowledge and skills of the entire health team and improve the quality of care provided. At present, it is difficult to find any area of health care not affected or improved by some aspect of telemedicine. It has become impossible and actually not ethical to consider distance health action, even in a wartime or post-war context, without the use of telemedicine. Telemedicine has become an imperative for what has succeeded so well for personal, professional, and commercial needs: the use of telecommunication and computer technology; now into the service of the connection of a patient and his health professionals, but quickly integrated into the organization of an entire health and care system. Although telemedicine has continued to be sophisticated, it has remained inaccessible to most countries. The need to develop rapidly and massively the quality and quantity of permits. The lessons learnt are precious, but they must be made accessible to the greatest number, so that the use of telemedicine becomes as within everyone's reach as the use of a mobile phone.

1.5.2. Wearable Health Devices

Wearable health devices facilitate continuous monitoring of physiological parameters. Consumer-level products, such as smart watches and activity trackers, have gained popularity in recent years. These devices enable assessment of aspects like posture, movement, heart rate, sleep quality, and physical activity level, among others. Many research groups are collaborating with healthcare professionals in order to provide clinical-grade sensors that can monitor patients' vital signs in real-time, thereby allowing remote treatment and preventive healthcare, as well as lowering hospitalization costs. The goal is for a network of portable monitoring devices and biosensors to be connected to smartphones, allowing the data to be uploaded to the cloud. Once there, algorithms queue and analyze the data to identify patients who need attention from healthcare providers, allowing doctors to evaluate the patients without an office visit.

The main challenges for developing more advanced wearable health devices are limited power supply; signal quality; lack of high-performance sensors ready for this particular use; lack of integration practices; size, weight, and comfort constraints; data overload; and most importantly, accuracy and security of the signals being monitored. It is expected that, in the coming years, wearable health devices will help to boost remote, preventive, and personalized medicine. Future clinical implementations may involve wearable drug delivery systems, patches with wireless biosensors and actuators communicating with smartphones, as well as body-area networks that would consist of multiple biosensors communicating with each other and transferring the data to smartphones. Such networks of connected body sensors could be relied upon for real-time remote monitoring of vital signs and physiological parameters, allowing identification of clinical events or symptoms and prediction of long-term results for patients, especially for those monitored after being discharged from the hospital.

1.5.3. Robotic Surgery Systems

Modern robotic-assisted surgical systems can be defined as minimally invasive surgical devices that are capable of enhanced surgical dexterity via: a small robotic platform and specialized instruments and surgical tools in a flexible configuration; a master-interface that can easily translate hand motions of the surgeon, with haptic feedback, into the hand movements of the robotic instruments; a sophisticated software architecture that provides motion scaling, tremor filtering, and instrument collision detection; and a hardware-in-the-loop real-time computation engine capable of executing motion commands at high frequency rates while providing haptic rendering of sensitive biological structures. The introduction of robotic-assisted minimally invasive surgical systems has created an entirely new sub-field in the discipline of surgery, at once delicate and powerful, that taps into advanced technologies and engineering principles previously

only available outside the operating room. Robotic-assisted minimally invasive surgery has indeed transformed, and will continue to transform, the actual practice of surgery, truly both an art and a science. Robots play an essential role in this revolution, providing performance capabilities that far exceed those of even the best of human surgeons. Robotically-assisted surgery is already routinely used in urology, gynecology, thoracic, cardiothoracic, and a few select general surgical procedures with excellent patient outcomes and satisfaction. Other surgical specialties, such as orthopedics and neurosurgery, have yet to experience robotic-assisted minimally invasive surgery. When these surgical disciplines adopt robotic-assisted surgery, as they inevitably will, robots will become a central element of the modern surgical armamentarium.

1.6. Integration of Mechanical Devices in Healthcare

In this section, several areas of mechanical devices that deliver benefits to otherwise able-bodied and disabled people in their daily lives will be discussed. These devices integrate to act as either augmenters of current capabilities or entirely new capabilities to ameliorate damage done via injury and disease. Prosthetics, orthotics, and assistive technologies are all areas that focus on delivering repairs, gain, or replacement to specific functions through mechanical devices. As such, they differ in specific methods and deliver benefits at the system level as augmenters, enablers, or substitutes. However, at higher levels of abstraction, the specific technical details that differentiate them disappear. We will first explore prosthetics and orthotics systems at lower-level details and augmenters and enablers at a higher level.

