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Advancements, Trends and Future Prospects of Lower Limb Prosthesis

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ABSTRACT Amputees with lower limb loss need special care during daily life activities to make the movement natural as before amputation. No such work exists covering the main aspects from causes of amputation to the psycho-social impact of the amputees after using the prosthetic device. This review presents for lower limb prosthesis; the study of lower limb amputation, design & development, control strategies & machine learning algorithms, the psycho-social impact of prosthetic users, and design trends in patents. Research articles, review papers, magazines, letters, study reports, surveys, and patents, etc. have been used as sources for this review. Traumatic injuries and different diseases have been found as common causes of amputation. Design & development section illustrates design mechanisms, the categories of passive, active, & semi-active prostheses, an overview of a subset of commercially available prosthetic devices, and 3D printing of the accessories. The control section provides information about control techniques, sensors used, machine learning algorithms, and their key outcomes. Quality of life, phantom limb pain, and psycho-social impact of prosthetic users have been summarized for different countries that are believed to attract the interest of the readers. We have also developed an open-source database "FAKH-50" for patents to emphasize the design trends and advancements in lower limb prostheses from 1970 to 2020. Overall trend analysis determined is in the descending order as the knee (48%) > ankle (28%) > foot (22%) > hip (2%) patents in the current version of our database. The forthcoming section highlights the challenges and prospects of the domain. A mutual observation demands the design of a bio-compatible, lightweight, and economic prosthesis to track the normal human gait by eliminating phantom limb pain. This will empower the amputees to live a quality life in society. This work may be beneficial for researchers, technicians, clinicians, and amputees.

INDEX TERMS Causes of amputation, lower limb amputation, lower limb prosthesis, design mechanisms, semi-active prosthesis, human gait cycle.

I. INTRODUCTION

Natural systems are the ample sources of stimulation for humans to lead technological developments. In recent decades advances in biomedical engineering empowers the community to develop artificial limbs to mimic the mobility of amputees. Lower limb amputation is common in humans and prosthesis restores the mobility for the lost limb to enhance the quality of life. Amputation is the loss of one or multiple human body parts due to some etiology. Limb loss often occurs due to traumatic injuries, certain diseases, and forced amputation due to surgery [1]. According to a new study, more than one million amputations occur globally that is one every "30" second [2].

Transfemoral amputees spent about 60% and transtibial amputees spent about 30% extra metabolic energy during the walk when compared with unimpaired persons. Similarly, walking speed may be 10% to 65% slower as compared to

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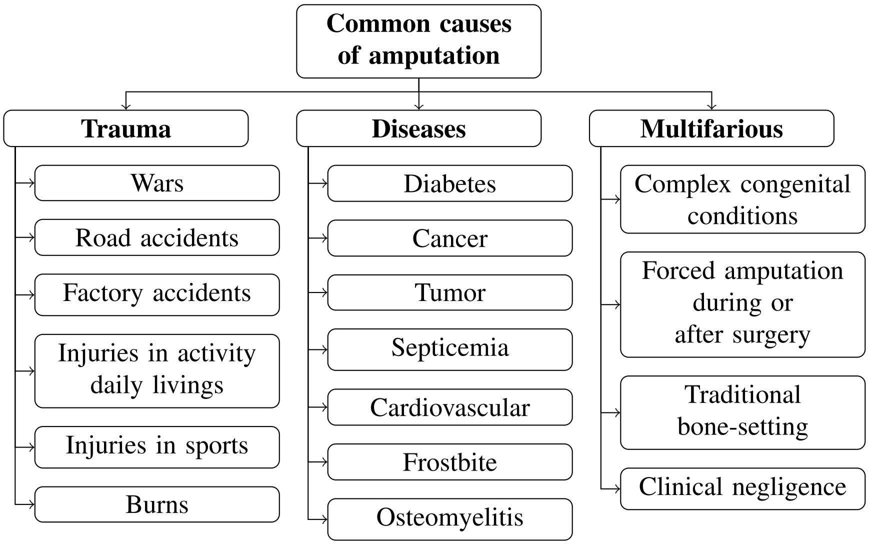

FIGURE 1. Common causes of lower limb amputations that happened in life routine matters have been illustrated. We observed the traumatic injuries, different diseases, and some multifarious as depicted in the Figure 1.

healthy individuals. Variations in the walking speed depend on the level of amputation [3]–[5].

Therefore the amputees are equipped with the prosthesis as a replacement to restore mobility. The prosthetic devices serve the amputees to effectuate their activities and to overcome the inferiority complex. The lower limb prosthesis may include a mounting socket for the thigh, artificial knee, shank/pylon, and foot to perform the functions like a biological human leg. According to actuation power there exist three types of prosthesis which are categorized as passive, active, and semi-active. Passive take power of the user to actuate and active are actuated by applying power to the device. Semi-active is the concoction of both that uses some power of the user as well as external power.

The traditional lower limb prosthetic devices are passive in nature to approximately mimic the biomechanical behavior of the human leg. They offer the advantages of simplicity, lightweight, and economy but unable to adapt biomimetically due to static mechanical characteristics. Active prostheses on the other hand offer the potential to mimic more features to achieve near natural movement but also have some disadvantages in weight, height, cost, electric power as well as complex controlling systems. Semi-active prostheses may offer opportunities to syndicate the benefits of both passive and active prostheses providing a compromising solution of low weight, height, complexity, and cost. The approach allows the user to practice body power as an input to balance a portion of the human gait cycle. One of the most significant challenges in the development of a semi-active lower limb prosthesis is to provide self-powered actuation competencies comparable to the biological counterparts [6].

Surveys and reviews exist on specific domains of lower limb prosthesis. To the best of our knowledge, no such comprehensive review is available to fulfill the needs starting from amputation till the satisfaction level after using the prosthetic devices.

Methodology of the review starts from **section-II** on lower limb amputation, causes of amputation, and country-wise surveys on lower limb amputation; **section-III** describes the categories of prostheses, design mechanisms, commercial developments, and 3D printing of the accessories for lower limb prosthesis; **section-IV** presents brief information on control strategies, sensors, machine learning algorithms, and human gait cycle; **section-V** describes the summary of psycho-social impact of prosthetic users; **section-VI** is about the design trends in patents. **Section-VII** highlights the challenges, discussions, and future prospects for lower limb prosthesis. **Section-VIII** highlights the key contributions as concluded and suggested future work followed by abbreviations used in this manuscript.

II. LOWER LIMB AMPUTATION

Common causes of amputation have been reviewed by considering the globally available articles. This section also presents the worldwide survey analysis of some countries for the lower limb amputees. Trauma and different diseases may be the major cause of lower limb amputation. An embodiment of common causes of amputations illustrated in Figure 1 is grouped into three categories involving trauma, diseases, and some multifarious. Traumatic amputation may happen in the wars, due to road and factory accidents, during sports, in daily life activities, and due to burns. Diseases like diabetes, cancer, tumor, septicemia (blood infection), cardiovascular, frostbite (injuries to body tissues due to extreme cold), and osteomyelitis (bone infection) may cause amputation at different stages. In infants, it may be due to complex congenital conditions. Traditional bone-setting and clinical negligence may also lead to amputation. Amputation may need to acquire during or after some special surgery which is the forced amputation.

A. CAUSES OF LOWER LIMB AMPUTATION

L. B. Ebskov [7] analyzed the relationship between amputation levels (foot, below knee, through knee, above knee and hip) and etiology in Denmark from 1978 to 1989. Based upon WHO (World Health Organization) classification of ''4'' etiology groups i.e. vascular insufficiency, diabetes mellitus, malignant neoplasms & trauma were extracted. Amputations due to vascular insufficiency with and without diabetes mellitus were decreased for the considered period while amputations due to tumors and remain unchanged due to trauma. A significant reduction was seen in above-knee amputations for vascular insufficiency and trauma group with and without diabetes mellitus.

Melzack *et al.* presented a study report on 125 patients without limb with phantom limb pain experience in ''41'' patients. Out of ''41,'' ''15'' were limb-deficient by birth and ''26'' had lost their limb up to an early age of 6 years. The shape, size, movement, and temporal properties of the phantom were described. It was argued that experiencing the phantom provides evidence of a distributed neural representation of the body which is determined genetically [8].

Speckman *et al.* examined the association of demographic and clinical variables with the risk of hospitalization for LEA (Lower Extremity Amputation) patients due to hemodialysis incidents from 1996 to 1999. The effort concluded that diabetes is a potent risk factor for LEA in new hemodialysis patients [9].

D.C. Obalum, G.C.E, and Okeke determined the pattern & outcome of lower limb amputations in the private tertiary hospital for the period of ''10'' years at Nigeria since 1997 to 2006. Records of theatre, ward, and case studies of the patients with LLAs (lower limb amputations) were considered with the observation of most cases in young adult males that were mostly due to motorcycle accidents. The mortality rate was high in amputees due to diabetes. The majority of the stumps of amputees were healed by the primary intention even suffering from stump wound infection and it was stated to be the most common complication [10].

Burgoyne *et al.* examined the incidence of phantom limb pain in children and young adults having amputation due to cancer in the first year after amputation. The proportion of the patients with pre-amputation pain using a retrospective review of medical records was also examined. Fisher's exact test was used to examine for an age threshold of 18 years (elder Vs older). Pre-amputation pain was found in 64% of the patients [11].

Dillingham *et al.* studied a comprehensive perspective on epidemiology and time trends in limb amputations and in-deficiency in the United States. Data was collected from Healthcare Cost and Utilization Project between 1988-1996 to calculate the rates of congenital deficiency, trauma, cancer, & dysvascular as causes of amputations. Trends over time were also examined using linear regression techniques. It was concluded that the risk of amputations increased with the age for all causes and was observed to be highest among blacks having dysvascular amputations [12].

Probstner *et al.* studied the lower limb amputations due to cancer to determine phantom pain and related conditions. The analysis of means, medians, and other proportions was performed from verbal numerical data after follow-up at the physiotherapy department. Phantom limb pain which is a phantom sensation was highly prevalent among the patients of cancer [13].

