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Review

Upper Limb Bionic Orthoses: General Overview and Forecasting Changes

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Abstract: Using robotics in modern medicine is slowly becoming a common practice. However, there are still important life science fields which are currently devoid of such advanced technology. A noteworthy example of a life sciences field which would benefit from process automation and advanced robotic technology is rehabilitation of the upper limb with the use of an orthosis. Here, we present the state-of-the-art and prospects for development of mechanical design, actuator technology, control systems, sensor systems, and machine learning methods in rehabilitation engineering. Moreover, current technical solutions, as well as forecasts on improvement, for exoskeletons are presented and reviewed. The overview presented might be the cornerstone for future research on advanced rehabilitation engineering technology, such as an upper limb bionic orthosis.

Keywords: biomechanics; exoskeleton; rehabilitation; robot-assisted therapy

1. Introduction

The current state-of-the-art in bionic orthoses has its beginning in classical antiquity. The first known works related to this topic were created by Archytas from Tarentum in 350 BC. He invented several mechanical devices, such as a flying bird powered by steam [1]. His works gave rise to modern robotics. In the Middle Ages it was common to construct devices, which now can be named androids, for entertainment. They were given roles to welcome guests at the entrance, play instruments, open the door, or do other simple activities. To power the androids, former constructors used gravity, energy stored in a spring, or flowing water. The word "robot"—describing a mechanical machine—was used for the first time in the science fiction play "Rossumovi Univerzální Roboti" by Czech writer Karel Čapek in 1920 [2–4]. The following decades brought dynamic development in robotics due to intense research and numerous projects being worked on all over the world—simple robots have been expanded to currently used, sophisticated and complex devices.

An example of a medical device which design shares similarities with robotic devices is an orthosis. The word orthosis comes from Greek "ortho" and means "to straighten" [5], thus the purpose of the orthosis is to stabilise joints and groups of muscles that have suffered an injury. The creator of the first known orthosis was French surgeon Ambroise Paré in the middle of XVI century [6] whose metallic brace was introduced for correction of scoliosis. Although it did not exploit any movement, since then, orthosis devices have been constantly improved. US military efforts in increasing endurance and force of human muscles have led to the idea of a bionic orthosis.

The first attempt to construct human muscles amplifier was made by General Electric company in 1965 [7]. The project was called Hardiman (Figure 1a) and was expected to increase human lifting capability up to 650 kg. Unfortunately, it generated a raising force of only 340 kg and the orthosis was enormous. After several attempts of improving, the Hardiman project was abandoned. In subsequent

decades many constructors tried to overcome limitations of contemporary materials. Finally, in the early 1990s, the technology was sufficiently advanced to build a compact version of Hardiman. One of the first patented exoskeletons was the "Three axis mechanical joint for a power assist device" created in 1994 [8]. Its main objective was to amplify a human muscle force.

While assistive devices for primarily healthy soldiers were developed, it was 1970 when robotic solutions finally found way to be applicated in a health purpose. That year an orthopedic surgeon from Toronto, Robert B. Salter, investigated regeneration and healing possibilities of articular tissues coming from continous passive motion (CPM) observed on rabbits. This research was the key which promoted healing joint cartilage by appropriate motor treatment [9].

Now, we observe more tries to implement the idea of exoskeletons in biomedical engineering, especially in engineering of rehabilitation systems [10–15]. We can divide bionic orthoses into two groups: the first group is intended to restore muscles to their original efficiency (Figure 1b), while the second (Figure 1c) is supposed to improve daily life of people having paresis [16].

The purpose of this article is to review the latest technology used in constructing a bionic orthosis meant for rehabilitation, as well as to indicate the direction of its future development. As a bionic orthosis we mean a rehabilitation device which, by means of dedicated software, automatically determines the state of the rehabilitation process and, if necessary, supports it. The element "bionic" suggests using biological factors for purpose of control strategy. It must be noted that this article will not deal with the question of neurological aspects, because of its complex nature, which is described more fully by Gassert et al. [17] . Smart orthoses are the future of modern medicine and it is reasonable to claim that using bionic orthoses in rehabilitation of the upper limb may be more effective than currently used methods [10,18–27].

The literature review was made with the help of "Scopus", "Google Scholar", "IEEE Xplore" and "Research Gate". The general search phrases were a combination of words: "rehabilitation", "robot", "exoskeleton", "upper limb", "orthosis".