Prosthetics and orthotics refer to assisting mechanical devices that directly attach to and replace some of the functions of limbs in able and disabled-bodied users. Classification can be roughly grouped into upper-limb vs lower-limb that could then be sub-categorized by specific functional capabilities or level of assistance or user ability. Currently, most of the specialized function devices are passive or body-controlled devices. Some independence has been achieved using actuated robotic devices that have been powered by external control and power-supply systems. The focus on higher-level controller systems has led to advancements in actuation types in terms of power, efficiency, volume, and weight.

The field of assistive technologies can loosely be defined as specialized devices that remove barriers or act as enablers to tasks that for various reasons cannot be performed by otherwise able-bodied users. Examples include devices like wheelchairs, lifts/modifications for building access for physically disabled users, talking computers, and communication devices for users impaired by neuro-infection paralytic disease.

1.6.1. Prosthetics and Orthotics

Prosthetic devices replace lost body parts, while orthotic devices change the function of existing parts. Together, these devices can improve function and life quality tremendously. Both medical and mechanical; both simple and technologically complex; both single-purpose and multi-purpose devices have been developed to fill these needs. Prostheses are not just insensitive hooks anymore; modern prosthetic arms, fingers, knees, feet, legs, and face parts can perform several body functions, use sensory input, contain live cells, and are increasingly being controlled by nerve signals. Technology has brought us powered hands and limbs using artificial muscles which can compress, expand, twist, and bend lots better than traditional mechanical devices. Controlled electronically or using nerve impulses, some powered prostheses assist people to do things they had to stop.Clearly, the more advanced the device, the more sophisticated the person. Some amputees want nothing more than a hook, which is a functional tool. Technology has no right to push them towards research, investment, complications, high probability of failure, and in a worst case worst quality of life. Another future challenge: how much technology do we want in our bodies? Investors should be thinking about all sorts of prosthetic and orthotic devices that middle or lower class people could afford; devices for other limbs not just hands; devices that recognized and adapted the user's needs. Some users would want a device which acts like a natural limb; would want nothing more than walking fast, steady, and noiseless over centuries. There is already a big market; by 2004 it was around $8 billion.

1.6.2. Assistive Technologies

Devices that fall into this category are assumed primarily to improve functional capacity or to promote treatment compliance, but they are not necessary for physical functioning. A conventional wheelchair is one of the oldest and widely used assistive devices, which is used for mobility of disabled people who have lost the ability to walk due to a variety of reasons including injury, congenital defect etc. However, although the wheelchair provides small-scale freedom of movement, it still requires the user to have some ability to operate and maneuver the device. In order to address this limitation, a powered wheelchair was developed as a solution. But for some disabled people, an electric wheelchair may still not be suitable since they cannot adequately operate the electric switch on the device.

Due to the limitations of conventional wheelchairs, diverse kinds of mobility assistants have been developed which can be used to help individuals with more severe disabilities. A highly-modified convertible Segway that can carry a disabled person in their sitting position has been developed. This kind of personalized transport system is semi-autonomous, meaning that it requires the user to have some ability to control the

movement of the device. In this case, the controller used is the joystick placed on the device, which allows its user to operate the Segway by leaning in the direction of desired movement. Being a personalized transport system, the Segway-MC is capable of working both internally and externally, meaning that the disabled user can perform his/her activities either inside the house and outside as well respectively while being assisted by the device.

1.7. Impact of Medical Devices on Patient Outcomes

It is clear that medical devices can impact the healthcare experience, either via directly modifiable interactions in the patient journey via a medical device or from longer-term health status change as the result of treatment. From a statistical perspective, we can denote the potential for devices to improve functional capacity/daily activities and from a person-centered perspective, the possibility that interaction with a medical device can help a patient have a more acceptable life, and thus decrease the burden of treatment. Particularly in chronic disease, we note the very long duration of treatment may encompass many years, and thus the acceptability or burden which can be described as health-related quality of life does have substantive impact.