Loucas *et al.* examined and identified the type as well as the degree of psycho-social preparation provided to the child and family before amputation. Children & adolescents who need to acquire limb amputation because of cancer treatment face many physical as well as emotional challenges. Preparatory interventions alleviate positive coping & improve long-term adjustment by decreasing anxiety and postoperative distress during pediatric cancer treatment. The findings demonstrate about lack of studies to date to adequately address psycho-social preparation before amputation for such patients [14].

Our observations accentuate the need for especial psycho-social counseling of the patient and the family in case of traumatic or forced amputation.

B. COUNTRY WISE SURVEYS FOR CAUSES OF LOWER LIMB AMPUTATION

Causes of amputation for a custom benchmark have been summarized in Table 1 for about the last two decades. Information presented in the table was analyzed by the surveyors by considering the medical history of the amputees available to them mostly from the hospitals. The custom benchmark includes the publication year, country for which survey was done, the number of patients considered, survey period, and etiology considered for this analysis. The etiology of the table describes the diseases and trauma as major causes of amputation for the mentioned surveys.

Vamos *et al.* examined trends in non-traumatic LLAs for a period of ''10'' years in people with & without diabetes in England. It was found that there was a reduction in minor & major cases of amputation for the study period. Overall perioperative & 1-year mortality rate was not changed significantly between 2000 to 2004. The findings highlighted the importance of diabetic prevention strategies and controlling risk factors for LEAs in diabetic patients [36].

In their next study, Vamos *et al.* described recent trends in incidence of non-traumatic amputations among people with & without diabetes to estimate the relative amputation risk among diabetic patients in England. They identified that all the patients of 16 years old who underwent any non-traumatic amputation between 2004 to 2008. Age and gender-specific incidence rates were calculated using the yearly diabetic population. This national study suggested that the overall population burden of amputations increased in diabetic people at a time when the number & incidence of amputations decreased in the aging non-diabetic population [37].

TABLE 1. Country-wise survey of lower limb amputation.

[Ref#]	Year	Country	# of Patients	Survey Period	Etiology (Study of causes i.e. trauma & diseases)
[15]	2005	Thailand	216	05 Years	Incidents and vascular diseases
[16]	2007	Nigeria	1642	15 Years	Trauma, tumor, diabetes, traditional bone-setting
[17]	2009	Korea	4258	24 Years	Trauma, peripheral vascular disease
[18]	2009	France	17552	01 Year	Bone disease, injury, neurological disease
[19]	2011	Australia	3400	01 Year	Trauma and diabetes
[20]	2012	Tanzania	162	02 Years	Trauma, diabetes
[21]	2012	Australia	186	01 Years	Diabetes, peripheral arterial disease, trauma
[22]	2012	Iran	624	09 Years	Trauma
[23]	2013	India	155	02 Years	Vascular diseases, trauma, and carcinoma
[24]	2013	Iran	160	05 Years	Trauma, vascular problems, and infection
[25]	2013	Iran	216	10 Years	Trauma
[26]	2015	New Zealand	892	07 Years	Diabetic type-2
[27]	2016	Sri Lanka	85	01 Year	Diabetes mellitus, vascular disease, septicemia
[28]	2016	Pakistan	123	03 Years	Trauma
[29]	2017	Bahrain	45	01 Year	Diabetes mellitus
[30]	2019	Nigeria	136	10 Years	Diabetes neuropathy
[31]	2019	Pakistan	5836	04 Years	Trauma and diabetes
[32]	2020	Ireland	172	09 Years	Non-traumatic (vascular)
[33]	2020	Cameroon	172	02 Years	Trauma
[34]	2021	Nigeria	93	05 Years	Peripheral vascular diseases
[35]	2021	South Africa	152	01 Year	Peripheral vascular diseases, diabetes mellitus

Table 1 presents information on lower limb amputations for different countries focusing the major causes of amputation. Second column refers to the publication year of the article/survey. Among the countries mentioned, France showed greater number of amputations in the minimum period of 1 year.

Moxey *et al.* quantified the global variation in the incidence of LEAs in the light of the rising prevalence of diabetes mellitus. They performed an electronic search using EMBASE and MEDLINE databases from 1989 to 2010 for incidence of LEAs through systematic reviews and PRISMA standards. Incidence of all types of LEAs varies in range from 46.1 to 9600 per 10^5 in the diabetic population compared with 5.8 to 31 per 10^5 in total population. Major amputation range varies from 5.6 to 600 per 10^5 in the diabetic population and from 3.6 to 68.4 per 10^5 in total population. Significant reductions in the incidence of LEAs were shown specifically for the population at risk after introducing the diabetic foot specialist [38].

It is remarkable to suggest the common standards for the surveyors to float the information worldwide for clinicians, researchers, and developers. And it should be an iterative survey after a specific period of time that may be suggested by medical professionals.

C. HEALTH RISKS AFTER LOWER LIMB AMPUTATION

Rajiv Kumar Singh and Guru Prasad did a follow-up of individuals after LLAs & ascertain the mortality rate. Features associated with population or treatment were also highlighted for mortality. It was concluded that mortality after amputation is extremely high and increases in diabetic people or in those who are not adjusted with the prosthesis after amputation [39].

Katleho *et al.* systematically reviewed the prevalence of PLP (Phantom Limb Pain) and the associated risks in amputees using different databases. After clear risk factors for PLP, the study will provide empirical evidence useful for clinicians to identify the priorities to diagnose, treat and prevent PLP [40].

After analyzing the health risks after LLAs, it is summarized that amputees suffer from PLP and adjustment issues. The pain feels at its extreme in diabetic amputees and in those who are unable to adjust to the prosthesis. Such factors may lead to the death of an amputee. Long-term mortality is not addressed in low and middle-income countries.

III. DESIGN AND DEVELOPMENT IN LOWER LIMB PROSTHESES

Prosthetic developments are artificial replacements for the lost human body limb. An optimized design depends on factors like bio-compatibility, cosmic, lightweight, and on the feedback of patients who already used a similar design. This section presents a few such design mechanisms and developments for lower limb prosthesis. The categories of lower limb prosthetic developments is shown in Figure 2 focusing on the power of the prosthetic devices. Passive prosthesis (energetically passive) does not impart any power to the system for actuation therefore amputee has to move the leg using the body power. Active prosthesis are fully powered and semi-active uses normally the power of the user during the stance phase while provides the power to the prosthetic device in the swing phase.

A. GENERAL CATEGORIES OF LOWER LIMB PROSTHESIS

Summaries of the passive, active, and semi-active prostheses have been described in this section. Foot, below-knee (transtibial), and above-knee (transfemoral) prostheses are the key focus of the section.

The SACH (Solid Ankle Cushioned Heel) was known to be the first prosthetic foot. It is attached directly to the prosthetic shank to achieve the foot action through the elastic behavior of heel and toe [41]. Angular relation of the foot to the shank

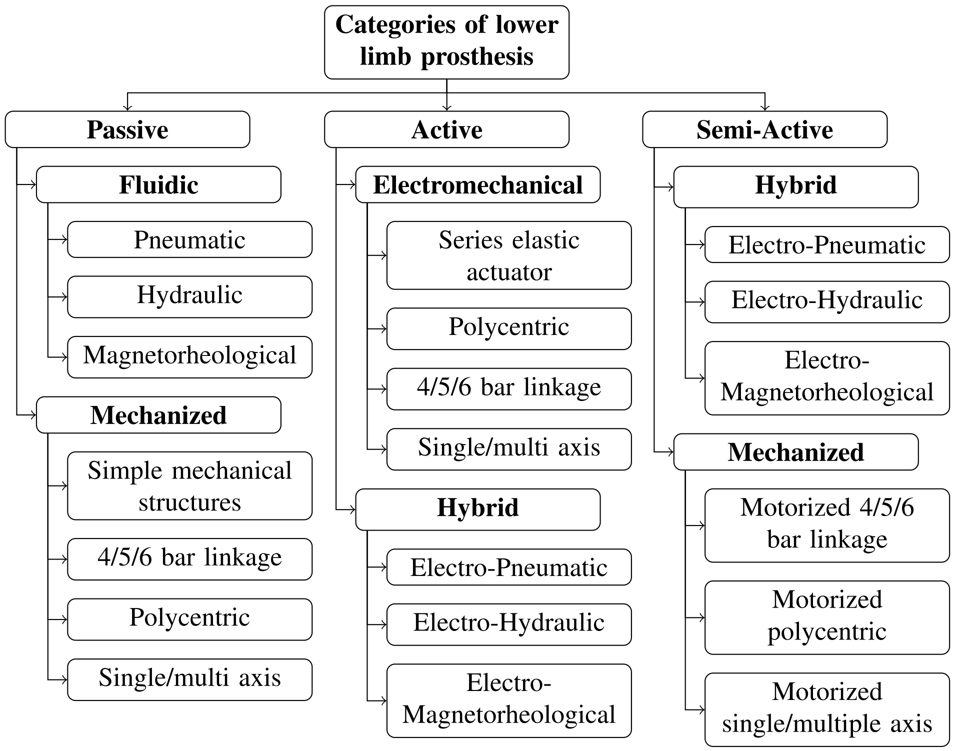

FIGURE 2. Lower limb prosthesis are classified as passive, active, and semi-active keeping in view the actuation power.

is adjusted during assembly providing the desired heel height adaptable to each shoe [42].

Daher [43] in 1975 performed experimentation to examine the durability of SACH foot subject to cyclic testing. Results showed that permanent deformation & changes occur in resistance at heel within only 5,000 cycles performed for an amputee of 100 Kg weight. Materials mentioned in [44] are being used to manufacture SACH include polypropylene, polythene polymer, composites, Carbon, glass, and Kevlar fibers. Another development [45], [46] of dynamic foot ESAR (energy storing and return) is preferred because of its elastic behavior for gait symmetry. ESAR has greater push-off power, a high center of mass velocity, extended forward propagation as compared to SACH.