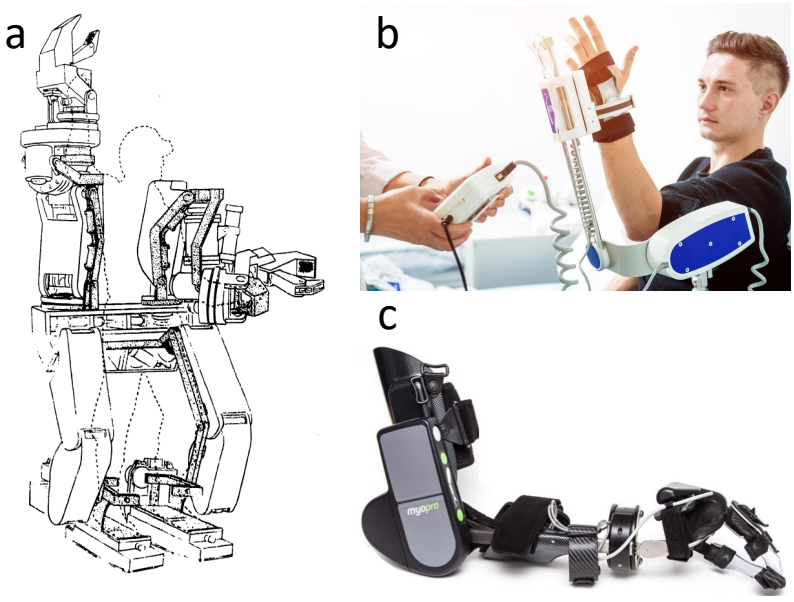

Figure 1. Examples of bionic orthosis solutions: (**a**) Hardiman (figure by Bruce Fick and John Makinson), (**b**) Myopro (reproduced with permission from [28], Myomo, 2020), (**c**) Patient on continuous passive range of motion machine (figure from [29]).

2. Medical Device Regulations

One of the most important aspects of constructing biomedical devices are ethics and law restrictions. Referring to human rights, especially to right to health, it is neccesary to guarantee a highest quality health care service, which by definition cannot make ones condition worse. Thus,

all of the products intended for sale are nowadays covered by specific directives and regulations provided by countries and organisations. The most recognized is Chartered Engineers Certificate or simply CE introduced by European Union for economic purposes. Individual regulation units that take significant part in global trade include the Food and Drug Administration (FDA) in the USA and Pharmaceuticals and Medical Devices Agency (PMDA) in Japan [30,31]. With reference to smaller entities, their regulations law commonly rely on one of the mentioned above in order to facilitate movement of products. For example, a medical device directive of ASEAN (Association of South-East Asian Nations) refigures European standards and some of the FDA's methods [32].

The common property of all of the regulations is fact they are based on risk assesment [33,34]. The result of such a procedure is assigment of proposed device to one of the risk classes, where 1st is with lowest risk and the last one level (in all cited is equal 4) is highest. This classification affects further steps in certification procedure, e.g., restrictions, and that is why some standarisation work is carried out between the greatest units [35].

Focusing on authors regional law, i.e., Poland and European Union, a main applicable directive is Medical Device Directive (MDD) 93/42/EEC, which is compatible with ISO 13485. In this case a bionic orthosis will be classified in class IIb, as an active therapeutic device that exchanges energy to the human body in potentially hazardous way [36]. The main difference betwen classes is that a compliance with directive of class I could be examined and declared by producer while classes IIa, IIb and III require qualified institutions verification. As to the requirements, they are a set of general principles that must be fulfilled in process of the CE certification. Referring to some of them, a device must be designed to avoid the risk of electric shocks during both normal and single fault condition. Moreover, alarm systems must be provided in case of any power failure. Those describing mechanical construction require usage of biocompatible materials and protection against mechanical risks resulting from, e.g., moving parts. Same general restrictions are found in the FDA's list and are expanded by non-clinical performance testing. In opposition, the FDA has a database e-CFR where already certificated devices are placed with appropriate information, such as class of risk and requirements—information cited above is taken from paragraph 890.3480 "Powered lower extremity exoskeleton" (upper is not available) [37].

Instead of compliance with Machine Directive 2006/42/WE and therefore Electrical 73/23/ewg, which are additionaly required in EU members law, appropriate ISO standards should be respected due to two things. First of all, they give precise information about parameters and it values and secondly EU directives are based on ISO standards [38–40]. It should be mentioned that problems such as mechanical resistance could be simply solved by 3D modeling software.

Requirements concerning on relevant staff and patient training, and providing real time information about the state of patient and device could be omitted, due to modern multimedia systems which will be described later in this article.

The most problematic aspect seems to be a clinical trial. In order to be authorised for such tests it requires approval not only from regulatory authorities but also research ethics committee. The overall process of an evaluation is based on a comparison between possible forces produced by device and acceptable loads of human body which are known from biomechanical research. The problem occurs when these parameters became individual, i.e., are not known or may vary in time, e.g., people with osteogenesis imperfections. This situation may in most cases lead to rejection of the application, which is completely understandable. However, this raises the question what new procedures should be taken into account, how new rehabilitation devices should be designed and which parameteres require detailed research to allow patients with these particular cases to the newest technology.

