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A REVIEW ON PROSTHETICS AND ORTHOTICS FOR AMPUTEES AND DISABLED

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Abstract: This case study gives an overview of the prosthetics and orthotics used on patients for better gait rehabilitation. Many people suffering from various muscular and neurological diseases, lower-limb amputees, elderly are dependent on various prostheses and orthoses for a better quality of life. The review is considered under three categories: above-knee prosthesis, below-knee prosthesis, and orthotics. Each group is divided into its subdivisions with respect to the part of the body it is suspended. This paper reviews the currently available prostheses and orthoses. An analysis of the various designs and materials for each device, as well as the discussion of their limitation, are provided.

Key words: gait rehabilitation, lower-limb amputees, orthotic devices, prosthetic

I. INTRODUCTION

Prosthetics and Orthotics are mechatronics systems that are designed to replace a missing part of the body structurally and functionally and to increase the physical abilities of amputees and disabled. In the past years, transfemoral prostheses (above the knee prosthetics) have developed to microprocessor control systems from simple mechanical systems. The trans-tibial prosthesis, also referred to as below the knee prosthetics are used to provide gait rehabilitation after the below-knee amputation caused by several problems such as cancers, infections, neuroma, or severe injury [1][2][3]. The prosthesis is usually suspended to the residual limb of the below-knee amputees. The residual limb must be well-formed, round, and healed adequately at the end for the suspension of the prosthesis. The significant advancement of prosthetics goes back to the time after the Second World War, when a team at the University of California, including James Foort and C.W. Radcliff, developed a quadrilateral socket by developing a jig fitting system. The usage of jigs helped in holding the residual limb in the right position, making it fit in the socket, providing a convenient and comfortable walk to the amputees. Considering the complications involved in the usage of jigs in prosthetic limbs, there have been advancements under it involving plastic materials like carbon fiber. With the increase in technology and extensive usage of Artificial Intelligence, specific electrical circuits are included in the prosthetic limb, allowing them to operate similar to a fully functional human leg. Myoelectric limbs are one of these advancements which control the limbs by converting the muscle movement into electric signals, indeed inducing smoother usage. This paper gives a review of the literature on the below-knee prosthesis that are currently in use.

Orthotic devices have been developed to assist people suffering from various muscular or neurological diseases. It is also extensively used for stroke survivors and older people in gait rehabilitation. Each gait cycle has two phases – the stance phase and the swing phase. The stance phase of walking is composed of a weight acceptance phase (~ 40%) and stance termination phase (~40-60%). The knee exhibits an enormous moment and considerable flexion in the weight acceptance phase [2]. The primary objective of these orthotic devices is to support the knee during weight acceptance phase and to provide free movement during the swing phase. Various methods offer a locking and unlocking system that locks the knee in an extended position, which keeps the individual throughout the stance [4]. Within this paper, we discuss the different orthotic devices and their mechanisms which support the needy people.

II. EXPECTATIONS OF PROSTHETIC AND ORTHOTIC DEVICES

A. User-friendly

Prosthetic and orthotic devices play a significant role in gait rehabilitation. Although many factors affect gait rehabilitation such as physical therapy, surgical care, psychological support, the quality of the prosthetic or orthotic devices is mainly concerned. People prefer more comfortable and user-friendly devices. Such devices must be capable of withstanding the load and must support the user with his daily activities while providing comfort and safety. The function of these devices varies depending on the user and the terrain. These devices must quickly adapt to user requirements. Thus, a proper understanding of the physical and functional needs of the user has to be studied. The prosthetic and orthotic devices must ensure comfort and maximum mobility for their excellent performance.

B. Adaptability and robustness

The prosthetic and orthotic devices must be preferable over all terrain. Some of the devices are not suitable for some terrains. It must be able to operate across all terrain and should be able to withstand varying weather conditions. The devices must be more compact and less bulky, which makes it more adaptable. Robustness refers to the state where it can function under typical conditions and for an extended period.