Seid *et al.* focused on semi-active knee prosthesis and designed the MR (magnetorheological) damper valve to control the swing phase of the transfemoral prosthesis. Three optimized parameters were the frictional force, damping coefficients, and force offset to govern the damping force as well as displacement of the damper. The simulation showed a 71% reduction in weight as compared to the existing MR damper [47].

Tommaso Lenzi designed and developed a semi-active hybrid transfemoral knee prosthesis for stair ambulation. It involved the spring-damper system in combination with an electric motor and an active variable transmission system. Authors claimed the prototype to be light weight=1.7 Kg being significant as compared to powered prostheses. It works in passive mode for walking and in the active mode for stair ambulation [48].

Another work presents the electro-hydraulic design to build a semi-active transfemoral knee prosthesis for level ground and stair ambulation. The prototype was tested on two amputees and the movement during active mode for the swing phase was improved [49].

Sup *et al.* design and build a powered transfemoral prosthesis using a pneumatically actuated powered tethered device. They designed a load cell to measure force and moments on a three-axis socket. The design was tested to provide the required torque to the joints to achieve a more normal walk [50].

Lukas *et al.* proposed the design of a powered transtibial prosthesis for amputees walking on the treadmill & ascending stairs. Simulation of the lightweight poly-centric design was capable to fit in the anatomical foot profile providing physiological energy and less socket torque. It was good to improve electrical efficiency by affecting required torque and speed at the output of the motor thereby reducing the load of the main transmission system. The proposed prosthesis was 36.8% lower build height (12 cm) and was 40.9% weight effective (1.32 Kg) as compared to that of Ottobock [51].

Dong *et al.* proposed a powered transtibial prosthesis with SEA (Series Elastic Actuator) based design that was built with the geared five-bar spring mechanism. It mimics the biomechanical movement of the human ankle by reducing the peak power of the motor providing a 70 kg subject net

TABLE 2. General overview of a subset of commercially available lower limb prosthesis.

[Ref#]	Brand	Company	Type	Amp	Sensors	Actuators	Control scheme
[53], [54]	SACH	Ottobock	P	Foot	Sensors not used	Rigid (No actuators)	Stiffness/support
[55]–[57]	Orion	Blatchford	P	TFA	IMU, FSR, piston stroke sensor	Hydraulic & pneumatic	Adjustable damping
[58]	Plie	Freedom Innovations	P	TFA	IMU, inductive sensor (knee angle), strain gauges, & pressure sensor	Hydraulic	Adjustable damping
[59]	GENIUM	Ottobock	P	TFA	IMU, knee angle and knee moment sensor	Hydraulic	Adjustable damping
[60]	RHEO KNEE	Ossur	P	TFA	IMU, knee angle sensor, and axial load sensor	Magnetorheological	Adjustable damping
[61]	EmPOWER*	Ottobock	A	TTA	Pressure, contact, temperature, impedance, and EMG sensors	Electromechanical	Active impedance
[62]	POWER KNEE	Ossur	A	TFA	IMU, knee angle sensor, and optical switches	Electromechanical	Active impedance
[63]	SmartIP†	Blatchford	SA	TFA	IMU and force sensors (flexion)	Hydraulic, pneumatic, & stepper motor	Adjustable damping
[64]	PROPRIO FOOT	Ossur	SA	TTA	Accelerometer and angle sensor	ESR & Electromechanical	Adjustable damping
[65], [66]	C-Leg	Ottobock	SA	TFA	IMU, strain gauges, and knee angle sensors	Hydraulic	Adjustable damping

Table 2 presents brief information about a subset of prosthetic developments available commercially. The terms that have been used are described as Amp ↪ Amputation, P ↪ Passive; A ↪ Active; SA ↪ Semi-active; TFA ↪ Transfemoral amputation; TTA ↪ Transtibial amputation and the rest are illustrated in the section of abbreviations. *EmPOWER is the leading name of BiOMs. †SmartIP is leading name of IP (intelligent prosthesis) that is the first known semi-active prosthesis developed by Blatchford company UK for above-knee amputees. Information published/known through literature about the brand (written here as stamped by the company), sensors, & actuators, etc. for the prosthetic devices in Table 2 has been mentioned briefly.

positive energy. The actuator was 35.3% energy efficient with a reduction in the motor's peak power from 150W to 132W during a normal walk on treadmill trials [52].

Among the three main categories of prostheses discussed above, the design of a semi-active prosthesis seems to be an appropriate choice for the amputee keeping in view the cost, simplicity, and lightweight.

B. COMMERCIAL DEVELOPMENT IN LOWER LIMB PROSTHESIS

This section describes the state-of-the-art commercially available lower limb prosthetic devicesas described in Table 2. The table provides an overview of the prosthetic devices with a focus on the brand, company, type of prosthesis, type of amputation, main sensors, actuators, and the control scheme used.

Fluit *et al.* compared the controlling strategies for commercial as well as research knee prostheses to conclude the development challenges for active transfemoral prostheses. Authors considered "10" commercial & research knee available to describe their working principle, intent recognition, transition rules, and evaluation of prosthetic control for speed & speed adaptability during the walk. The challenges highlighted were described with three different aspects. Firstly to take the measures of patient satisfaction, secondly, the commercial market prefers simple methods rather than sophisticated ones, and thirdly testing the prosthesis in a controlled environment with the approval of FDA (Food and Drug Administration) [67].

The **SACH** foot shown in Figure 3(a) was designed in 1957 with the approval of the prosthetic research and development committee. The foot was non-articulated designed to be structural support without any elastic behavior for a male adult amputee [68].

The **Orion** shown in Figure 3(b) is a microprocessor-based passive transfemoral prosthesis that utilizes both the hydraulic & pneumatic actuators. The starting control that is difficult and sensitive is adjusted by the hydraulic actuator owing to adjustment of damping coefficient to produce the knee controlling torque during flexion (maximum 130°). Knee extension mode with various speeds is controllable with the pneumatic actuator. It has a lithium-ion battery with power on the battery indicating status as an audible warning if running at low power [55]–[57].

The **Plie** shown in Figure 3(c) is a microprocessor-based passive hydraulic prosthesis developed by Freedom Innovations. It is strongest and rugged than other microprocessor-based knees having 10 to 20 time fast response for stumble & fall protection. The total weight of the device is 1.235 Kg (without the accessories like socket, pylon, and foot, etc.) and it can bear a maximum of 125 Kg patient weight [58].

The **GENIUM** shown in Figure 3(e) is a microprocessor-based passive hydraulic prosthesis equipped with IMU, knee angle, axial force, and torque measuring sensors. The IMU comprises a gyroscope & the acceleration sensors that are responsible to measure the real-time acceleration as well as the position of the prosthesis in the space. Knee angle and moment sensors provide the information about angle and forces generated respectively. Knee flexion and extension angles are controlled through adjustable damping of hydraulic unit [59].

The **RHEO KNEE** shown in Figure 3(d) is a microprocessor-based passive magnetorheological prosthesis

FIGURE 3. This figure shows images of commercially available passive, active, and semi-active prostheses from left to right. All the images have been combined into one picture and the sources have been cited in the description given in the section of "commercial development in lower limb prosthesis."

for above-knee amputees capable to adapt continuously according to the environment and the walking style. The built-in microprocessor detects the movement to exhibit the natural walk even on difficult terrain. It is capable to automatically learn to easily navigate the slopes, brisk places, and tight spaces confidently [60].

Figure 3(f) presents the complete assembly of the transfemoral prosthesis using GENIUM. It comprises the mounting socket for thigh, GENIUM knee, pylon, foot, and the fitting accessories.

The **EmPOWER** shown in Figure 3(m) is an active transtibial prosthesis that restores the functionality & power of a lost human leg without any power from the user. Besides the level ground walk, it can move on up ramps, stairs, and hills. Bionic ankle-foot improves the normal gait pattern of the user because of active power propulsion avoiding joint pain. When compared the seven non-amputees with amputees wearing conventional passive prosthesis and then bionic ankle-foot, it reduced the metabolic cost by 8% and increased the walking velocity by 23% [69]. Another research shows a comparison between step-to-step transition work & demand of metabolic energy during level ground walk & inclined up to 5° using the passive and active transtibial prosthesis. The comparison was performed for six individuals having transtibial amputation with six able-bodied at a standard speed. Results showed that the active prosthesis generated 63% greater trailing limb step to step transition work as compared to the passive prosthesis. It was concluded that the ankle-foot bionic prosthesis improved the ankle power, metabolic rate, and step-to-step transition during level ground walk [70].

The **POWER KNEE** shown in Figure 3(n) is an active power intelligent transfemoral prosthesis designed to restore the lost power of muscles and the symmetrical movement pattern. It provides active movement to the amputee for both the stance and swing that enables them to step forward. The knee significantly reduced the rehabilitation time for newly wearers providing them the symmetrical distribution of weight and natural human gait pattern. The net weight of the device is 2.7 Kg (without the accessories like socket, pylon, and foot, etc.) and it can bear a maximum of 165 Kg patient weight [71].

The **SmartIP** shown in Figure 3(p) presents the concept of adaptive above-knee prosthesis actuated through hydraulic, pneumatic, and electromechanical power. This is a semi-active prosthesis, exhibiting a comfortable gait even at fast walking speeds due to variable damping. The majority of the active amputees are able to control this prosthesis during level-ground walking and may need additional support from the device to stop, during ramp and stair descent [63], [72]. A comparison was done between physiological cost index and walking speeds to improve the walking ability of the prosthesis for two elderly above-knee amputees. It was concluded that elderly above-knee amputees in a better physical condition were on merit with superior control of swing phase despite the age difference [73].

The **PROPRIO FOOT** shown in Figure 3(q) is a semi-active transtibial prosthesis developed by Ossur.