In conclusion, the lack of clarity in the current legislation is caused by dynamically developing technology. For this reason, existing directives and regulations for medical devices are too general to give a clear view on all of the robotic aspects. The natural course is adaptation of these procedures to systematically improve solutions, and the best evidence of this has been the recently released IEC standard 80601-2 for medical electrical equipment, especially part 78 "Particular requirements for basic

safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation" [41]. This will hasten an implementation of the bionic orthosis and will popularize them, which in effect will result with extended experience. Thus all of the patients will be given a chance to use modern technologies.

3. Mechanical Construction

Progenitors of the modern bionic orthosis were used to improve human muscle force. They had a simple and non-autonomous control system, while the majority of current robotic technology use brain–computer interfaces [42–48]. Primitive exoskeletons were unnecessarily heavy, with their weight reaching over 700 kg [49]. It was caused by the weight of materials and drives used in their first prototypes. The basic construction material used to build bionic orthoses in the middle of the 20th century was steel (with breaking tensile stress-to-density ratio of 75), which was because of its strength properties [50]. For the same reason, in combination with old type massive actuators, these devices had enormous sizes. Therefore considerations of mobile solutions had to be abandoned [7].

In the last applications we can distinguish several types of motion assistance: active devices, passive device, haptic device, coaching device, active exercise and passive exercise [51]. The first construction is recently one of the most developed due to its multipurpose, light weight and price competitive potential [52]. The main features of mechanical design of such orthosis are the actuating and transmission system as well as applied materials (Figure 2). Same as in prosthetics, weight, mobility and comfort play a significant role [53,54]. However, prosthetic devices offer an additional inner space which allows placing actuators and transmission mechanisms in device contours [55–57]. Thus, the choice of the actuating unit may affect the entire apparatus.

Most frequently, the elbow joint is the one which is driven directly with a motor installed on lateral side of the arm. This solution, as well as rigid transmission (e.g., n-bar linkage, gear) requires a special attention to compatibility of joint rotation axes and bionic orthosis axes. Currently, several types of mechanisms are used for this purpose, including: direct matching of joint centres, linkage for remote centre of rotation, redundant linkage structure, and serial linkage attached to distal segment [58]. Incorrect matching of rotation axes can lead to exoskeleton damage or limb injury [15,59,60].

In opposition to these solutions that are very bulky or actuators cannot be placed directly in joint axis [61,62]. It is possible to use flexible transmission. The best example of such appliance is a tendon driven system. In the simplest way, appropriate parts of the body are connected to motors via a Bowden cable, thus making them mostly unnoticeable and providing frictionless movement [63,64]. On the other hand, the mechanism imposes an antagonistic control thereby redoubles the number of actuators. It is possible to avoid this phenomenon with pulley mechanism application, but simultaneously, as with rigid solutions, construction gets more complex and enlarged [65,66]. Moreover, underactuation must be taken into account.

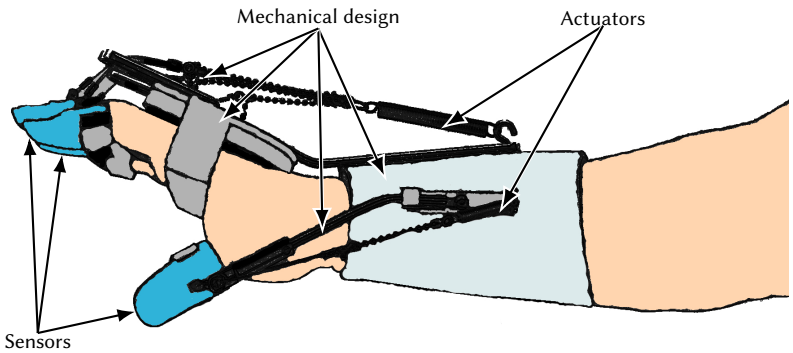

Figure 2. Components of a bionic orthosis - adapted with permission from Saebo, 2020 [67].

Aspirations to build lighter active orthosis, which would be useful in everyday life turned engineers' attention, in the aspect of applied materials, to alloys. Similar strength properties,

significantly lower weight, and higher breaking tensile stress-to-density ratio (162) than steel were the reason why aluminium is often used in modern bionic orthoses [68,69]. In general, materials used to create an exoskeleton are: bakelite, surgical stainless steel, aluminium alloys (copper, magnesium, or manganese), acrylonitrile butadiene styrene (ABS), polylactide (PLA), or shape memory alloys (SMA) [44,68,70–75]. A compilation and comparison of properties of the aforementioned materials can be found in Table 1.

Table 1. Properties of materials used in the production of bionic orthoses.

	Tensile Strength (MPa)	Yield Strength (MPa)	Density (kg/m^3)	Processing Difficulty	Price (USD/kg) *	References
Stainless steel	500–700	200	8000	Medium	25	[50]
Aluminium alloy	510–540	430–480	2810	Difficult	15	[68,69]
PLA	800	70–100	900–1500	Easy	2	[72,73]
SMA	1000	200	6500	Difficult	100	[70,71,76]
Carbon fibre	2800–5000	840	1600–2000	Very difficult	25	[75]

* Estimated values based on wholesale prices of 2016-12-05 (not applicable to SMA [76]).