C. Durability

Durability is one crucial factor that every user considers. Users are often unsatisfied with less durable products. Maintenance is another essential factor. The more routine the device is maintained, the more it lasts. So the prostheses and orthoses must be simple and easy to repair, requiring minimal parts for repair. Moreover, the device must be easy to clean and maintain.

D. Affordable

Cost plays a crucial role in the decision process of whether to wear a prosthetic or an orthotic device. An amputees' inability to afford the prostheses can significantly affect his quality of lifestyle. A lot of older people who depend on gait rehabilitation can have a better quality of life if these prostheses are affordable. These must be cost-effective not only during the purchase but also for the maintenance. Thus, the availability of these devices in a more accessible manner can have a better impact on the user lifestyle.

III. CURRENT PROSTHETIC AND ORTHOTIC DEVICES

Prosthetics and orthotic devices have a significant role in gait rehabilitation. An extensive literature study was conducted with over one hundred articles, patents, and research papers on various prosthetic and orthotic devices for the lower limb. These were then classified as upper knee prosthetics, lower knee prosthetics and knee orthotics. Some of the prosthetics developed in the recent years are shown in Table-1.

Table-1. Prosthesis developed in recent years

Year	**Name of the Prosthesis**	**Type**	**Ref**
2006	Bionic ankle-foot prosthesis	Below knee	[5]
2008	Agonist–antagonist active knee prosthesis	Above knee	[6]
2008	Waterloo Active Prosthetic Knee	Above knee	[7]

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2008	SPARKy	Below knee	[8]
2008	IPAM (intelligent Prosthesis using Artificial Muscles)	Below knee	[9]
2009	Vanderbilt Transfemoral Prosthesis	Above and Below knee	[10]
2010	PANTOE 1	Below knee	[11]
2011	SmartLeg	Above and Below knee	[12]
2012	AMP-foot 2.0	Below knee	[13]
2013	Vanderbilt Transtibial Prosthesis	Below knee	[14]
2013	Cyberleg alpha	Above and Below knee	[15]

A. Upper knee prosthesis

Current prosthetics which are commercially available can be classified into different categories. Mainly there are three types, mechanically passive devices, microprocessor-controlled passive devices, and powered devices [16]. Studies show that comparing to the conventional passive prosthesis, a computerized prosthesis provide more degree of freedom and perfect gait conditions while consuming less energy. There are prosthetics available for each part of the leg. This includes hip, femur, thigh, knee, etc.

1) Prosthetic Knees: Knee is one of the most complex and stressed joints in the human body. It is essential for the movement and very vulnerable to get injured. So, any alteration in the join can cause an enormous change in the patient's gait [17]. The design of prosthetic knees is of two types. They are endo-prosthetic knees and exo-prosthetic knees. Endo-prosthetic knees are usually surgically implanted in the patient's body, whereas Exo-prosthetic knees are fitted outside the amputee's body cavity [18]. Exo- prosthetics can be further divided based on their mechanism as Active and Passive. The active mechanism is expensive, but they are more adaptable to different walking speeds [19]. There are different options for the passive mechanism, with various types of control levels, and they provide great assistance to amputees. An active or powered prosthetic knee is more similar to the biological human knee than the passive one. Hence, a powered prosthetic knee will be able to provide more efficient movement and gait [20].

Another popular mechanism for the prosthetic knee is Poly- axial knee with multiple centers. An example of this type is Ossur Total Knee [21] [22]. This type is based on a four-bar mechanism. In some developing countries like India, the four-bar polycentric joint developed by D-Rev [23] has been widely used recently. And it has provided better assistance compared to the single-axis joints. Low-cost passive mechanisms that aim to facilitate able-bodied kinematics have also been introduced in India. For example, in India, a model has been developed using an automatic early stance lock, a linear spring, and a differential friction damping system [24]. It provides better stability, especially in the swing phases.