Limited information was available/published at the website of the company, however; presented here that is observed through its functioning. The ultimate goal was to replicate the mobility of human foot achieved by motorized ankle flexion. It comprises a motor & transmission system that actively controls the position of the ankle for no weight carrying activities. Such activities may happen during the swing phase and when the user is in the sitting position. The 3D gait pattern was analyzed while performing the kinetic and kinematic comparison between sixteen TTA and sixteen healthy subjects. It was concluded that the foot provided the increased dorsiflexion during the stair ambulation with increased kinetic and kinematics of the amputees [74].

The **C-Leg** shown in Figure 3(r) is a transfemoral prosthesis that is equipped with IMUs, strain gauges, and knee angle sensors. Strain gauges are installed in the tube adapter to measure anterior & posterior bending moment. The knee angle sensor measures flexion angle as well as the angular velocity of the knee joint. The measurements taken by these sensors are used for the detection of various gait phases/events to provide the necessary damping resistances during the stance and swing phase [65], [66].

C. RESIDUAL LIMB AND 3D PRINTED SOCKET

A prosthetic socket joins the residual limb to the prosthetic device. It feels strange at first due to the fact that our body is a living thing and may take some time to get used to it. The lower limb prosthetic socket comprises a liner and weight-bearing outer to mount on a residual limb as well as to fit with knee joint or pylon. A poorly fitted socket can cause skin problems, affect walking ability, impact balance, and painful to wear. An amputee can manage by minimizing the changes in the stump and consistently reviewing the skin to consult with the prosthetist [75].

D. MATERIALS/METHODS FOR 3D PRINTED SOCKETS AND ACCESSORIES

Miclaus *et al.* presented 3D printing methods & biomaterial properties of PLA (polylactic acid) or acrylonitrile butadiene styrene for the manufacturing of prosthesis and orthosis. Fused deposition modeling & stereolithography are famous methods used to manufacture medical devices. It was concluded that 3D printing methods for medical devices and new prototypes or functional devices to improve the patient's conditions has the opportunities for betterment [76].

Nguyen *et al.* reviewed the progress in 3D printing for the prosthetic socket for the last decade. The objective was to summarize the main techniques & results in prosthetic socket fabrication. The research community must look at low-cost production, less fabrication time, and lightweight. Addressing the solution to these challenges will be beneficial for prosthetic users [77].

Paterno *et al.* described the main parameters which are stress, displacements, volume fluctuations & temperature affecting the stump to socket interface which reduces the comfort/stability of limb prosthesis. Already available technological solutions for facing an altered distribution of these parameters were also described. Open challenges in the domain were highlighted with a possible future route towards achieving an advanced self-adaptable socket in real-time to complex interplay of these parameters during both static and dynamic activities [78].

Tao *et al.* presented the complete process for the design of lightweight passive prosthetic foot using polylactic acid (PLA) material. The structure of the passive prosthetic foot was customized & optimized to be lightweight using topology optimization. Safety of the structure was validated by using FE analysis followed by a strain gauge test [79].

Catalina Quintero-Quiroz and Vera Zasulich Perez reviewed different polymers used to develop lower limb sockets, external prosthetic & orthotic interfaces. Furthermore, they also evaluated the functional requirements of these as well as the possible skin problems faced. Thermosets, thermoplastics, foams, gels, and elastomers were explored among the famous types of polymers used to manufacture prosthetic & orthotic interfaces and sockets. It was estimated that between 32% and 90.9% of users had experienced excessive sweating, wounds, and irritation on the skin of the stump (residual limb). Further research was suggested for the development of these devices to be capable to prevent damages to the affected skin of the users [80].

Stevens *et al.* presented the guideline related to socket design, its interface, and the suspension of definitive transtibial prosthesis on the basis of the best available evidence. Their systematic review and meta-analysis suggested the recommendations enlisted here.

Recommendation 1: Static & dynamic pressure distribution of residual limb within socket are essential considerations for patient comfort, functioning & well-being.

Recommendation 2: Total surface bearing sockets were indicated to decrease fitting times & enable higher activity levels.

Recommendation 3: Compared to traditional foam-based interfaces, viscoelastic interface liners were indicated to decrease dependency on walking aides, improve suspension and load distribution, decrease pain & increase comfort.

Recommendation 4: Among modern suspension options, VAS (Vacuum Assisted Suspension) sockets permit the least amount of pistoning within the socket, followed by suction suspension and then pin-lock suspension.

Recommendation 5: VAS sockets were indicated to decrease daily limb volume changes in the socket while facilitating more favorable pressure distribution during gait.

Recommendation 6: VAS sockets require both awareness & compliance on part of end-user & are not universally indicated [81].

E. SENSING TECHNOLOGIES FOR SOCKETS

Various sensing systems have been described that play a vital role for sockets and their accessories for lower limb prosthesis in this section. This section focuses on the central role of sensing systems incorporated in the prosthetic sockets.

TABLE 3. Control strategies for lower limb prosthesis.

[Ref#]	Nature of work	Controlling strategy	Outcomes
[85]	Powered below-Knee prosthesis	Finite-state control	Natural movement and adaptable
[86]	Powered ankle-foot prosthesis	Finite state controllers	High mechanical power and torque
[87]	Powered prosthetic intervention	Finite-state impedance control	Enhanced awareness, stability, & power
[88]	Knee and ankle control	Impedance control	Reduced clinical challenges
[89]	Virtual prosthetic leg	Feedback linearization	Biomimetic and robust
[90]	Transfemoral prosthesis	Least square approach	Estimation of knee impedance
[91]	Transitions b/w ground and ramps	Fuzzy logic control	Effective control scheme
[92]	Mechanical knee	Predictive control	Better approximation of human gait
[93]	Dynamic swing phase model	Langrange dynamic analysis	Input compensation for better accuracy
[94]	Powered lower limb prosthesis	Adaptive dynamic programming	Testing of 300 gait cycles

Al-Fakih *et al.* reviewed operating principles, advantages, and disadvantages of conventional as well as emerging techniques used to interface stress measurements in transtibial sockets. Evolution of different socket concepts & interface stress investigations conducted for the past five decades prior to 2016. Outcomes of techniques presented had contributed to improve design & fitting of transtibial sockets [82].

Xu *et al.* presented an optimized socket design for LLAs by developing an integrated sensor system using a tri-axial force sensor system. The microsensor was designed with a force sensor array based on square shape silicon thin membranes with a thickness of 4um. The pressure of applied load on every membrane could be measured with the Wheatstone bridge developed using four piezo-resistors. Pressure and friction forces between residual limb and socket interface at three different loading conditions were measured successfully with this socket master system. Clinical trials showed that an optimized socket could be produced within 2 to 3 hours with 3D printing technology, hence enhanced the comfort for lower limb amputee [83], [84].

It is our observation that introducing the technology of soft sensors may address the solution to the measurements more precisely.

IV. CONTROL, SENSORS, AND MACHINE LEARNING ALGORITHMS EMPLOYED IN LOWER LIMB PROSTHESIS

Controlling methods, techniques and strategies have been elaborated in this section focusing the nature of work, controlling strategy and main outcomes.

A. CONTROLLING STRATEGIES FOR LOWER LIMB PROSTHESIS

Current control schemes presented for transfemoral and transtibial prostheses are effective but still, there are challenges to eliminate disturbances faced to track normal human gait. The controlling strategies discussed here have some advantages & disadvantages. These are potentially capable to enhance the performance of prosthesis, particularly when we compare with the passive prosthesis.

A few control strategies are presented in Table 3. The table describes the information in three different columns which are the nature of work, the controlling strategy implemented, and the key outcomes. From the table, it is clear that finite-state impedance control was observed to be the most commonly used technique. One possible observation of applying this technique may be that human joints actuate through the impedance. Finite state machine controllers need to tune a lot of parameters for the subject making it less practicable.

B. ROLE OF SENSORS AND INSTRUMENTATION IN LOWER LIMB PROSTHESIS

This section covers an effort done regarding the use of different sensors and their instrumentation characteristics achieved by different people. Accuracy, precision, threshold, etc. have been discussed. This section also determines the trends for the use of sensors in lower limb prostheses.

1) EMG BASED WORK FOR LOWER LIMB PROSTHESIS

A lot of sensing techniques are available to capture the data from muscle tissues of the lower limbs of the human body. EMG (electromyography) based techniques have been observed to be more likely used among them. It allows for the incorporation of the stimulation as an input from the nervous system of the user. The input is then sent to the controller, enabling intentional control of the prosthesis. As a result, more natural & physiological control is possible to design.

Toledo-Perez *et al.* studies on classification accuracy using 4 EMG based channels placed on the right limb of healthy persons. Analysis was performed with "mean absolute values," "zero crossings," "slope sign changes," and "waveform length." Principal component analysis (PCA) and SVM (Support Vector Machines) were used as algorithms. Results obtained were better in three channels as compared to four channels and using more channels may not guarantee 100% precision [95].

Another research was proposed on a single channel EMG signal for the continuous terrain identification technique using a simple classifier. They prepared the dataset for fifteen subjects and validated it for 10 subjects. The pseudo-Code pre-processes the data to prepare the dataset by dividing it into k equal parts. The algorithm of iterative feature selection was also proposed to provide the information to the classifiers effectively. Identification accuracy using feature selection algorithm was improved as compared to PCA technique.

TABLE 4. Overview of EMG based work in lower limb prosthesis.

[Ref#]	Objectives	Role of EMG	Outcomes
[98]	Exploiting muscle co-contractions	Potentials of antagonist muscles	Robust to EMG measurement
[99]	Impedance control of prosthetic knee	To align the users' intent	Knee movement control for amputees
[100]	Neural interface rehabilitation	12 muscles based EMG recording	Recovery of motor functions
[101]	Muscle activities during squatting	To measure muscle activities	Successful study of muscle behavior
[102]	Virtual (NN) myoelectric prosthesis	To detect and process from hardware	Fast calculation of AR coefficients
[103]	Intent recognition	To enhance recognition based intent	Estimation of ramp grade
[104]	Identifying locomotion modes	EMG based PR strategy	Design of custom algorithm
[105]	Control of ankle plantar flexion	To control powered ankle-foot	Restoring the walking velocity
[106]	Adaptive slope walking	To measure the inclinations	Reduces muscle fatigue

Average identification accuracies obtained by SVM, LDA (Linear Discriminant Analysis) and NN (Neural Network) classifiers were (96.83 ± 0.28)%, (97.45 ± 0.32)% and (97.61 ± 0.22)% respectively. However, the proposed algorithm had shown similar performance even with a single muscle approach (ANOVA, p-value > 0.05). The outcome of this proposed method showed a pronounced potential for the efficient lower limb prosthetic control [96].