It is also common to produce some parts using carbon fibre to make the orthosis lighter and more durable. Only a couple of years ago there were no rehabilitation devices fully manufactured of carbon fibre because of its poor ability to resist transverse loads [77]. However, in recent years, a bidirectional carbon fibre was created, which is characterised by a higher ability to resist transverse loads and a high breaking tensile stress-to-density ratio (2167) [75].

Formerly, a number of other materials were used [44], but because of their inadequate characteristics they have been replaced by modern metal alloys and plastics. Present bionic orthoses are made of different materials depending on their purpose. Lower limb or pelvic orthoses are exposed to higher stresses compared to the orthoses of the upper limbs, therefore, metal alloys and carbon fibres are usually used due to their strength properties. Orthoses of the upper limbs are not subjected to high stress or force and, consequently, materials used in their production are lighter and their machining process is easier. For this reason, it was natural to use 3D-printed PLA and ABS in orthosis manufacture process [78–83]. An additional advantage of using a 3D printer is low production cost, which can be lower than 35 USD for the entire construction—as with the prosthetics made at the Jacobi Medical Center in New York [84].

4. Actuators Overview

Most frequently encountered upper limb hardware systems are based on electric, hydraulic and pneumatic actuation [85–90]. In the past, primitive hydraulic drives were used in exoskeletons, as it was the only type of drive that could set in motion a heavy steel frame. The aforementioned Hardiman project was composed of a complex hydraulic and electronic network. With the technology development and new materials, engineers started to adapt, first of all, new lightweight motor based drives. Moreover, the number of smart materials used as an actuator in bionic orthoses is rising increasingly. In this type of materials we can observe change of physical properties or shape under the influence of, e.g., an electric, magnetic and temperature field [71,91]. An exemplary classification of described and others actuators is shown below (Figure 3).

Easily accessible, cheap and with wide range of power and size DC motors are the most common types of drives. Compared to others, they are distinguished by extensive experience and knowledge in control methods and that is why they are used in limb exoskeletons [92–94] and in stationary rehabilitation robots [95–98].These electric actuators can be divided into two basic groups: brushed and brushless.

Brushless motors (BLDC) have much higher torque and are more compact than brushed (Table 2), what is frequently used in elbow direct actuation [15,99], but that is not a rule and brushed motors also appear [87]. On the other hand, they require a dedicated control board to correctly change polarisation and so regulate speed/torque.

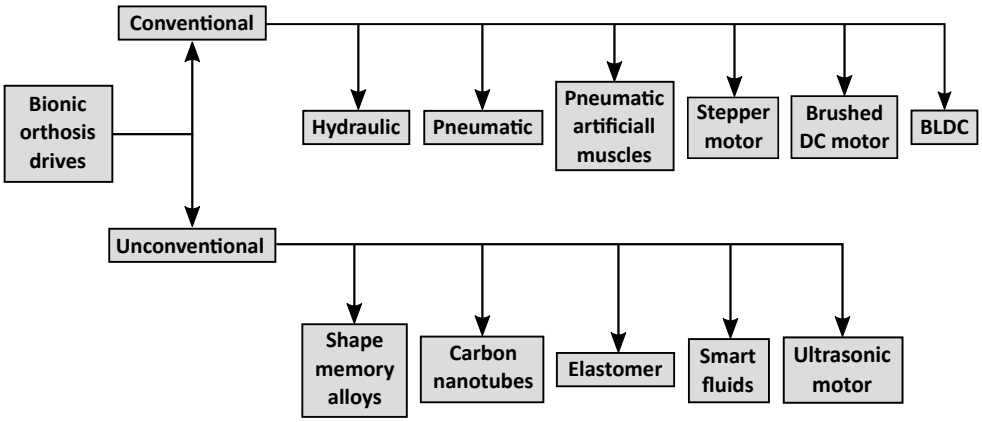

Figure 3. Types of bionic orthosis drives.

Brushed motors could be simply controlled by changing the voltage level, which makes them easy applicable; however, brushes wear over time, which shortens their lifetime. They are a base for other types of actuators such as servomotors or linear actuators—devices which consist of an integrated gearbox and feedback circuit and allows for precise displacement control, speed, and acceleration of the motor shaft [66,100]. It should be noted that both brushed and BLDC motors require an additional gearbox to generate appropriate power and speed [59,65]

Currently, the stepper motor is one of the simplest types of drive to control. Unfortunately, these motors have many serious disadvantages, such as discontinuous work (jumping), large dimensions (at high torque values), high energy demand, and high heat output during operation.