Six bar linkage has also been successfully used in some prosthetic knees. It has more design variables than the four-bar mechanism. Hence, the six-bar mechanism can be more functional [25]. In some recent researches, current prosthetics, especially the six-bar mechanisms, are assessed by Design for Manufacture and Assembly (DFMA) method. Also, the static strength model can be evaluated by the Finite Element Method (FEM) [26]. Some finite element models of the prosthetic knee are constructed by applying the Reverse Engineering method [27]. In this method, initially, the prototype is built by using IMAGEWARE and PRO/E. Secondly, based on the CT image, the parts are developed and finally, all the models are assembled.

The microprocessor technology allows the knee to respond instantly to the change in speed [28]. So it has been used in the most sophisticated prosthetic knees. Studies [29] have shown that the microprocessor-controlled knees are superior to that of conventional mechanical knees in case of performance. Comparing to other types, the microcontroller-based knees are having intelligent sensor and control systems. The mechanical structure of the microprocessor-controlled prosthetic knee [30] is represented in fig.1. That means providing normal and safe gait with very little energy consumption. The sensor system can detect the walking speed and gait phase. Also, the force-sensitive resistors and multi-axis force sensors such as the six-axis force sensor, are present in some models [30]. Microprocessor-controlled prosthetic knees can be again divided into variable-damping or semi-active prosthetic knee.

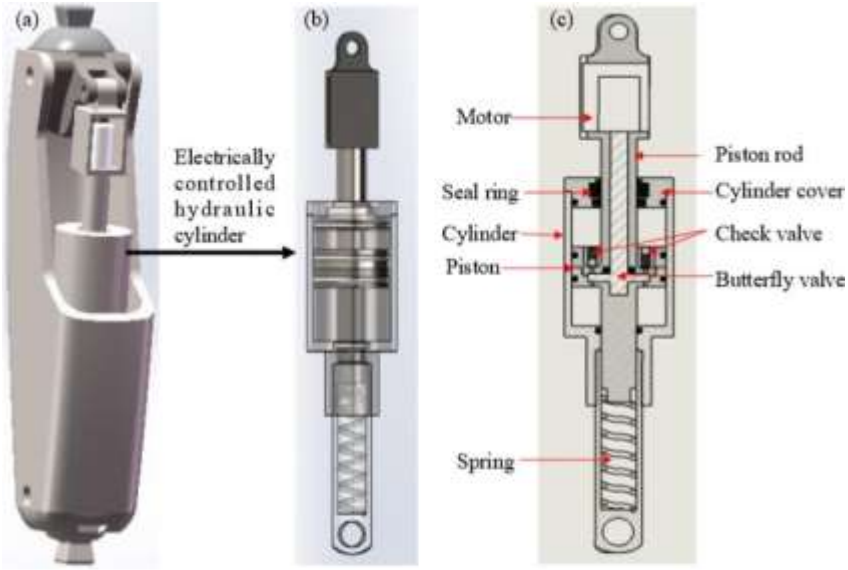

Fig. 1. The mechanical structure of the microprocessor-controlled prosthetic knee [30]

2) Prosthetic Hip: The hip joint is one of the most essential structures of the body as it supports the body weight in both the static and walking postures. Since it is the largest weight-bearing joint, the design of the hip joint should resist the fatigue failure of the hip [31]. It should also minimize the wear in the ball and socket [32]. The stress in the join can be reduced by increasing in contact area on the wear of socket and also by uniformly distributing the load the contact area [33].

Hip replacements are realized with different kinds of materials, which are biocompatible, resisting heavy stress, withstanding static and dynamic loads, and reducing frictional forces. Even certain combinations of metals, ceramics, and polymers are used [34]. Frequently used materials are titanium alloys, stainless steel, special high-strength alloys, alumina, zirconia, zirconia toughened alumina (ZTA), and UHMWPE [35]. Basically, the surgically implanted replacement should perform all the functions of natural one, and the replacement surgery is called Total Hip Arthroplasty (THA) or Total Hip Replacement (THR) [36]. A hip prosthetic usually consists of a femoral head, a femoral stem, an acetabular cup, and a fixation agent that connects the acetabular cup into the acetabulum of the pelvis and femoral stem into femur [37]. This is in the case of THR, but in the case of partial knee prostheses, only the femoral head is replaced. The hip resurfacing procedure also exists where the femoral head is reshaped. But some complications can occur in all these types of prostheses. An ideal prosthetic hip should be able to replace the mechanism structure and assistance the original joint has been providing [38].

