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ADVANCEMENTS IN PROSTHETIC TECHNOLOGY: ENHANCING SOCIAL ACCEPTABILITY AND REGULATORY COMPLIANCE

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ABSTRACT:

Prosthetic technology has advanced significantly from its inception in the 16th century, including current developments. Prosthetics, which replace missing limbs or body parts, have evolved from simple metal and wooden devices to complex, lightweight, and functioning artificial limbs. This research investigates the historical evolution of prostheses, classifying them according to application (e.g., transradial, transhumeral, transtibial, transfemoral) and regulatory requirements (Class I, II, III). The USFDA's role in regulating prosthetic devices is described, with an emphasis on safety, effectiveness, and adherence to federal requirements. Recent advances in prosthetic technology have centred on increasing user usefulness and comfort through patient input and new materials. Despite technical advancements, social acceptability remains an important consideration in prosthesis use. This is impacted by environmental factors, psychological adjustment, and personal preference for prosthetic equipment. Effective communication between prosthetists and users, as well as collaboration among experts, is required to optimise prosthetic therapy. The study continues by emphasising the need of ongoing innovation, user-centred design, and rigorous regulatory supervision in ensuring that prosthetic devices not only satisfy technical criteria but also fit with users' needs and preferences. Addressing these issues can improve the quality of life for those with limb loss, allowing them to live more full and independent lives.

Introduction:

Prosthetics refers to the field of research and expertise in designing and building artificial limbs.
Prosthesis refers to an artificial device built to replace a missing body part. The plural of a prosthesis is prostheses. These devices are worn by people who have lost limbs or those born with congenital limb differences.
A prosthetic device can support, shield, or make a medical prosthesis more usable. A prosthesis replaces a bodily part that was lost in an accident or has been missing since birth. Examples include a prosthesis alignment tool and artificial body components that have been surgically installed. The prosthesis improves its appearance rather than its usefulness. Recently, researchers began developing a prosthetic hand with moving fingers.
According to Ambroise Pare, a French physician, prosthetics first emerged as a science in the sixteenth century. Later, labourers created metal hands that could move independently or as a single unit to replace the upper extremities. Later, a single hook or an inactive hand wrapped in leather and connected to the forearm with leather, or a wooden shell mostly replaced the solid metal hands of the 16th and 17th centuries. Prosthetic design has evolved, and acceptability of its usage has grown with big battles. Following World War I and II, new lightweight materials and improved mechanical joints were developed. Over 100 million people across the world used these prostheses. Around 15% of Indians used these prostheses.

Classification:

Prosthetics are classified in two ways based on their applications and regulatory aspects.
I. Prosthetic devices are categorised into four categories depending on their applications and components. They are:

i. Trans radial
ii. Trans humeral
iii. Transtibial
iv. Transfemoral

i. Transradial
A transradial prosthesis is a prosthetic arm that is attached below the elbow. A passive gadget of this type serves just decorative functions. This sort of

gadget is only cosmetic. The opposite is an active prosthesis, which comes in two varieties. An active prosthesis is provided in two variations. A cable-operated prosthetic device operates by attaching a harness to the damaged shoulder and the other arm, letting the user to manually control the movement. The cable-operated prosthetic device has a harness that connects to both the afflicted and other arms. This lets the user directly control the movement. A myoelectric prosthetic implant uses specialised sensors to detect muscle activity in the upper arm and move the prosthesis, such as opening and shutting the hand. Myoelectric prosthetic implants detect muscle action in the upper arms using specific sensors and move the prosthesis to open and close the hands.

ii. Transhumeral

A transhumeral prosthesis is an artificial arm attached to the body above the elbow but below the shoulder. A transhumeral limb is more sophisticated than a transradial prosthesis because it lacks an elbow, making movement more difficult and complex to correct for. Transradial prostheses are easier than transhumeral prostheses since the elbow is lacking. This makes movement more difficult and compensation more complex. Transhumeral prosthetic devices can be both active and passive. Active and passive transhumeral prosthetic devices are also options. The majority of current active transhumeral prostheses employ myoelectric sensors or a mix of sensors and wires to move the prosthetic limb. Modern active transhumeral prosthesis use myoelectric sensors, or a combination of them. These sensors allow the prosthetic limb to be manipulated via wires.