In reference to the next group, pneumatic and hydraulic actuators, there are no applications using this type of drive due to oversized end-effectors and additional equipment (valves, regulators, gas tank and a compressor) which results in the relatively large and bulky system. A particular type of such actuators is the McKibben muscle modelled after the human muscle. A pneumatic muscle, used in several research exoskeleton projects [101,102], is a first applied and developed drive considered as a artificial muscle, because of a human muscle properties such as light weight and elasticity [103,104]. Nevertheless, it still possesses imperfections of pressurized medium actuators, more precisely, equipment requirements.

Table 2. Characteristics of conventional bionic orthosis drives.

	Power Density (W/kg)	Torque (Nm)	Dimensions (mm)	Weight (g)	References
Micro Servos Expert Electronics SL260	110	0.109	21.6 × 11.2 × 19.1	9.1	[105]
Coreless motor MicroMo 2224-012SR	675	0.728	⌀22 × 51.3	6	[105]
Artificial muscle Festo	46	-	260 × 30 × 30	136	[106]
Brushless motor Maxon Motors	125	9.8	60 × 59 × 56	80	[107]
Pololu Micro Metal Gearmotor	914	0.89	10 × 12 × 29.5	10.5	[108]
Pololu Micro Metal Gearmotor	136	1.57	⌀25 × 68	106	[108]

Recently, a growing interest to unconventional solutions is observed (Figure 4). The new generation of actuators, based on phase transformation materials and activated by different stimuli, is constantly developed in order to obtain units that are more efficient and have smaller dimensions.

These will definitely revolutionize robotics, including orthotics; however, most of them are in early design stages.

The most popular materials, which use a change in crystal lattice as the source of movement, are shape memory materials (SMA). They are activated with a temperature field, e.g., when SMA is formed to shape under an external load (martensite) and when it is heated, it will recover to original shape (austenite). Such a working principle offers silent work, small weight, high power density, long lifetime (Table 3) and the possibility to program a shape of the material, where it is commonly used in shape of a thin wire or a spring [54]. Nevertheless, shape memory alloys exhibit some serious problems, where relatively slow work and high bandwidth, associated with low thermal conductivity, are the main ones [71,109]. Whilst it may be used for a slow movement rehabilitation, a high hysteresis makes it difficult to control.

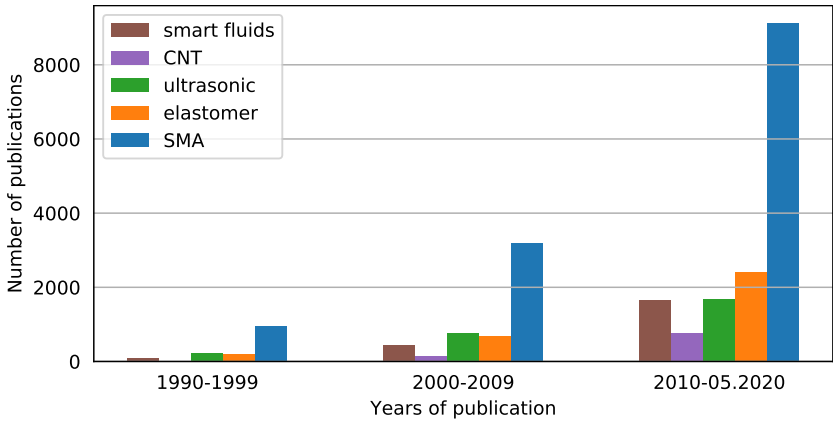

Figure 4. Publications on unconventional actuators.

Polymeric plastics and natural elastomers with elastic deformation capabilities are also used as materials for bionic orthoses drives. These materials increase the performance of conventional drives, such as pneumatic and hydraulic drives [110]. Polymers of this type possess high electrostatic features (material elongation in one direction under the applied voltage) [71]. There are also dielectric elastomers, which change their shape in two directions upon applied voltage [111]. A feature that currently disqualifies this solution is high voltage, expressed in kV, required to activate actuator [45,112,113].

Another material for smart actuators is carbon nanotubes (CNT). The CNT find their application in many areas of technology and medicine [114]. In bionic orthoses, their use was proposed in the early 2000s as material for artificial muscles [71]. However, satisfactory parameters of CNT actuators were recorded only in the tests published by Gendron et al. in 2016. The study created carbon nanotube polymer actuators containing metal chalcogenides: boron nitride (BN), tungsten disulphide (WS_2), and molybdenum disulphide (MoS_2). These supplements have a positive effect on elasticity, and increased strain and blocking force. CNT have good strength properties, especially the tensile strength is extremely impressive.

Intelligent fluids are also used in the production of bionic orthosis drives. Unluhisarcikli et al. [115] used electrotherapeutic fluid as an actuator in an upper limb rehabilitation robot. This material changes its dynamic viscosity under the influence of an electric field. Magnetorheological fluid (MRF) is a substance composed of ferromagnetic particles, which change their dynamic viscosity under the influence of a magnetic field. This substance was expected to improve drive operation in a hand exoskeleton [116]; however, they can be only applied in stationary devices due to required additional equipment, the same as in pneumatic/hydraulic case.