Hip prosthetics can be cemented or cement-less. Both models have their advantages and disadvantages. The prostheses can be modeled and assembled to perform Finite Element Analysis [39]. Studies show that according to the expectations of the amputees, some innovations such as shock absorption systems, wear resistance features, adjustable offsets, and model parts with adjustable parameters have been introduced [37][40].

3) Prosthetic Femur: Reconstruction or prostheses of the femur bone can be done by several surgical options. Endo- prostheses are mainly done in the case of a tumor, and generally, it is called Total Femoral Replacement (TFR) [41]. TFR found to be effective in limb salvage [42].

A prosthetic femur must be having a stem with distal and proximal ends. The available designs of prosthetic femurs are modeled in such a way that it provides medial-lateral fixation stability [43]. A collar is present on the proximal end, which has a distally facing surface [44].

Most of the femoral prosthetics designs have been developed with a short stem. Clinical trials and FEA show that these short stems preserve bone stock [45]. The analysis of femur bone prosthetic comprises the Compression test of the femur bone, Scanning and modeling, Material selection, and Static structural analysis [46]. When it comes to material selection, the selected materials should fit with the required properties [47] [48]. Titanium alloys are preferable in this case [49] [50].

B. Below knee prosthesis

A trans-tibial prosthesis consists of several divisions that help in the suspension of the prosthesis on the residual limb. The major parts are a socket, a pylon, a foot, and a suspension for the prosthesis. Before the suspension of the prosthesis, a liner is fitted to the patient to provide cushioning between the residual limb and the socket. The liner can be made of different materials such as polyurethane and silicone known for its resistance [51]. Describing in detail about three major socket designs used for Trans-tibial prosthetics, which are Patella Tendon Bearing (PTB), Silicone Suction Suspension (3S), and Vacuum-Assisted. Fig. 2 shows a below-knee prosthesis device (CYBERLEG alpha) [52].

Fig. 2. Below-knee Prosthesis CYBERLEG alpha [52]

1) Patella Tendon Bearing (PTB): These prosthetics is designed to place the weight bearing below the patella. The suspension offered is generated by a belt that is tightened around the amputee part of the thigh. The most common error made with PTB socket is the excessively tight fit in the popliteal area of the stump [53]. To make the area for pressure against the popliteal surface of the stump larger, the back of the socket is extended to increase the space between the hamstring tendons, cutting grooves so that it relieves the tendons during knee flection. The unloaded prostheses will lean forward with the pylon inclined 2-3 degrees, depending on the heel-cushion stiffness [54]. When the bodyweight is supported in the socket, and the pylon is vertical, the heel should be compressed enough to supply approximately one-third of the total support from the foot, with the other two-thirds being provided by the ball of the foot. Regardless of the fitting method employed, the socket for any patient must provide the same overall functional characteristics, including comfortable weight-bearing, narrow base gait, and as normal swing phase as possible consistent with the residual function available to the amputee after amputation [55].

The PTB socket is considered to be suitable for the primary amputees as the socket can be modified to accommodate any changes in the fixture in 12-18 months after the amputation. It is possible to relieve such areas more quickly than in a total surface bearing style socket if the amputee has a particular area of sensitivity on their residuum. The inner liner and hard outer socket of the PTB socket allow build-ups to be applied to the inner liner, making it easier for donning and doffing for an amputee with a bulbous residual limb [56] [57]. There are few contradictions to the PTB socket for current users. Active amputees find PTB socket trim lines and the suspension offered by the PTB too restrictive to knee flexing. Other than the trim lines and suspension, few users also struggle to find comfort due to the pressure applied on their patella tendon with is required for efficient operational functioning of the PTB. Inaccuracies have been reported using FSR [58]. The transducers were calibrated in situ, while it is attached to the inner socket of the transtibial socket. A Vanderbilt transtibial prosthesis model [59] is shown in Fig. 3.