iii. Transtibial

Transtibial prosthesis is a prosthetic limb that is placed below the knee. Since the knee allows for a lot of mobility without help, the prosthesis' principal job is to evenly distribute weight and give comfort. The prosthesis provides excellent flexibility and comfort, since the knee allows for full movement. Patients must be reconditioned for walking with a transtibial prosthesis since the mechanical foot normally does not move. Because the prosthesis is generally immobile, patients must be taught to walk with it.

iv. Transfemoral

The transfemoral prosthesis is the most complex of the four primary varieties. It substitutes a lost leg above the knee. It substitutes the lost leg both above and below the knee. The artificial knee joint is controlled by hip motion, hence the residual limb's strength has a significant impact. The strength of the residual limb has a significant impact on hip mobility, which controls the prosthetic knee joint. A transfemoral prosthesis often provides for seemingly normal mobility and function during a protracted rehabilitation procedure. After extensive therapy, a transfemoral prosthesis can restore normal mobility and function. A perfect socket fit is vital for both comfort and stability.

II. Prosthetic devices are grouped into three groups according to regulatory standards. They are:

A) Class I Prosthetic Devices

B) Class II Prosthetic Devices

C) Class III Prosthetic Devices

A) Class I Prosthetic Devices

For most of the class I devices, manufacturers are excluded from the premarket review, PMN [510(k)] submission, and PMA application criteria, and they are not required to seek for FDA clearance. The FDA does not mandate that these devices collect clinical data. As previously stated, class I devices must meet common regulatory standards such as medical device listing, labelling rules, device registration, and device listing. In addition, if the device is the cause of fatalities or other catastrophic injuries, they must preserve records and file reports. If a class I prosthetic device is being given for a novel application or employs a different basic scientific technique than a device that has been lawfully sold in that broad category, premarket notification filings [510(k)] are required. As a result, a 510(k) application may be required for a prosthetic device that incorporates novel technology.

B) Class II Prosthetic Devices

If a class I prosthetic device is supplied for a novel purpose or uses a different basic scientific approach than a device that has been lawfully sold in that broad category, a premarket notice filing [510(k)] is necessary. Consequently, if a prosthetic device employs unique technology, a 510(k) application may be required. The FDA allows the commercialisation of a device if it is considered to besubstantially identical. The FDA Modernisation Act of 1997 exempts some class II devices from the 510(k)-filing requirement. If the manufacturer believes that their product is both unique and low risk—risk that can be reduced with specific measures—they may pursue a de novo class II device classification from the FDA. The FDA will review the application and decide on the device's final classification.

C) Class III Prosthetic Devices

Class III devices require more premarket testing than Class II devices because of its increased risk. Manufacturers of class III devices must file a PMA application and provide a reasonable guarantee of effectiveness and safety. The word "reasonable assurance" refers to the availability of trustworthy scientific clinical evidence derived from rigorous clinical trials that assess the device's safety and efficacy. Less than 5% of the medical equipment under CDRH supervision is classed as high risk. A small number of class III devices are exempt from PMA due to the safety and efficacy of items on the market in 1976, when the medical device amendments were enacted. The PMA is a regulatory procedure similar to the humanitarian device exemption (HDE), which applies to devices having humanitarian applications and may include class II or class III devices. The HDE application, like a PMA application, must demonstrate that the projected benefit justifies any potential dangers in order to be granted. Any number of prosthetic devices can be submitted as an HDE application. (1)

USFDA regulations for Prosthetics:

The Centre for Devices and Radiological Health (CDRH) of the FDA is responsible for enforcing regulations on "Medical devices," which includes prosthetics. Although there are articles addressing medical devices regulation by FDA in the literature, these studies often focus on implants and other devices that represent a significant risk and a specific guidance is not provided for prosthetic industry. All new medical devices must be approved by the CDRH, which also categorizes them according to risk, evaluates studies that involve significant risks to human subjects, and aids in deciding particular proof, if any, or investigational studies are required to demonstrate the device's safety and efficacy before approving its sale in the United

States. Every prosthetic component must be attached. Before they can be commercialized in the US, every prosthetic device must adhere to Federal standards through CDRH protocols as mandated by 21 CFR Parts 800-1299. A medical device that is being tested on humans and is under investigation is referred to as "investigational device" prior to CDRH marketing approval.