There are many other drive technologies that may be used in bionic orthosis, but for many reasons they are not able to be applied yet or were already tested and resulted in some objections. For example, an ultrasonic motor, characterised by high torque at low speed, was examined by WOTAS researchers who found a problem with tracking slow voluntary movements [117]. Another example, piezoelectrics,

although simple structures with low rates of energy demand and precise operation, exhibit a very low force capability [118]. Same with ionic polymers, which, in opposition to the aforementioned examples, the main disadvantages of are the liquid environment of the actuator [112,119].

Taking into account above comparison of both conventional and unconventional actuators, a DC motor is, for this time, the best choice as a driving unit because of its low price, many control methods and universality (wide range of parameters, servomotors, linear actuators). However, in reference to the statistic from Figure 4, all the research progress of artificial muscles should be followed as it will dominate the actuators market, primarily affecting lightweight devices with high mobility levels, such as bionic orthoses.

Table 3. Characteristics of unconventional bionic orthosis drives.

	Power Density (W/kg)	Average Efficiency (%)	Density (kg/m^3)	Product Life Cycle (Number of Cycles)	References
SMA	1000–50,000	<5	6450	10^7	[71,109]
CNT	10–270	>22	1000	140,000 33% reduction	[71,114,120,121]
Elastomer	500–5000	25	1000	10^7	[71,110,111]
MRF	690	NDA *	3000	NDA *	[116]
Ultrasonic motor	36	18–80	1620	NDA *	[117,122]

* No data available.

5. Sensory System

Sensors corresponding to human senses are a necessary equipment for a bionic orthosis as both play control and safety functions. They allow the patient and physiotherapist to determine forces, which are essential for proper functioning of the orthosis/exoskeleton system and providing protection against injury. Exoskeletons share the same transducer technologies as other robotics.

We can designate several popular sensor technologies: touch sensors, encoders, force/torque sensors, relative position sensors, absolute position sensors and distance sensors. Moreover, different sets of cameras are used more often for distance measurement or shape recognition and interpretation. Lee et al. [123] divided sensors into two basic groups: position-movement and force-pressure sensors. The first group includes: encoders, linear variable differential transformers, potentiometers, accelerators, inclinometers, magnetic sensors, electro-goniometers, and MEMS Inertial Sensor Devices. The second group includes: strain gauges, force/torque sensors, pressure sensors, piezoelectric sensors, piezoresistive polymers, and capacitive force sensors. A basic comparison of tranducer technologies used in orthoses is presented in Table 4.

First of all, limit switches should be installed in all moving parts of a bionic orthosis, which cut off power supply to the orthosis in an emergency situation (e.g., when the inclination limit is exceeded). These sensors are passive type—they do not affect the control (no feedback) and operate only in two positions (on or off), without intermediate states. The electrical limit switches have a very short response time, which makes them ideal for protection against undesirable inclination of a bionic orthosis. They also support first level safety mechanism—passive mechanical end stops [124].

The Hall effect sensor was used by Wege et al. to measure inclination angles of individual parts of an orthosis [125]. Scientists used also a force sensor acting in three planes with the accuracy of 0.08 N to control strength of joints in an arm exoskeleton [126]. An important element of the bionic upper limb orthosis is the hand grip force measurement, consequently a special sensor was designed for this task [127]. Its purpose is to adjust the hand grip force to prevent damaging the grasped object. For this purpose, a Von Frey hair (a monofilament fibre) was used. Thanks to that, the sensor senses pressure as low as 0.087 N/mm^2.

Table 4. Sensors used in bionic orthoses.

Sensor	Main Advantage	Main Drawback	Usefulness in Bionic Orthoses
Touch sensor	Feedback improvement	Complex	Optional
Force/torque sensor	Could be estimated by the current	Difficulties in measurement in dynamic conditions	Yes
Encoder	Simplicity	Relatively big	Yes
Accelerometer	Versatility	Limited accuracy of determining device orientation	Yes
Inclinometer	Simple posture control	Usefull in specific conditions	Optional
Gyroscope	Precision	Requires additional electronics	Yes
Distance sensor	Protection against breakage	Need to use several sensors	Optional
Camera for shape recognition	Increases rehabilitation efficiency	Expensive	Optional

In research associated with balance assistance of a hip exoskeleton robot the control strategy is based on sensors data as interaction force between exoskeleton and human thigh (force sensors), posture detection (inertial measurement units), ground contact detection (pressure insoles) [128]. Some of these sensors can be successfully implemented in upper-limb orthosis control system.

Some robotic devices can have a camera that recognises shapes using advanced algorithms. Use of the camera is designed to adjust the strength when gripping and lifting objects. The most important tasks of shape recognition algorithms are: extracting the object from the environment, determining the distance and position of the object, and passing this information as soon as possible to the main processor. However, those operations require advanced algorithms and are suitable for stable and repeatable conditions [108].