Quality of life can be described as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. So to expand upon that, numerous models either summarize a patient's perspective on life satisfaction or in a more complex manner attempt to provide evidence how health status directly or indirectly influences a person's overall life satisfaction. While at some level it could be claimed that a patient's direct life experience is the ultimate arbiter of the appropriateness of treating and saving that functional status, there are many arguments as to why payers would need to have access to comparators that help them assess appropriate value for treatments and thus medical devices.

Increasingly, clinical trials are being implemented with multiple perspective-based endpoints with HRQOL, indirect costs from lost productivity or cost-effectiveness from modeling with these inputs are substantial components in device risk assessment, review post-market and post-market surveillance, and reimbursement. There is therefore a responsibility to the regulators, companies and payers to ensure this information is available by way of the content of clinical investigation, and in the longer term have evidence-based models that can help in predicting the expected HRQOL and cost-effectiveness impact.

1.7.1. Quality of Life Improvements

The physical and psychological burden of every disease, ranging from skin conditions to malignancy, imposes an individual cost on the afflicted patient beyond the financial burden placed by the wider system of socially and personally borne additional costs of disease. This presents strategic challenges at a global scale but also provides opportunities for the use of technology to alleviate distress. Many of the developments work toward ameliorating the suffering of patients by directly bypassing the underlying pathophysiology or by facilitating clinician and patient interactions. Chronic disease is an increasing burden, in part due to longer life expectancy, with the associated individual need for devices which may be accompanied by long-term changes in amounts of required resources. With many current forays into technology-driven solutions to healthcare problems being led by start-ups and private investment, there is an additional need to investigate the effects of these devices on the quality of life of patients and to balance the resulting effects.

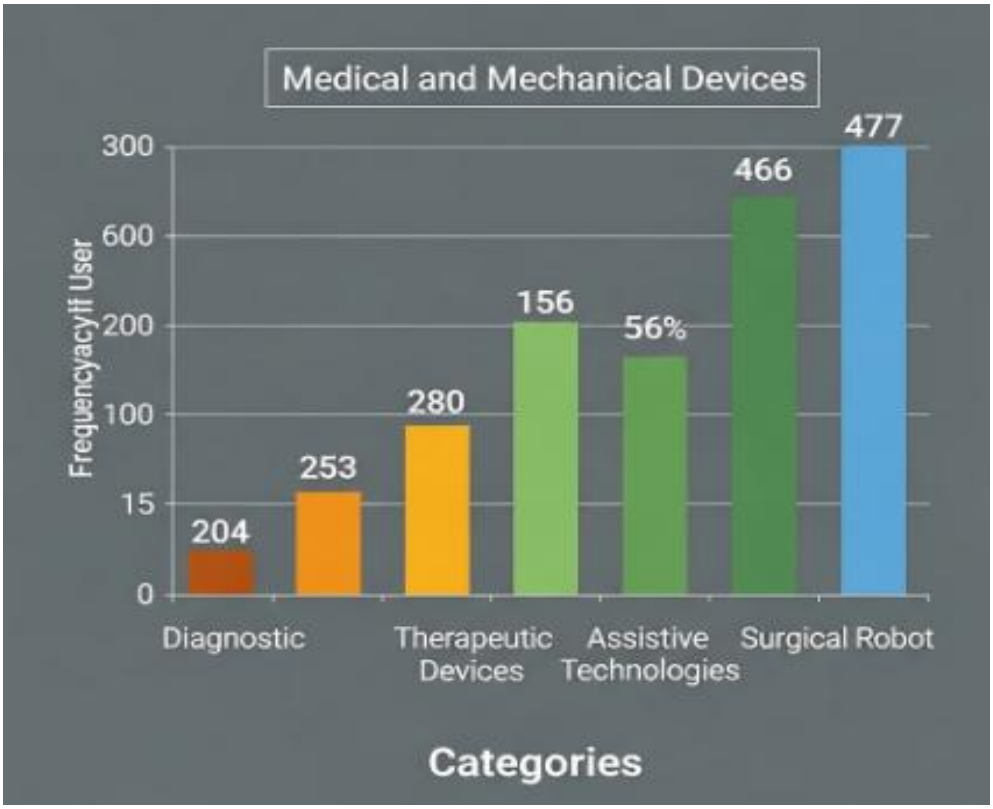

Fig: Medical Devices of Medical and Mechanical Devices in Modern Healthcare Systems.