Most prosthetic parts and controls, although not all of them, are categorized as class I. The FDA exempts almost all class I devices from premarket notice. The majority of class I devices makers, or researchers choose to undertake studies utilizing these devices even if evidence on clinical effectiveness and safety may not be necessary to receive FDA authorization for marketing in US. Class I, class II devices require additional special controls due to their higher risk. Premarket notification (510k) submissions are necessary for the majority of class II devices, but not all of them. Most often, they compare the intended use and technology of the device with those of a product that has already been marketed using the 510(k) process. Certain class II devices occasionally require limited clinical data. The most dangerous devices are those in class III, and a PMA is required, usually with prospective clinical data to show safety and efficacy. (1)

Development of the Prosthetic Technology

One key component of translational research is patient involvement in the creation of novel treatments. This type of "patient science" or "citizen science" has been endorsed and encouraged more recently by legislators and other stakeholders. Still, it is widely recognized from biological studies show that applying experiential knowledge to the research and development (R&D) process might be difficult. Giving consumers a detailed image of what the innovation might look like is difficult to do methodically. Moreover, it is challenging to connect users' experiential knowledge to the proposed innovation [2].

Regarding the creation of prostheses, developers have stated that they don't often get the chance to speak with consumers directly about the functionality and design of the devices [3]. Research on user preferences and desires for the functionality and design of prostheses do

exist, but may have insufficient validity to be used directly in practice, like in the case of solely asking doctors to act on behalf of users [4]. Additionally, because of the small sample size, users with a variety of amputations and models are asked about prosthesis constraints and design priorities in qualitative and exploratory research without being divided into subgroups [5].

Generally speaking, though, these kinds of studies can provide insightful direction for R&D aimed at enhancing the utility and usage of prostheses. There are various approaches to gathering information about preferences and development needs, ranging from more indirect and closed investigations to direct and open questions regarding user wishes in qualitative surveys. These could include studies on functional (technical) rejection reasons, the importance of everyday chores that are challenging for people using current prostheses, and the ranking of recommended features that could be improved [5-7]. It may be necessary to consider whether to accept trade-offs between invasiveness and functional benefits when using prosthetic technology that carries a risk, such as intrusive control procedures [8].

Open-ended inquiries regarding desires could inspire the creation of fresh concepts and viewpoints. One drawback of this type of questioning, though, would be that users start to adopt a mindset of contentment with the status quo. Furthermore, some of the innovations anticipated by creative prosthesis manufacturers might not come to pass and, when they are Societies 2020, 10, 10 6 of 20 submitted for review in a survey, might be unthinkable for users if they are unable to test a prototype. It is challenging for users to connect technological advancements or particular device characteristics to their unique prosthetic experiences, according to Benz et al. [9] (p. 288). Users and developers must communicate more frequently and at various stages of the development process. Every few weeks or months, a prosthesis development project involves making a number of design and functional decisions. Users are, however, frequently only marginally—if at all—involved in these choices. After months of work have been put into the creation, they might then simply be requested to test demonstrators. Additionally, product descriptions are frequently too ambiguous to allow users to assess the prosthesis fairly. The more diverse the test user base, the more generalizability there is. Shorter iteration cycles of user feedback and development advancement can also close the gap between what users want and what developers can imagine.

Improvements in the design of Prosthetic technology:

While prostheses were still composed of wood, metal, glue, and leather until the twentieth century, they were getting more practical. From the late 15th to the nineteenth centuries, France and Switzerland created artificial limbs that could rotate and bend utilising cables, gears, cranks, and springs. However, these gadgets still required manual adjustments. For example, an artificial hand might be cranked closed around a fork, but the individual would still require another hand to operate the crank.

During the 1900s, manufacturers began to create more practical prostheses by replacing wood and leather with plastics and other artificial materials. However, most individuals, including veterans, were unable to afford some of the finest prostheses available. Many of these gadgets were specifically intended for specialised purposes, such as piano playing. They would not become more widely available to veterans until World War I, when prosthetic manufacture for troops with limb loss surged in Great Britain. According to Jeffrey S. Reznick, Ph.D., Chief of the National Library of Medicine's History of Medicine Division, such wartime production (and repair) did occur at military hospitals. Soldiers rehabilitating in those institutions were equipped with prosthetic limbs as part of their treatment.

Today’s prosthetics look and work very differently from those made before the late 20th century. More lightweight and durable materials such as plastic, aluminium, titanium, and silicone are common in today’s prosthetic devices. They also fit closer to the user’s remaining limb.