Fig. 3. Vanderbilt Transtibial Prosthesis model [59]

2) Silicone Suction suspension (3S): To attain the desired suspension, a precise and exact fit of the Surlyn socket was necessary, for which multiple fittings of transparent check sockets were also used, for which the process required fitting as many as six check sockets for each prosthesis. To enhance the comfort of the patient, a pin that engages a ring in the end of the silicone liner is used to secure the prosthesis. This indeed has proven to be quite well accepted by the patients fit, and with practice, they can engage the ring in the first try of the patient [60]. The fit of a Silicone Suction Socket has few necessary steps like firstly the prototype is to be fitted with a transparent socket and distal end chamber. A link between the liner and the socket is then established dynamically during patient fitting with the aid of compliant silicone gel.

The negative impression is set up beforehand in proper alignment on a flat surface with respect to the parasagittal line drawn. The proximal portion is aligned on top of a Plaster of Paris (POP) distal extension block in proper bench alignment after the cast is cut into two parts along the axis drawn. The distal extension block is pre-shaped to accept a coupling ring. This coupling ring allows the socket to be connected to a VAPC gold alignment unit I the assembly of a prototype prosthesis [61]. There is a critical factor in the alignment of the leg. It was the outset if the foot was directly placed in the socket during weight-bearing a sideways shift to the socket occurred, tipping the socket against the stump, causing excessive pressure. In this regard, the suction socket wearer walks differently from the amputee wearing side hinges on a corset [3] [53] [62]. If at all the suction is lost, it would not be a severe problem, as the leg falls off the stump. This can be handled by wearing a light strap around the stump, which holds on to the leg if in case of loss of suction. The suction below-knee prostheses are unique in that they do not require auxiliary suspension systems such as straps, cuffs, thigh lacers, to maintain the socket to the residual limb [63].

Active amputees gain from the lower trim lines possible with 3S design. Proprioception is increased due to weight-bearing over the entire residual limb and proper pressure distribution at the socket walls. It is believed that the overall socket pressure is reduced due to the entire surface of the residual limb accepting the weight in the 3S socket. Few disadvantages, such as the 3S sockets, are not recommended to amputees with visual disturbances as it may lead to more difficult donning and doffing that the PTB socket and amputees with excessive soft tissue may find it more challenging to get comfortable due to the creasing of the silicon liner.

3) Vacuum-Assisted: This method is also known as negative pressure, elevated vacuum, or dynamic vacuum. The suction suspension is created with direct contact between the liner and the socket wall. This system uses a mechanism or pumps that suck the air between the liner and socket, creating a negative pressure that is the same across the entire surface of the stump. To seal off the system by not allowing the negative pressure to be affected, an external sleeve or seal is used at the top of the socket. Among all the new suspension options, Vacuum Assisted sockets permit the least amount of pistoning within the socket [64]. This statement was proved when Kahle described an agreement between two high-quality level - 2 and one low-quality study offered grade B evidence that vacuum-assisted socket reduces movement of the residual limb within the socket. These modern systems provide improved suspension in comparison with the historical standards of sleeve suspension and supracondylar suspension. Upon extensive study in this topic in the past, authors have cumulated a well-defined set of potential benefits associated with this socket suspension system. Few of the benefits include a decrease in the daily volume of changes as well as the maintenance of a better socket fit.