The EMG signals are cyclic and not stationary by nature while performing the dynamic activities, which demands to apply special pattern recognition techniques [97].

After reviewing the EMG based work it is an observation that the EMG control technique also has some disadvantages, like fatigue, motion artifacts, and the possibility for electrodes to be misaligned.

Overall work is shown in Table 4 for the use of EMG sensors in lower limb prosthesis with different perspectives. Then EMG sensors have been used with muscles on different parts of the lower limb to measure the muscle contraction and expansion to capture the body movement in the real world. The table summarizes the objectives, the role of EMG sensors, and the key outcomes for the articles included.

In [98] as mentioned in Table 4, the authors applied PCA to knee flexion and extension separately on a dataset. The dataset was collected on a single male subject of 53 years old weighing 85 Kg. He was asked to perform a periodic series of phantom-knee extensions at 25%, 50%, 75% & 100% of maximum possible extension for 60 sec while standing upright. The steps involved were the subtraction of mean and computing the eigenvalues & eigenvectors from the covariance matrix linked with each 2D dataset. The boundaries of the impedance manifold were then calculated by taking the first principle component of each dataset and representing it in the original flexion/extension coordinate system.

In [99] as mentioned in Table 4 authors presented a volitional control framework for impedance control for a desired stiffness and damping. The dataset was collected on three male subjects of ages between 20 and 60 years. The EMG-based intent database corresponds to 100 sec flexion and 100 sec extension at various angles. The average root mean square errors of tracking the trajectory of the prosthetic knee using the EMG based volitional control & the intact knee of the "3" subjects were 6.2° and 5.2°, respectively.

C. ROLE OF SENSORS AND MACHINE LEARNING ALGORITHMS FOR GAIT PHASE/EVENT DETECTION

Juri *et al.* reviewed the gait partitioning methods which is a fundamental issue for the researchers of the domain. They addressed the choice of sensor, body segment for sensor installation, and the computational methodology. Authors defined the "7" divisions of the gait cycle with the nomenclature for stance (60% of the gait) and swing (40% of the gait) phases. These divisions are necessary to define to be followed by the researchers to reach towards an optimized solution for on common standards [107].

Huong *et al.* reviewed the algorithms for the detection of gait phases for lower limb prosthesis. The authors compared sensors (IMU, EMG, & force sensors) and methods (Thresholding and algorithms such as HMM (Hidden Markov Models), ANN (Artificial Neural Network), DLNN (Deep Learning Neural Network), CNN (Convolutional Neural Network), & hybrid methods combining HMM as well as fully connected Neural Networks) based publications for last decade. They declared the IMU sensors to be best suitable for the gait phase and event detection. They concluded about the mentioned algorithms that time complexity is still an issue in real-time gait detection because of too large size of matrices [108].

The algorithms mentioned in the previous reference were tested and validated on the dataset obtained from seven healthy subjects who performed daily walking activities on flat ground and a 15° slope. Only one inertial measurement unit (IMU) was attached to the lower shank to receive the signals. The dataset was divided into training & validation datasets for every individual. The average mean square error (MSE) error between model prediction & actual percentage for the gait was computed to be 0.00522 [109].

Floriant *et al.* reviewed the different algorithms of machine learning used to recognize or predict the locomotion activities to automatically adapt the behavior of assistive devices. The algorithms applied in many of the studies were SVM, LDA, HMM, KNN (K Nearest Neighbor), DBN (Dynamic Bayesian Network), and LSTM (Long-Short Term Memory network). The focus was to discuss the characteristics of sensors and algorithms, accuracy, and robustness. Published

TABLE 5. Comparison of machine learning algorithms.

[Ref#]	Activity	Algorithm/Technique	Sensors Used	Outcome
[119]	Gait event detection	Finite state-machine method	Gyroscope, inertial & force sensors	Accuracy > 90.12
[121]	Fall detection	Custom algorithm	Force sensors and accelerometer	Accuracy=97.1
[123]	Terrain identification	Fuzzy logic multisensor fusion	Accelerometer, gyroscope & FSR	Accuracy=98.74, Real time
[124]	Estimation of foot position	Extended Kalman filter	Inertial, accelerometer, gyroscope	Low cost & ease of kinematics
[125]	3D foot trajectory	State Space method, EKF, NG	Tx(mobile), Rx(anchor) network	Light weight & economical
[126]	Pedestrian tracking	Custom algorithm	Inertial & magnetic sensor	Effective work for pedestrians
[127]	Foot assessment trajectory	NewtonâGauss, Kalman Filter	Wireless ultrasonic sensor network	For healthy & injured persons
[128]	Stance phase detection	ZUPT KF, clustering	Inertial, pressure & magnetic sensor	Robust towards fluctuations
[129]	Step detection, parameterization	K-means clustering	Triaxial accelerometer	Beneficial for gait assessment
[130]	Foot angle estimation	FPA algorithm	Magnetoinertial sensor	Good to train walking patterns
[131]	Terrain mapping foot control	Neural network & clustering	Radar, inertial and EMG sensors	Better inertial motion
[132]	Estimation of gait phases	Rule based algorithm	IMU, and potentiometer	Low cost, good precision

studies for the above-knee prosthesis considered were 32, the highest among the articles. The sensors were considered to collect kinematic, kinetic, physiological, and extrinsic data with accuracies reported of the global mean of 90%. The algorithms were implemented as high-level controllers to an automatic adaptation of the behavior of lower limb prosthesis. They suggested sensor fusion improve accuracy and adaptive framework to improve the robustness of the algorithm. One significant feature of the algorithm discussed was the length of the window which varies between 50 to 900 for different phases of the human gait cycle. For the human gait cycle, they proposed the term prediction as to the classification of locomotion mode before critical timing and recognition as classification of locomotion mode after the critical timing. One of the studies which were CNN-Based for intent recognition Using IMU on active lower limb prosthesis used the dataset CIFAR-10. Canadian Institute for Advanced Research (CIFAR) contains 60,000 images of 32 × 32 pixels and RGB channels on 10 different classes. They mapped the moving state of a healthy leg and an amputee's motion intent prior to the next transition of the prosthesis. The experiments showed that the recognition accuracy was at a high level of 94.15% for the able-bodied and 89.23% for the amputees on ''13'' different classes of motion intent on different terrain [110]–[112].

Eslami *et al.* presented a functional approach for estimation of knee angles on the basis of thigh motion using data of IMUs and a motion camera system on a group of able-bodied. Data were collected using two IMUs on two male participants and a camera system for three different scenarios at a speed of 0.5, 1, and 1.5 m/sec on a treadmill. They used the Gaussian process regression to build the relation between thigh and knee movement. They argued that no such exact model has been presented so far and it might be challenging what deviations should be acceptable between thigh and knee angle to know the joint position [113], [114].

The authors presented the classification model of mental tasks through electroencephalogram (EEG) on the notion of transfer learning addressing the issues of data scarcity. The work was validated using CNN and SVM. The accuracy of the results was highest i.e. 86.45% for a standard benchmark of various works by other people for the same dataset as described in [115].

This work presented an ensemble framework comprised of multiple SVMs by combining weighted classifiers using knowledge of amino acids on the protease datasets. Datasets PR-746, PR-1625, Schilling, and Impens were tested and validated. PR-746 is a multivariate classification dataset with one attribute and 6590 instances. Protease is an enzyme that functions to break down the proteins into smaller polypeptides. The genetic algorithm was used for the mentioned inflectional virus in the article. Feature-kernel SVMs were applied to achieve the optimized results [116].

Sinha and Patil discussed various types of biometric technologies, soft biometrics, biometric standards, applications, and feature extraction in their book. The main types are physiological and behavioral biometrics. The behavioral has direct/indirect relations with the brain activities and cognitive capability of the human brain [117].

The cognitive ability of the human brain and the assessments have been endeavored by a few researchers who worked enough theory to conceptualize the assessment of the cognitive ability of the human brain. The word 'cognition' is nearly associated with the brain, and thus assessing the cognitive ability is a developing area of research around the world [118].

Table 5 shows a comparison of machine learning algorithms used to control lower limb prosthesis. The table presents concise information for custom benchmarks including machine learning algorithms applied, sensors used, activity performed, and the key outcomes for the articles studied. This table also presents clearly the accuracy of human gait tracking for a few articles.

In [119] as depicted in Table 5 the gait event detection with an accuracy > 90.12 given uses the dataset introduced by Mannini *et al.* using an HMM-based model. The first part of this dataset was acquired on treadmill walking and the second part of this dataset was collected on an overground straight corridor [120].

In [121] as depicted in Table 5 another dataset ''TST FB4FD'' based work presented which contains the data acquired using smart shoe pair. The shoes are specifically

TABLE 6. Satisfaction and psycho-social impact of lower limb prosthetic users.