Virtual Sensors allow to estimate the robot/user interaction force and motion [129]. It is cheaper and equally effective alternative to standard contact force and motion sensors. The Virtual Sensors design is based primarily on position sensors, such as optical encoders or linear potentiometers.

In the case of pneumatic artificial muscle, Tjahyono et al. [130] proposed additional sensors. One of them is a ring entwining the artificial muscle made of a conductive elastomer. It measures changes in electrical conductivity when the pressure in the artificial muscle increases, thus determining the circumference displacement. The other sensor is a carbon-fibre nylon equipped with a sliding electrode and two end-fix electrodes. A sensor of this type is a flexible potentiometer responsible for measuring longitudinal displacement of the artificial muscle. Another example is a polypropylene deformation sensor that measures electrical conductivity (changing with the change of polymer chain length) to obtain information on deformation.

6. Control System Feedback

Feedback of different signals was not used in control systems at early exoskeletons development. In those times, robots were built with master/slave control systems. A breakthrough in the field of exoskeleton system control was the use of an interaction force between the human body and the exoskeleton system [131]. Nowadays, most of rehabilitation devices do not use feedback. Instead, they rely only on the physiotherapist's judgement and actions, sometimes being able to pass information about the patient's condition (based on biochemical signals) and current parameters of the device. This situation can be deemed inadequate, because rehabilitation systems should use biochemical signals obtained from the rehabilitated person to adjust their operation. In this case the physiotherapist could only perform a supervisory function (Triggered Passive Control

Model) [132–136]. For this reason this type of feedback bears often the name of a full biological feedback (Figure 5).

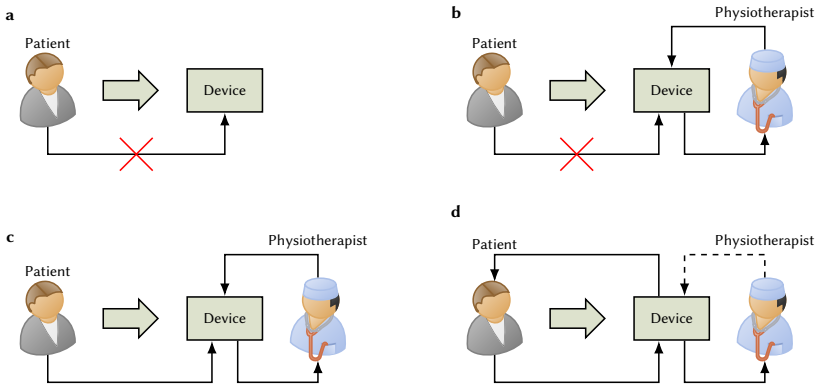

Figure 5. Types of rehabilitation systems: (**a**,**b**) no feedback—open loop, (**c**) classical feedback—closed loop, (**d**) full biofeedback—closed loop.

There are many measures to register change in a person's physiological state and the most common are: electromyography (EMG), electroencephalography (EEG), electrodermal activity (galvanic skin response—GSR or electrodermal response—EDR), slow cortical potential (SCP), hemoencephalography (HEG), heart rate variability (HRV), respiratory sinus arrhythmia (RSA), as well as other respiratory and temperature biofeedback [27].

The most frequently used signal to recognise stimuli is the EMG. For years, EMG has been used to control an exoskeleton in tasks, like supporting movements [137] or rehabilitation [138]. High efficiency of EMG signals used in control is presented by Palkowski et al. [139,140]. However, interferences, which occur during signal processing, can lead to system malfunction. For this reason, different types of filtration are used. The most common of them are: Hilbert transform [141], Fourier transform [142], and continuous wavelet transform [143,144].

EEG is used as a control signals in a brain–computer interface (BCI), which allows the patient to control the rehabilitation process directly by using brain waves. An extensive literature review of EEG-based BCIs has been prepared by [145]. High performance of computer control systems based on EEG has been proven,i.a., by Cantillo-Negrete et al. [146]. The results give hope for faster and more effective rehabilitation for people with cerebral palsy [147,148]. Along with many advantages of using EEG to control a bionic orthosis, this method has one basic defect—control is very complex and requires long-term preparation from a patient [149]. Scientists are trying to solve this problem by using hybrid BCI systems [150]. The popularity of EEG as a control signal is increasing, which can be depicted by how many studies are focused on it every year (Figure 6).