C. Orthotics

A literature review of the current orthotics was conducted, which helped understand their design constraints, performance, and limitations. Most of the knee orthoses were to assist people with quadriceps muscle weakness (QMW) [4],[65], [66], stroke patients [67], [68], [69] elderly people [70], [71], [72], [73] and in gait rehabilitation [74], [75], [76], [77], [78], [79], [80], [81], [82], [83], [84].It is also designed for paralyzed people and lower- limb amputees [85], [86]. These devices assisted patients with their knee flexion and extension movements [75], [76], [80], [87], gait movements and raising mobility tasks as well. Various forms of knee orthoses are available in the market. It includes Knee-Ankle-Foot Orthoses (KAFO), Stance- control KAFO (SCKAFO), Powered Knee Orthoses (PKO), robotic assists, exoskeletons, etc. Various mechanical and biomechanical tests are carried to understand the performance of the devices. Most of the biomechanical tests consist of a walking test [4], [70], [72], [81], [82], [85], [88], [89], [90], [91] where the individual is asked to walk a certain distance with and without the orthotic device. The results are then compared for the evaluation. Sit-stand and stand-sit tests [65], [68], [73], [91], [92] are also performed to check the locking system performance which helps in gait assistance by providing a locking mechanism during weight acceptance phase and allowing free knee flexion during the swing phase. Treadmill experiments [69], [70], [77], [78], [81], [82], [89], [92] are carried out to verify the ground reaction forces. The important measured parameters are gait speed and gait pattern. It also evaluates the difference in knee angle with the applied torque. Patient comfort is another essential parameter that is considered. They test muscle movements using an EMG [65], [66], [67], [70], [73], [77], [83], [84], [87], [93]. The unit integrates various sensors to calculate the appropriate parameters. Table-2 explains the various types of sensors and their positions, which are used in various orthotic studies.

Table 2: Sensors used in different orthoses

Sensor Type	**Sensor Location**	**Reference**
Potentiometer	Ankle or Knee	[19], [20], [24], [28], [29], [30], [32], [37], [44]
Accelerometer and/or gyroscope	Shank and/or thigh	[33], [36], [48]
Force Sensitive Resistors	Sole of foot	[20], [24], [25], [30], [33], [39], [44]
Force sensors	Knee	[23], [48], [50]
EMG	Other	[16], [24], [29], [30], [31], [38], [39], [40], [42], [43], [48], [49]
Inertial measurement units (IMU)	Thigh or hip or foot	[28], [30], [37], [38], [39], [44], [45]
Strain gauge goniometer	Knee joint	[21], [30], [32]
Hall effect sensors	Knee joint	[30], [32]
Pressure sensors	Foot	[33], [37], [41], [45], [48]

In most knee orthotic devices, the PID controller is used as a controller [68], [70], [72], [77], [79], [80], [86]. Motion cameras and video cameras are used to analyze the motion of the individual [4], [65], [69], [86], [94]. Some experiments use optoelectronic measurement systems to assess the kinematics and kinetics of the human body accurately [74].

Fig. 4. KEA prototype mounted on a standard KAFO with articulating ankle joints [65]

1) KAFO: Knee-Ankle-Foot Orthoses are full leg braces intended for individuals with knee extensor weakness. There are three types of KAFOs – passive, stance control KAFO (SC-KAFO), and active devices. Passive KAFOs or conventional KAFO designs provide stability throughout the stance by locking the knee joint at a particular angle. This can lead to an inefficient pattern of gait and hip hiking. SC- KAFOs overcomes passive device limitations. They mimic the biological spring-like function of the knee by integrating spring-loaded knee locking mechanism, which supports during the weight acceptance phase and thus allows free movement during the swing phase of the gait. Active KAFO devices comprise actuators which provide additional power to replicate the patterns of physiological gait. Knee-extension assist(KEA) was a type of KAFO designed for everyday use and assisted individuals with difficulty performing stand-to-sit and sit-to-stand mobility tasks. The KEA prototype mounted on a standard model KAFO with an articulating ankle joint is shown in Fig.4 [65]. The main objective was to provide an external knee-extension moment to KAFO [66]. These devices undergo both mechanical and biomechanical tests to understand their performance and viability. Depending on the features of the device, biomechanical tests include ground-level walking, stair-descent, stand-sit, and sit-stand trials. For patients with spinal cord injury, passive knee orthoses that utilize functional electrical stimulation (FES) cycling has been developed to improve motor function [95].