Factors Influencing Social Acceptability of Prosthetic Use:

The enhancement of social acceptability is being influenced by a number of elements, including

Environment

People with limb loss themselves have rated social outcomes as more important for assessing quality of life outcomes than their physical impairment, so the acceptability of assistive technology depends not only on its efficiency but also on the reactions it elicits in those around the user. A functional outcome following amputation has been found to be predicted by having strong social support, in addition to the perceived quality of life.

A patient's surroundings as position within them are crucial factors to consider, as the definition of impairment is contingent upon the context in which it is used. A "disabled" identity was mostly experienced by those who had lost limbs, according to their reports. Prosthesis users' perceptions of functional outcomes in relation to using them have been frequently related to their social settings. Higher levels of satisfaction and lower levels of anxiety have been observed in patients who feel accepted by their social surroundings. Thus, comprehending the social reality of prosthesis users can increase the likelihood of successful prosthetic fittings in addition to fostering greater empathy.[10-17]

Expectations, Psychosocial Adjustment, and Human Significance:

The general topic of possibly traumatic limb loss must be taken into consideration when attempting to evaluate issues connected to prosthetic usage. A person's psychological reality may be profoundly affected by losing a limb due to trauma or illness. People who have lost a limb frequently experience decreased self-worth, increased anxiety in social situations, despair, and possibly post-traumatic stress disorder, in addition to possible substantial pain. This means that a person's capacity to eventually accept and incorporate a prosthesis into their life is greatly influenced by how well they cope with the trauma of losing a limb. An individual's reaction to circumstances that demand adaptation and have a major influence on their life is known as psychosocial adjustment. Even though it appears that good psychosocial adaptation is one of the most potent promoters of subsequent prosthesis usage and a high quality of life, influential factors on this adaptation have not received much attention. Although there is evidence to support the notion that active coping, general (dispositional) optimism, a propensity for "downwards social comparison," and the perception of some degree of control over one's own circumstances are all positive indicators of good psychosocial adjustment, Widehammar et al. conjectured that early rehabilitation care can play a major role in the development of effective coping. Therefore, it may be necessary to give this particular goal extra consideration in standard rehabilitation regimens.[18-21]

Another crucial component in the early phases of therapy is expectation management. According to a number of research, matching users' initial expectations is positively correlated with their later reported pleasure, indicating that setting reasonable expectations is crucial for preventing disappointment as well. The extent to which this is applied, nevertheless, sometimes seems inadequate. According to interviewees in a Uytman research, they were not adequately informed about how quickly they would advance. Conversely, a crucial and much-disregarded element is the excitement that can be generated when a patient who has lost a limb receives a useful replacement.[22-25]

It's possible that noticing an improvement in their abilities may set off a positive feedback loop that will eventually enable them to successfully integrate the prosthesis into their daily lives. User motivation to continue training with their gadgets can be increased if early successes are maintained and reinforced. Users are encouraged to continue broadening the range of activities they can enable with their system because the prosthesis is easier to use and feels more natural as a result of their increased expertise with it. Murray discovered that when users view their prosthesis as a valuable instrument that supports activities they identify with their personality, such positive associations are common. These can include social activities like taking dance classes or going out to clubs at night, spending time with or playing with their kids, or improving their skills at work. Individuals who prioritise their independence are more likely to successfully incorporate a prosthesis into their daily lives if they believe the device will allow them to accomplish more chores on their own. Driving a car is one of the experiences that most users felt was extremely important and has been regarded as one of the most liberating in relation to both upper and lower prosthesis use. [14,16,26,27]

Individual Choice of a Prosthesis and Communication with Prosthetists and Peer Networks:

Positive outcomes are facilitated by effective communication between the prosthetist and the user, according to research on this interaction. Improving the relationship between prosthesis providers and users could begin with acknowledging that collaborative decision-making necessitates participation from all parties. Prosthetic acceptability has been discovered to be influenced by a number of aspects, one of them being an individual choice of the prosthesis itself.[21,28,30]

According to Biddiss and Chau, there is an eight-fold increase in the likelihood of consumers sticking with their system if they were part of the choosing process. Users undoubtedly differ in their priorities and objectives, which is one explanation for this. While some users choose dependability and functionality, others prefer attractive design elements or adjustable prosthesis covers.The kind of prosthesis that users find most helpful in their daily lives will also depend on these personal values. Additionally, they have a significant influence on the sentimental connections people have with particular systems [20].