[Ref#]	Description of Work	Survey mode	Psycho-sociality	Suggestions
[136]	Satisfaction for prosthetic services	Questionnaire	Quite satisfied	Need betterment on uneven ground
[137]	Mobility of amputees' satisfaction	Questionnaire	Greater QoL	Further Investigation
[138]	Pain & psycho-social adjustment	Questionnaire	Feeling severe PLP	Type of pain should be addressed
[139]	QoL among amputees of LLPs	Questionnaire	Satisfactory QoL	Deprived amputees need rehabilitation
[140]	QoL among patients with prosthetic leg	Questionnaire	Early ambulation suggested	Amputees required continues assistance
[141]	Investigate mobility of patients	Questionnaire	Quite satisfied	-
[142]	Risk factors after limb loss	Questionnaire	Successful coping	Timely healthcare for rehabilitation
[143]	Effectiveness of LLPs for adults	Follow-up	Majority were satisfied	Effectiveness of prosthetic interventions
[144]	To investigate mobility	Questionnaire	Quite satisfied	Access to repair, follow-up
[145]	Use of prosthetics and satisfaction	Short forms	Highly satisfied	Improved design and QoL
[146]	Quality of life of patients with LLA	Short forms	Better perception about QoL	Study on job market

designed for the purpose of fall detection installed with 3 FSRs (Force Sensing Resistors) and one inertial unit. Moreover, this dataset comprises "32" different falls as well as "8" ADLs (Activities of Daily Living) performed by "17" healthy subjects having ages between 21 & 55 years [122].

D. REAL-TIME GAIT TRACKING TO ACHIEVE A NORMAL GAIT PATTERN

To the best of our knowledge, less work is found in which real-time movement of a prosthetic wearer is mapped to the normal human gait pattern. However, the summaries of the work explored are presented here.

Zahedi *et al.* presented a new concept of the adaptive prosthesis for transfemoral knee prosthetic control. They argued that there is a need to work on optimal alignment and geometry to sense the speed during the walk. They considered a commercially available passive pneumatic knee with a motorized control damping. They used a microprocessor to control the knee flexion angle of 140° on the basis of data collected from the force and position sensors on 7 amputees. A memory card was used to store the gait cycle phases. They indicated that most of the active amputees can control the prosthesis during level-ground walking and may need additional support from the device to stop, during ramp and stair descent [63].

Jantzen *et al.* designed a DSPIC (Digital Signal Peripheral Interface Controller) microcontroller based semi powered stance control swing-assisted transfemoral prosthetic device. The system was equipped with an electro-hydraulically controlled passive knee, spring-loaded piston rod with a lead screw located within it, spool valve, small brushless DC motor, battery, microcontroller unit, sensors (IMU, absolute encoder, and load cell), stance to swing damping with a range of (1∼100) N.m.s/rad. Kinematic data were collected using infrared motion capture system and force-velocity data using hydraulic cylinders on the able body on a treadmill. The range of damping was calculated in the previous work of authors by analyzing the data on healthy persons. The walking controller was tested for stance, pre-swing, swing flexion, and swing extension for a 90 sec walk on an instrumented treadmill with a speed of 0.8 m/sec. Results of the prototype were compared with graphs of passive Rheo knee and Ossur [133].

Asymmetrical gait behavior may lead to changes in musculoskeletal degeneration in transfemoral amputees. Data collection was performed on 15 healthy subjects in two different sessions. In the first session they wearing the non-microprocessor based prosthetic knee along with a 20 m long path at a speed of 1.11 m/sec. In the second session the participant used the microprocessor based prosthetic knee to walk at a self-selected speed of an average of 1.19 m/sec. Wearing an active prosthesis provides better kinetic gait symmetry which is effective to reduce the degenerative musculoskeletal changes in the amputees [134]. Asymmetrical gait behavior also leads to morphological changes in transfemoral amputees. Data was collected in a walking test at a comfortable, self-selected pace along a 10 m path. The ground reaction force was measured using nine walkway-embedded force plates at a sampling rate of 2000 Hz.

A mediolateral ground reaction impulse between healthy and amputated limbs during straight ahead walk should be counterbalanced. Statistical parametric mapping calculates the mediolateral ground reaction impulse to achieve the gait symmetry during the stance phase [135].

V. PSYCHO-SOCIAL IMPACT OF LOWER LIMB PROSTHETIC USERS

Feedback of patients after wearing the prosthetic limbs is a key source for design optimization. It is beneficial to improve the design parameters of prosthetic devices thereby facilitating QoL (Quality of Life) to the wearer. Table 6 presents a comprehensive summary of the feedback collected from prosthetic users of different countries. It was observed that "questionnaire" for the survey was applied in most of the studies considered. Column #3 of the table describes the psycho-social impact on the QoL of the amputees. And the last column of this table highlights the suggestions given by the wearer to be used as feedback for the research community.

A. QOL, SATISFACTION AND PSYCHO-SOCIAL ADJUSTMENT

Fuhs *et al.* reviewed the findings on the role of emotional (depression, anxiety), motivational, cognitive, and perceptual factors in PLP. Their findings indicate that emotional factors may be less important than chronic pain. Future work is needed on psychological factors and the interactions [147]. D. DESMOND and M. MacLachlan *et al.* reviewed the profile of psychology in prosthetic & orthotic research using MEDLINE search for a duration of 25 years. They have witnessed relatively a few substantial psychological contributions for the journal. Practitioners can address to develop psychological dimensions in technological development in the field [148].

Berke *et al.* did a comparison of satisfaction concerning socket fit, pain, skin problem, sweating & nuisances using the survey method. They found important differences in overall satisfaction and suggested the need for continued practitioner education & system evaluation [149].

Abdulkadir Ayudin and Sibel Caglar Okur did a survey for comparison of satisfaction concerning socket fit, pain, skin problem, sweating & nuisances with or without socket. Standard benchmark of TAPES (Trinity Amputation and Prosthesis Experience Scales) and BDI (Beck Depression Inventory) were used. Though the test socket increases the cost it reduces the pain thereby increasing the satisfaction level of the patient [150].

Hafner *et al.* were aimed for psychometric evaluation of prosthetic users to determine test-retest reliability, mode of administration (MoA) equivalence, standard error of measurement (SEM), & minimal detectable change (MDC) of standardized. The results showed the enhanced ability of clinicians & researchers to select, apply, & interpret scores from the instruments administered to prosthetic users [151].

Wyss explored the issues related to the provision of appropriate technologies for prosthesis & compared these across different economies of low as well as high-income countries of the world. They did an online survey found that higher cost for prosthetic is an issue raised by all countries. Authors were certain the work will be useful to prioritize prosthetic services by researchers, health care planners, and government organizations internationally [152].

This review was done to show scientific productions on psycho-social and physical adjustments to amputation. It also highlighted the satisfaction level of prosthetic users in the last 10 years. Articles related to psycho-social adjustments, anxiety, higher rates of depression, and body image disorders had been observed among amputees. Gender, PLP, employment status, and daily hours of prosthetic use influence psycho-social adjustment. Physical adjustment subject to be affected by amputation level, age, education background, daily prosthetic use, ambulatory devices, and commodities. The greatest prosthetic dissatisfaction areas found were color and weight. Transtibial amputees tend to be more satisfied than transfemoral amputees [153].

B. REIMBURSEMENT ISSUES OF PROSTHETIC USERS

Baumann *et al.* discussed the social and psychological factors to improve prosthetic care in Germany using online resources. The key findings were reimbursement issues for psycho-social adjustments for prosthetic users. An attempt was already made to discuss reimbursement issues for stakeholders like insurance companies, health economics, doctors, producers, and prosthetists. The authors appreciated these efforts and suggested to continue taking into account the users, representatives and HTA (Health Technology Assessment) [154].

VI. DESIGN TRENDS IN PATENTS FOR LOWER LIMB PROSTHESIS

This section comprises the discussion about patents published in the United States. The objective of this section is to familiarize the readers with trends in patents for different body parts of the lower limb in prostheses.

A. DATABASE "FAKH-50" DEVELOPED FOR LOWER LIMB PROSTHESIS

US patents available at google patents are considered with defined criteria in the section of inclusion and exclusion. Overall work has been reviewed published in patents about mechanical designs, materials & 3D printing of sockets, liners, sleeves, and other related accessories of LLPs since 1970. These considerations have been addressed for "FAKH-50" depicting the four legends involving the foot, ankle, knee, and hip. The histogram shows the trends as well as advancements which are maximum for the knee and minimum for the hip. The count and percentage of the work are shown in Figure 4 for lower limb body parts. Overall trends analyzed are in descending order as knee > ankle > foot > hip for the considered criterion. For the knee, there are 228 patents (48%), 131 patents (28%) for the ankle, 105 patents (22%) for the foot, and 11 patents (2%) for the hip design in the database.

The histogram in Figure 5 presents an idea about trends in the development of LLPs. Decade wise contribution of the researchers has been presented for lower limb parts. This figure reflects the highest demand for above-knee designs.

The search was performed at https://patents.google.com/ and more than 1000 patents were found and 475 patents are considered in our FAKH-50 database. The inclusion and exclusion criterion has been described briefly in the forthcoming section.

1) INCLUSION CRITERIA FOR FAKH-50

In this database designs of different parts of LLP including foot, ankle, knee, and hip have been considered. Mechanical design, design of accessories like sockets, sleeves, liners, & joints, etc. related accessories are included in this database. Sensing mechanisms as accessory and methods to fabricate sockets or liners are also included in the database. It is pertinent to mention that designs for ankle-foot prostheses have been differentiated on the basis of design dominance.