SCKAFO or stance controlled SCKAFO uses microprocessor control, has a more reliable switching mode, and has multiple settings for different types of terrain. A design named Ottawalk-Variable Speed (OWVS) aims to provide variable knee flexion resistance and increase mobility in daily activities [4]. Quasi-passive architectures have been developed to minimize the weight and power requirements. A Quasi- Passive Compliant Stance Control Knee-Ankle-Foot Orthosis implements a linear spring in parallel to the impaired knee joint, which compliantly supports the motion during the stance phase. It then enables the leg to swing freely to initiate the next step. The design consists of a compliant stance control module (CSCM) incorporated into a standard KAFO. Various tests were carried out to determine and evaluate the reliability, latency, resilience, and dynamic performance of the developed model [2], [88]. An Automated Stance Controlled Knee-ankle- foot orthosis (ASCKAFO) controls the stance phase using an integrated actuator system with a set of sensors. They match the gait events that occur naturally to solve other design weaknesses. Thermoplastic materials have been utilized in designing the model. Several tests were carried out to access the precision and efficiency of the materials and components to be used [74].

Active KAFOs consist of actuators that provide power during the push-off phase, which needs the highest energy expenditure. Thus, active devices, compared to walking with passive devices, minimize the additional metabolic activity arising from compensatory strategies. One such project under active orthosis was CYBERLEGs. They developed a compact robotic ortho-prosthetics for functional replacement and assistance at lower-limbs. They were able to assist actively with everyday activities [85]. Several active orthoses help to strengthen knee movements for weak knee extensor patients and others that provide walking assistance knee joint rehabilitation [70], [86].

2) Powered Knee Orthosis (PKO): Powered Knee Orthoses are portable devices used in rehabilitation therapies for gait assistance [71]. Most of the existing PKO systems are either equipped with complex hydraulic, pneumatic, or more compact electric motor functions. Most orthoses are powered by a few combinations of geared with electromagnetic motors. Fig. 5 shows a developed PKO device with gearbox [76]. The crucial aim of these devices is to improve the back-drivability and produce high torque without using any controller with the actuator. Back-drivability is the functionality of a motor that is gear- driven, with the load attached even if the external power is removed. These devices were actuated using brushless DC motors (BLDCM) [75], [76], [93], which offered more advantages over the conventional one. These PKO devices were able to provide back-drivability by performing knee extension, and knee swing with the actuator turned off. The higher applied torque allowed faster knee movement [75], [76]. PKO is also used to control the hip and knee angles for gait assistance. This algorithm analyses the individual’s kinematic gait model, and the desired knee joint angle is estimated from the hip joint angle measurements [72]. EMG monitored PKO system provides assistive commands according to the user’s motion intention, which is tracked by EMG signals [77], [82]. Electronic and control architecture based powered orthosis for knee has also been designed for gait rehabilitation [78].

Fig. 5. A developed PKO device with gearbox [76]

3) Robotic assistive devices: Numerous studies have reported the effects of a rehabilitation robot. One such design developed is Robot KAFO, which is a robot rehabilitation device attached to an ordinary Knee-Ankle-Foot Orthosis. This device’s principal objective is to assist the knee movements, observe kinematic patterns, and muscle activation during gait [67]. The use of robotic devices for physiotherapy allows performing exercises regularly [96]. A design based on adaptive impedance control was developed considering the highly challenging locomotive tasks for repetitive rehabilitation training, which provides a more comfortable and natural motion. The proposed strategy applies a speed-dependent walking pattern and estimates the robotic stiffness associated with the interaction of human orthosis by observing the interaction torque at knee joints at different knee angles. It was validated that the robotic stiffness modulation based adaptive control strategy was able to recognize and customize the therapy according to the user’s effort [79]. Another robotic device called COWALK-M was designed to assist stroke patients with mild hemiplegia to move the paretic knee joint during daily activities [89].