Acknowledging one's own obligation to participate in decision-making is a crucial first step since disengagement can cause problems if patients subsequently believe that the decisions made are incorrect. A prosthetist should always give the user as much information as necessary to help them make an informed decision regarding the prosthesis they choose as well as other phases of the rehabilitation process in order to support this cooperative effort.[28,29] Studies have indicated that medical practitioners often underestimate the amount of information patients require or want for this reason; therefore, a greater understanding of the critical role this knowledge transfer plays is likely to have a positive impact on results. Good communication between the prosthetist and the user is the foundation for many other factors related to the successful integration of a prosthesis into a user's life, in addition to the fact that the simple act of involving patients in the prosthesis selection process itself results in higher instances of continued use. This includes, among other things, establishing reasonable expectations, considering objectives and preferences, motivating users to stick with the initially taxing training stages, and offering a reliable and steady support system in the event that problems arise.

It's important to keep in mind, though, that a prosthesis user's relationship with their healthcare providers may not always be able to give them the

information sharing, comfort, and support they need. Therefore, other prosthesis users with greater expertise can be a great resource. Early post-amputation contact with other prosthesis users can significantly boost patients' confidence by reassuring them that their initial doubts and challenges are common and can be overcome, according to research by Gallagher and Maclachlan. [24]

When offered this kind of chance, the study participants evaluated it as extremely beneficial, and some said they had wished they had been able to do so. Meeting someone who can attest from own experience that mastering one's system is feasible and worthwhile might instill confidence and hope in new users, especially as prosthetic acceptance appears to be a long-term process. In the study by Hamill et al., the subjects evaluated their interactions with other people who had experienced similar things as their strongest form of "support connection," viewing these people as someone they could talk to about any questions, they might not have felt comfortable asking the medical staff.[14,27]

Enhancements in Prosthetic Therapy:

Prosthetic therapy can be enhanced by several ways such as cooperation between professions in Research and Practise. In the field of prosthetic care, there is a need for increased professional communication. It has been noted, for instance, that systematic research by prosthetists would be significant, but that study is typically conducted in clinical settings or by researchers who are not professionals in the subject. According to the British Association of Prosthetists and Orthotists, prosthetists have an express and required duty to contribute to research. Practitioner-conducted research would improve generalizability by as nearly representing real-world settings as feasible, such as patient variety. Simultaneously, a well-established research culture in practice ensures that findings are recognized and applied more broadly by practitioners. Directly informing practitioners of the findings of the acceptance study could also be a possibility. In any event, there has to be a greater sharing of knowledge between prosthetists and social science and acceptance researchers.

Prosthetic therapy enhancement can also be done by the help of education and training of professionals. The advantages of allowing practicing prosthetists to undertake research or collaborate with researchers on evaluation tests involving single users (which could involve prosthetists doing outcome assessment tasks) have already been discussed. The findings of social science research on prosthetic care ought to be incorporated into prosthetist education courses for them to reach their target audience. Since users must have new prostheses fitted or adjustments made to existing ones every few years, they often accompany users throughout their whole lives, starting with the first fitting process. It follows that in order toassist the user, for instance with prosthesis selection and adaption procedures, prosthetists should be knowledgeable with all pertinent acceptance criteria, such as social aspects and psychosocial adjustment processes. Research findings that are currently infrequently applied in daily practice may provide them with an extra useful source of information. Additionally, integration of the best available evidence into practice is listed as an explicit and required responsibility of prosthetists by the British Association of Prosthetists and Orthotists.[28,29,30]

Conclusion:

The journey of prosthetic technology from its origins in the 16th century to the present day has been marked by remarkable advancements in design, functionality, and social acceptance. Today, prosthetic devices range from simple to complex, offering individuals with limb loss a wide array of options to enhance their quality of life. The classification of prosthetic devices by regulatory bodies like the USFDA ensures that these devices meet stringent standards of safety and efficacy before they reach the market.

The social acceptability of prosthetic use is influenced by various factors, including environmental context, psychosocial adjustment, and individual choice. Understanding these factors is essential for prosthetists and healthcare providers to facilitate successful integration of prosthetic devices into users' lives. Effective communication, collaboration, and education among professionals and with prosthetic users play a crucial role in enhancing prosthetic therapy and promoting user satisfaction.

As prosthetic technology continues to evolve, it is imperative to prioritize the needs and preferences of prosthetic users, foster innovation, and maintain regulatory compliance. By doing so, we can ensure that individuals with limb loss have access to safe, effective, and socially acceptable prosthetic solutions that empower them to lead fulfilling lives.

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