2) EXCLUSION CRITERIA FOR FAKH-50

This section describes the excluded work for the database. Prosthetic related work related to procedure/training, cosmic covers/limb guards, prosthetic alignment/adjustment/fitting/training devices, controlling strategies, controller designs and drawings, etc. for the said four human body parts have been

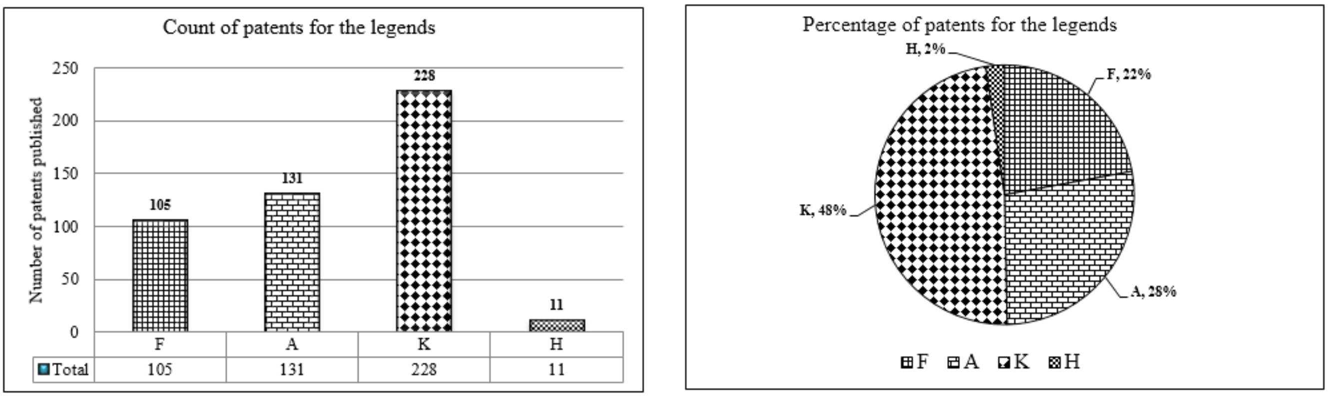

FIGURE 4. This figure shows the count of patents in lower limb prostheses as per inclusion and exclusion criteria. Patents studied were 105, 131, 228, and 11 for prosthesis related work for foot, ankle, knee and hip respectively.

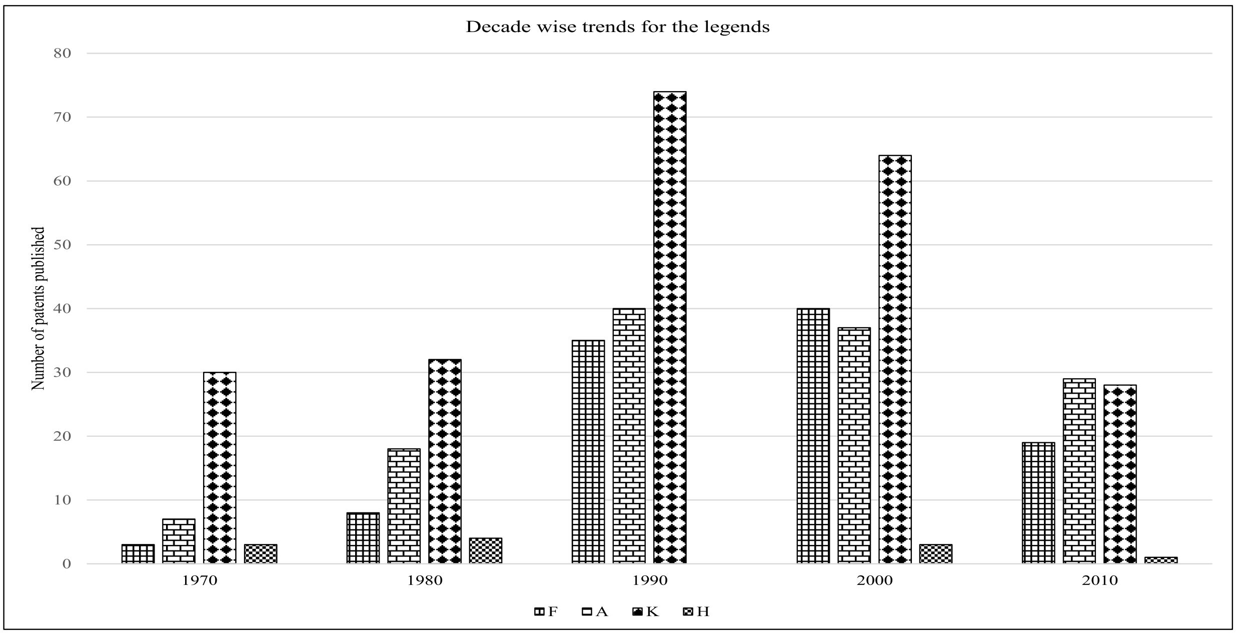

FIGURE 5. The histogram shows the patents published for the design of the foot, ankle, knee, and hip. Design and accessories like liners have been considered in our open source database FAKH-50 which involves patents from 1970 to 2020.

skipped from the database. Complete and partial designs with two or more body parts are excluded from the database however a few of those are summarized next as a part of this review.

B. FOOT

The patent provided a foot prosthesis with a heel plate to contact with the ground and ankle plate which extends vertically from the heel plate when the heel plate is in contact with the ground. A leg prosthesis with an upper end part mountable with person's body, a lower end part, and clearance enhancer. A clearance enhancer is an L-shape plate including a base plate as well as an upper plate. The base plate is mounted in such a way as to remain in contact towards the lower end of the leg prosthesis. Many mounting openings are available in the upper plate to receive the required number of fasteners to connect with the upper plate to the ankle plate of foot prosthesis to provide ease to the lower portion of the leg prosthesis to overlap the ankle plate of foot prosthesis [155].

The invention of authors describes an instrumented prosthetic foot for a controller based leg prosthesis. The foot consists of a connector to connect with a prosthetic leg and ankle structure along with a sensor to detect variations in weight distributions. An interface is available to receive the signals from the sensor and to transmit to the controller [156].

C. ANKLE

Harris *et al.* published a patent on lower limb prosthesis comprising an ankle unit with pivotal mounting to the foot component. The ankle unit consists of an ankle joint mechanism containing a hydraulic piston and cylinder assembly to provide hydraulic damping when the ankle joint flexes. A vacuum mechanism consisting of a pneumatic piston as well as cylinder assembly to generate a vacuum. Hydraulic piston, pneumatic, and cylinder assemblies are arranged in such a way to generate the vacuum mechanism during plantar flexion of ankle unit [157].

Herr *et al.* published a patent on artificial foot and ankle joint comprising a curved leaf with spring foot member equipped with heel and toe extremity. It also has a flexible elastic ankle member to connect the foot member to rotate the ankle joint. The motor provides torque to the ankle joint for foot orientation at contact-less surface support. It also stores energy in a catapult spring which is released along with the stored energy in leaf spring to propel forward the wearer. Ribbon clutch well prevents the foot from unidirectional rotation beyond a predefined position. A controlling damper was incorporated to lock the ankle joint and absorb the mechanical of the spring. Control & sensing mechanisms work together to control the motor and the damper during the walking cycle for level walking, stair descent, and stair for different time intervals [158].

Herr *et al.* provided a powered ankle foot prosthesis that provides power just as a human does at terminal stance which increases metabolic walking economy in comparison to the conventional passive elastic prosthetic devices. The prosthesis consists of a unidirectional spring which was configured parallel to a force controlled actuator having series elasticity. This prosthesis was capable to provide high mechanical power positive work for normal human walk [159].

D. KNEE

The lower limb prosthesis comprises an attachment, a shin, foot, and knee joint. The knee joint section pivotally connects with the attachment section. Shin and knee joint pivotally connect with the shin section. The knee joint is a dynamically adjustable damping mechanism to control knee flexion. A sensor unit is installed to generate sensor signals for the walking environment. Different damping levels determine the swing and stance phases of the human gait cycle [160].

Presented a 3D printed lower limb modular prosthesis printable with composite fiber filament, nylon, or metals. The production process includes a 3D printer with the capability of routing fibers in a specific programmed layer. The parts of the prosthetic system could be designed for direct patient end-use and maybe energy returning in nature [161]. This invention is about the design of a liner for limb prosthesis which is characterized by a foam layer consisting of a plurality of foam strips and a plurality of elastic fabric layers. The foam layer is sandwiched between elastic fabric layers & liner for limb prosthesis consisting of a cone or cylindrical shape having open and closed ends [162].

E. HIP

A hip joint prosthesis includes a connection securing device, an artificial leg, and a controlling unit to control an extension movement and step length provided in the hip joint of an artificial leg [163]. Another design describes a prosthetic hip joint to support the artificial leg of the patient. The leg consists of a socket, mount, and a joint axis when rotated in a sagittal plane. The hip may include a roller on the loaded arm which extends medially from the end of the upper leg thereby engaging the outer surface of the socket to transmit the load directly to the prosthetic leg [164].

VII. CHALLENGES AND FUTURE PROSPECTS

Promising developments in the field of lower limb prostheses allowed the experts to be optimistic about the future. This section shows the future challenges and prospects in the area of lower limb prosthesis for the stakeholders like researchers, producers, organizations, pharmaceutics, surveyors and trend analyzers, etc.

A. CHALLENGES IN LOWER LIMB PROSTHESIS

As there is massive room for improvement in lower limb prostheses, it encourages many researchers to introduce cutting-edge technology in maximum components of the prosthesis. It will provide an ease of improvement for the fabrication of prostheses as research and development of lower limb prostheses demands a multidisciplinary approach to collaborate the various fields. For example, myoelectric controlled prosthetic limbs which are the most exciting developments of the field need to incorporate mechanical moving parts, electric circuits, bio-electronics, and materials science. The limb performs functions by using electrical signals from the nerves of the amputee to the prosthesis to mimic the movement of a human leg. The lower limb prosthetic devices are sophisticated but preferred to be simple and elegant. Significant growth for a number of manufacturers of these prostheses has been seen worldwide. Every product which improves the usability and reliability of an amputee is going to lead a win-to-win situation for society. Researchers are working on implantable stumps, which may eliminate the need for a socket. Along with these efforts parallel developments in the domain of prosthetics, bioprinting, robotics, and super human like body parts will no longer be just a fantasy [165].

B. DISCUSSIONS AND FUTURE PROSPECTS FOR LOWER LIMB PROSTHESIS

Causes of lower limb amputation due to cancer are suggested to be carried out in the countries mentioned in Table-1. Committees should be formed to conduct counseling sessions among patients who required lower limb amputation due to some diseases or trauma. Surveys on limb loss by birth or at an early age will also be of great interest to serve fruitfully to clinicians and researchers. The occurrence of lower limb problems in old age people is common due to weakness and other psychological issues. Special care and life awareness are the important aspects to suggest through counseling. In case of damaged tissues, rehabilitation using therapeutic sources, prompt checkup, rest, and a special diet, etc. may be suggested.