4) Exoskeletons: Exoskeletons were explicitly designed for stroke survivors. They are also used to retrain the neural system of people with paraplegia. Exoskeletons utilize mechanical actuators to help patients generate gait patterns and provide functional benefits to the users. Knee strength is highly correlated with the ability to perform independent sit-stand motions. An exoskeleton was developed to restore symmetry and to provide external assistance. A knee exoskeleton actuator that uses fiberglass leaf spring has been designed to improve torque control and thus assist the sit-stand movements [68]. Another novel hybrid device called FEXO has been developed that combines Functional Electrical Simulation (FES) with a compliant exoskeleton that focuses on controlling the rhythmic movements of the knee. The motion pattern of the knee angle per torque applied is observed for the evaluation of FEXO [80]. A power-assisted pneumatic-based exoskeletal system for gait rehabilitation was developed for rehabilitation that helps the users in gait assistance [81]. An exoskeleton system to assist patients for lower limb movements is available in the market [87], [90].

Lower limb orthotic devices were also developed for gait assistance. It assesses the sensitivity and relative timing of the system of sensors used in the device [91]. One such design uses pneumatic artificial muscles as actuators [97]. Knee orthotic device has been developed with variable stiffness and damping to simulate hemiparetic gait. It also tested for the orthosis effect on the dominant and non-dominant limbs [69]. Digital Goniometers can be used for measuring the knee-joint position that helps in the application of orthosis [94].

IV. LIMITATIONS AND SCOPE FOR IMPROVEMENT

Different scholars have looked differently at the relationship between beneficial pressure distributions, skin irritation, and wound healing. The synthesis between these two views is obtained in an understanding that decreased pistoning decreases the shearing forces, which, in turn, reduces the incidence of skin disruption and pain. Detaining the movement of the limb within the socket may lessen the irritation over both healthy and ulcerated tissues, allowing for granulation and healing of existing wounds. Despite the benefits associated with vacuum-assisted sockets, it is not universally indicated [64]. Supporting to this context, many have reported specific problems caused by the use of vacuum-assisted socket like skin blisters during improper wear. In addition to this, vacuum-assisted sockets also require higher maintenance when compared to other suspension systems.

All orthotic devices are developed to assist people with walking disabilities. They help in gait assistance by supporting the person during the weight acceptance phase and allowing movement during the swing phase. Bulkiness is the major limitation of the orthotic devices. The bulkier the design is, the less comfortable it is to the user. Another limitation is that some devices often exhibit a delay in the gait assistance, which hinders the regular gait pattern leading it to a slower and uncomfortable outcome. Most of the testing process is done on healthy individuals. Testing on patients who needs gait assistance could infer better results. Detailed gait function must be assessed rather than just gait speed and number of steps for better interpretation of results

The future scopes of these orthotic devices are described below. A small and light-weighted design could be developed, which provides excellent patient comfort. Conducting tests of the devices on impaired volunteers helps to examine the performance of the system in its expected scenario. Making the devices portable for long-distance walking and providing more significant force for gait assistance makes them more user-friendly. Further improvement must be made for the speed of the device such that it assists the patient during gait without any delay.

V. CONCLUSION

This paper gives a wide review about the types, methods, and recent developments in lower limb prosthetics and orthotics. Various prosthetic and orthotic devices have been discussed in this systematic literature study. These devices help people with disabilities and amputees by providing them with gait assistance and thus have a significant role in gait rehabilitation. Different types of above-knee prosthetics, including knee, hip, and femur, and their mechanisms have been discussed. The types of sockets used in the below-knee prosthesis have also been described in detail. Under orthotic devices, the different mechanisms of KAFOs have been analyzed and compared. Electromyography (EMG) is used in several mechanisms to examine the effect of these devices on muscle activations.

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