On the other hand, technological solutions require durable solutions on a product timescale, such as those witnessed in orthopedic joint replacement or pacemaker insertion. Efforts must be made to examine clinical and quality of life outcomes as they pertain to the devices themselves and to barring-off within-device testing. Comparisons to other forms of treatment are not sufficient. Devising a simple joint-specific quality of life metric, however, is worth the effort, as it would allow the surgery to be compared with other forms of treatment available. Quality of life metrics are used to compare non-surgical treatments; the principle disadvantage of joint surgery, namely, that it cannot easily be reversed.

1.7.2. Cost-Effectiveness

Introduction In any healthcare system with limited resources, the rule of economy mandates that the purchasing decisions made for its various components must reflect the overall objective to maximize the attainment of societal objectives and consequently the long-term sustainability of the entire health system. The health system therefore has to operate as an integrated complex adaptive system and not as a series of interacting mechanisms or devices driven by market forces. In the case of medical devices, priority setting either in the evaluation of medical device technology or in the planning of the use of resources in the area of health providers needs to ensure that assessment and evaluation criteria are clear, relevant, and applied consistently. Effectiveness is only one aspect of a more comprehensive problem of the guidance of public choice and priority setting. Lists of devices and services that are considered uneconomical are one method to formalize the decision-making processes and communicate them but by no means the only one. The devices and procedures that have been included in stages I to IV of the combined assessment program are not necessarily those that will be considered acceptable by, or for which providing treatment will be deemed financially and socially justifiable by, third-party intermediaries. The fact that a particular device is not included in these reports does not indicate that it is to be regarded as uneconomical. Third-party intermediaries must still justify their decisions with regard to funding. The criterion for assessing cost-effectiveness should ideally be the lifetime cost per unit of improvement in quality-adjusted life years for patients on whom the device is being used. This requires the best evidence available to estimate a model of the relationship between cost, health gain, and length of life for patients with the pathophysiological problems that the device is designed to treat.

1.8. Conclusion

In summary, adaptive mechanical systems are increasingly being used in medical practice. Giant structures, which exceed human dimensions and cannot be used in an ordinary physical form, demand the development of a whole range of new control systems. Robots are today used for high-accuracy, tedious, unsteady and hazardous tasks. Many people expect that robots will be used in hospital operations, in conjunction with artificial intelligence, to prevent medical errors, provide a second opinion, and predict the course of the disease and the effectiveness of treatment. However, it is already clear that the use of robots implies not their replacement, but rather the modification of human activity in accordance with the changing tasks, functions and responsibilities within the professional team. The aim was to positively change the quality, safety, and effectiveness of the assistance. In daily practice, robots allow more free time for the nurses, enhance the collaborations, and so on. In conclusion, one of the major trends in modern science and technology is the creation of increasingly complex systems. Their nature and purpose are guided by the general laws of the world's development, primarily by the principles of self-organization, the optimization of functionality and power, as well as the transition from a mechanical basis of the material world to a thermodynamic basis. The strategies for the creation of systems and devices of this kind are provided by the discovery of abstraction and the science of decision-making. Our development shows that the functional basis of decision-making science can be formulation of intelligent decision algorithms and methods of development of decision planning. The solution of this problem for the medical robotics devices can lead to a qualitatively new stage of developing devices in this area.

1.8.1. Future Trends

Medical devices are a major part of everyone’s life, bringing positive health benefits through expertise, proper care, and technological innovation. In today's health care system, however, medical devices have become subsumed in a greater system of commercial enterprise, creating a dynamic environment that fosters products that are lower priced and increasing comfort with technical complexities. Future developments will accelerate changes that are already underway: increased use of remote patient monitoring that permits more and better personal health record management; greater integration of medical devices and IT systems to permit continuous and real-time analysis of device performance; intelligent sensors that minimize patient intervention while providing better and more comprehensive patient status information; readmission avoidance and patient monitoring technologies that focus on chronic disease; and innovative business models that reduce device cost to the users and create new incentives for better patient care. Specialized, implantable devices that continuously monitor vital

signs will eventually replace invasive sensor use. Third-party health monitoring services will grow more into patient data, enabling more line-to-line health insurance premium models.

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