Time efficiency in algorithms is highly demanded even though after achieving the highly accurate figures to avoid early and late gait phases. To the best of our knowledge, no such direct algorithm was found to map specifically the biomechanical behavior of the muscles with the lower limbs of the body. This leads to the deviation from normal human gait creating the issues of PLP. Considerations of daily life activities discussed in [166]–[169] are necessary for the robustness of the algorithm to be tested on the prosthesis. These may involve different angles of approaches for varying terrain, variable speed, indoor/outdoor environmental interactions, variable load to be carried by the prosthetic wearer, and leg transitions, etc.

It is still challenging to make the movement natural for the prosthetic wearers. The formal study of the biomechanical behavior of the limb and developing its computational model may be the prerequisites to fulfill this challenge. The concept of soft robotics (soft sensors) is recommended to overcome such issues. A trend of triaxial force sensors, IMU sensors, shear, pressure, and FSRs have been seen for different measurements in lower limb prostheses. Though a lot of work exists to capture the muscle movements using EMG sensors but performance was not adequate because of placement and muscle variations. Its sensitivity is not stable due to moisture present in the contact between skin and sensors. Furthermore, it needs to re-calibrate every time the device is worn by the user.

Residual limbs are still demanding highly bio-compatible, lightweight, and cosmic printed parts like sockets for the prosthesis. Bio-compatibile and lightweight materials play a pivotal role to enhance the usable time of prosthetic devices thereby reducing phantom limb pain. The usable time of prosthesis should be increased to hours whereas mentioned in some articles for a few minutes. Considering such factors may be beneficial for safe standing, comfortable sitting, full range of motions & longer walking distance.

Diabetic foot ulcers (DFUs) resulting in devastating economic crises for patients, families & society. It has a high prevalence rate in the developing countries when compared with developed countries among diabetic Mellitus patients. Foot examination provides ease of diagnosing foot ulcers in diabetic patients. The budget estimation must include clinical & social impact of the patients. The key issue still to be solved is how to reduce these expenditures along with the morbidity & mortality related to DFUs. The developing countries should consider the economic burden seriously to overcome this national crisis [170]. Estimation showed that treatment expenses of neuropathic ulcers, chronic infected neuropathic foot, advanced DFUs (care, limb amputation), and neuroischemic foot (bypass) was approximately US$56, US$165, US$1080, US$960, US$2650 and US$1960, respectively [171].

After studying different surveys on satisfaction, psycho-social impact, and QoL for lower limb amputees we come to the following findings. It is a challenging demand to fulfill the satisfaction level of prosthetic users in society. It may also lead to living them a better QoL with a good psycho-social impact. It is of utmost importance to produce cost-effective solutions to fulfill the needs of prosthetic users in low-income countries. There is a great need to address the economic issues of amputation to insurance and funding organizations to resolve reimbursement issues for the individuals during or after availing the prosthetic devices as well as services. It is indeed of great appreciation to arrange life comforts for them including job resources with handsome quota and especial sports.

Design trends and advancements in patents show maximum work (48%) for knee design and minimum work (2%) for hip joints for human lower limb body parts. Quantitative analysis showed maximum (48%) of designs exist for the knee reflecting the higher demands for transfemoral amputees.

VIII. CONCLUSION AND FUTURE WORK

The conclusions of the effort are always stimulating to meet the demands for more advancements. Major advancements/trends after reviewing the literature of the multiple domains of lower limb prostheses are presented here as key contributions to this work. In this regard, an effort has been put to successfully compile the comprehensive review in the domain of lower limb prosthesis with multi-dimensional approaches. Table 7 comprehensively presents the aspects of the domain reviewed, advancements/trends, and conclusions/future work in the different domains of lower limb prosthesis.

Causes of amputation in most of the countries are found useful for the various case studies of amputees. Vascular & diabetic diseases are observed to be the most occurring causes of amputation in the whole world. Around 485 Million people are diabetic patients worldwide and the foot of diabetic patients are being cut due to wounds after every 30 seconds. American and European surveys highlighted all the causes of amputation along with high mortality rate. Trauma is another major cause of amputation that often occurs because of road/factory accidents and various others.

Design and development efforts play a central role to mimic the biomechanical functions of the human leg. A systematic understanding of passive, active, and semi-active prosthesis as presented in Figure 2 may give a better understanding before the final design requirements. Research and development work is suggested for the future to overcome the human gait deviations from the standard mean normalized human gait curves. This will contribute to the lightweight and economic designs that may be beneficial for lower or middle-income countries.

3D printed sockets need careful consideration in material selection in the context of biocompatibility, lightweight, comfortable socket design, design of liners, and its printing. A weight-effective transtibial prosthesis [51] explored uses the polycentric design that weighs 1.32 Kg. The design was

TABLE 7. Trends, advancements and future work for lower limb prosthesis.

Sr#	Aspects of the domain	Trends/Advancements	Conclusions/Future work
1	Lower limb amputation	**A**. Common diseases causing more amputations are: Diabetes & vascular diseases	**A** (**i**) Perform surveys for cancer related amputations in low income countries. (**ii**) Iterative surveys should be performed & design common standards for surveyors.
		B. Health risks: (**i**) Phantom limb pain (**ii**) It may lead to death for diabetic patients.	**B**. Required the design of highly bio-compatible prosthesis exhibiting more natural gait to cover both aspects of amputee health.
2	Design and development	Passive and active designs	Optimal design of semi-active prosthesis generating power, equivalent to the human leg is suggested.
3	Materials and 3D printing	Poly lactic acid & carbon fibre are being used for printing the parts.	Bio-compatible, light-weight, durable, cosmic, and economic material for prosthesis is a future challenge.
4	Control strategies	Finite state machine controller was observed being used mostly for impedance control.	Design more real-time controllers giving the reliable results with minimum tuning parameters.
5	Sensors for LLPs	IMUs and EMGs are being used mostly.	IMUs are fine but soft flexible sensors are suggested to be designed alternate to EMGs.
6	Machine learning algorithms for LLPs	No such algorithm was found to relate thigh stimuli to the leg movement.	Design the algorithms to sense stimulus generated from thigh muscles to obtain more natural gait.
7	Quality of life of amputees in society	**A**. Satisfied but with less usable time.	**A**. Improve long hours use of prostheses by using more bio-compatible materials and designs.
		B. Middle class families are unable to afford specially for active prostheses.	**B**. Insurance and charity based organizations may resolve the reimbursement issues.
8	Design trends in patents	Found 48% patents for the design of knee as mentioned in our FAKH-50 database.	It shows currently the higher demand for transfemoral amputees.

in comparison to the commercially available prosthesis of Ottobock but it was in the research phase.

Control strategies and state-of-the-art machine learning algorithms need to address the time competency. Machine learning algorithms play a vital role to improve the efficiency of desired work. A novel algorithm to directly relate the stimuli generated by the thigh to the motion of the human leg is an open challenge to be addressed. Accurate functioning of the prosthetic leg is another challenge for the researchers to avoid the asymmetrical behavior of the gait. The correct tracking of the real-time human gait by the prosthetic devices will enhance the long hour time of use and it may also reduce phantom limb pain.

Surveys for some of the countries considered elaborate about satisfaction level, psychological adjustment, and QoL. Services, accessories, mechanical designs, and mechanisms need to be cost-effective to facilitate the amputees. Cost-effective solutions may switch the amputees to wear commercial prostheses rather than traditional orthotics or only sockets. The traditional ways of limb replacement for amputees seem to be a source of severe PLP. The database "FAKH-50" developed by authors for patents shows a clear picture of trends in LLP since 1970. Trends show the percentage for the work done for foot, ankle, knee, and hip of lower limb parts of the human body. The database will be updated with more features in the future. This work may be beneficial for researchers, technicians, clinicians including health care or cure planners, sportsmen, amputees, and prosthetic centers/organizations.

This study is limited to the contents related to lower limb amputations and the main aspects of lower limb prosthesis. Magazines, letters, and theses have rarely been used as a part of this review. Commercial products rely on the information published on the company websites and a few articles. Contents related to exoskeletons and orthosis are not part of this review. Only the design trends for foot, ankle, knee, and hip for the last 50 years have been analyzed quantitatively through the US patents in the current version of our database FAKH-50. Abbreviations that are very common or used one time in this manuscript have been omitted from the forthcoming section of abbreviations.

ABBREVIATIONS

The abbreviations used throughout this manuscript are defined alphabetically in this section. These are introduced where appeared first time in the manuscript, elsewhere short form is used.

ADL Activity Daily Living
ANN Artificial Neural Network
BDI Beck Depression Inventory
CIFAR Canadian Institute for Advanced Research
CNN Convolutional Neural Network
DBN Dynamic Bayesian Network
DFUs Diabetic Foot Ulcers
DLNN Deep Learning Neural Network
DSPIC Digital Signal Peripheral Interface Controller
EEG Electroenceography
EMG Electromyography
EKF Extended Kalman Filter
FAKH Foot, Ankle, Knee and Hip
FDA Food and Drug Administration
FPA Foot Progression Angle
FSR Force Sensing Resistor
HMM Hidden Markov Models
HTA Health Technology Assessment
IMU Inertial Measurement Unit
KNN K Nearest Neighbor
LDA Linear Discriminant Analysis

LEA	Lower Extremity Amputation
LLP	Lower Limb Prosthesis/Prosthetics
LLA	Lower Limb Amputations/Amputees
LSTM	Long-Short Term Memory Network
NN	Neural Network
PCA	Principal Component Analysis
PLP	Phantom Limb Pain
PLA	Polylactic Acid
QoL	Quality of Life
SACH	Solid Ankle Cushioned Heel
SEA	Series Elastic Actuator
SVM	Support Vector Machines
VAS	Vacuum Assisted Suspension
WHO	World Health Organization

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