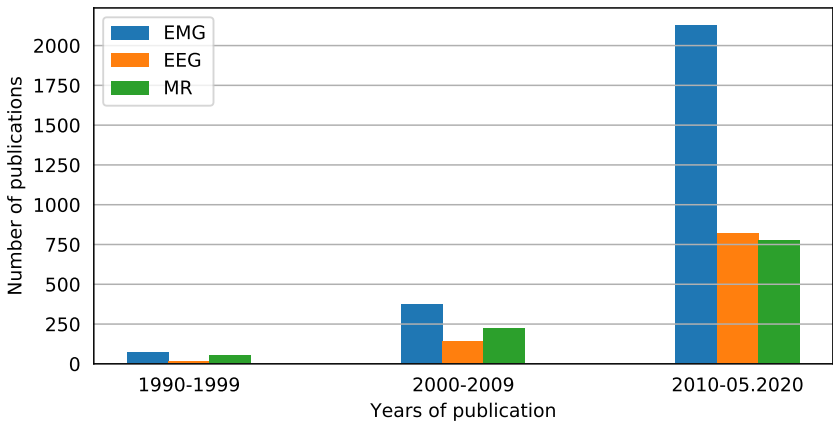

Figure 6. Publications on bionic orthosis control signals.

A novel control method is the use of neuroimaging by functional magnetic resonance imaging (fMRI). With this method, brain activity can be visualised while performing actions and processed into control signals [96]. At the moment, the method is only a concept and cannot be implemented due to technological limitations. Another way to control a bionic orthosis are signals derived from relative changes in blood flow volume. The data measured by impedance plethysmography are -=the electrical impedance variability caused by the flow of blood through the studied area. The measuring method requires placing at least four electrodes—two voltage and two current electrodes—in the studied area (e.g., the upper limb) [151].

A similar form of medical examination of myocardial function is an electrocardiogram (ECG). ECG records the potential difference between two electrodes located on the torso, being in fact the electrical activity of the myocardium. ECG signals provide a wide range of information on the degree of strain and fatigue of the monitored organism. ECG might be performed with phonocardiography (PCG), which records biomechanical cardiac activity on the basis of sound signals [152]. Reading signals using this method is a simple task and can be done with a simple instrument. In medical research, PCG is not widely used and has not been developed for many years. Its main disadvantage is disturbances detected by the phonocardiograph, which hinder the analysis of the results. However, a method for classifying sound signals was proposed by Redlarski et al. [153], thanks to which the basic defect of the above test can be eliminated. This allows PCG to be successfully used to control a bionic orthosis.

7. Modern Computer Methods in Medical Engineering

7.1. Machine Learning

Jagodnik et al. [154] demonstrated the use of reinforced learning in rebuilding muscle memory in patients with spinal cord injury who were using functional electrical stimulation (FES). Bionic orthoses can also benefit from machine learning. The idea of using reinforced learning in rehabilitation aims at maximising the effectiveness of the treatment. This is possible thanks to the personalisation of the device, which minimises the impact of bionic orthotics on the patient (appropriate adjustment of force). Celadon et al. [155] compared three methods of machine learning: linear discriminant analysis classifier (LDA), common spatial patterns proportional estimator (CSP-PE), and thresholding algorithm (THR). The aim of that study was to isolate signals from EMG, responsible for the movement of individual fingers of a healthy person, to improve the therapy with rehabilitation robots. The best results, with a small number of electrodes (up to 24), were obtained for the CSP-PE classifier. In another survey, the support vector machine classifier (SVM), improved by the cuckoo search swarm algorithm, was used for hand gesture recognition [140,156]. The results turned out to be very satisfying, providing 98.12% correct classification. Other widely used classification methods are: adaptive neuro-fuzzy inference system (ANFIS) [157], *K* nearest neighbours algorithm (KNN) [158], and decision tree (DT) [159]. We believe that the use of other machine learning methods like Multilayer Perceptron (MLP) or Random Forest (RF) can be very effective as in the case of our previous research [140,156,160].

A common problem during rehabilitation is the loss of concentration and decrease in engagement during repetitive activities, which can lead to less effective treatment. To overcome this problem, a conceptual measurement and stimulation system of patient engagement (the smart learning mechanism—SLM) was proposed [161]. The SLM made use of comprehensive signal processing systems and machine learning techniques. Regression models based on artificial neural networks and a naive Bayesian classifier (NB) were used in the study to compare performance [161,162], which showed the superiority of the NB method. The NB was less susceptible to deviations of input signals and showed greater accuracy regardless of the number of outputs. However, both methods should be compared experimentally to confirm their suitability.

7.2. Multimedia Systems

The use of multimedia systems is becoming more common in physical rehabilitation. The growing popularity of this solution is associated with research showing the positive effects of this method compared to traditional methods of rehabilitation [163–167]. The use of multimedia systems allows for: increasing immersion going beyond the sphere of physiological sensations (into the sphere of psychological feelings) and to integrate the received sensations using the senses hearing, sight, and touch. The main advantages of using VR in rehabilitation are: increased patient motivation, accuracy of movement mapping, and cognitive fidelity. Focusing on multitasking does not require constant supervision of a physiotherapist, progress monitoring, the option to repeat the same exercise repeatedly checking its correctness and option to save the patient's profile in the system. However, you cannot be completely sure of the effectiveness of using multimedia systems in rehabilitation. In Australia, extensive research was carried out that did not show a significant impact of the use of multimedia systems on the effects of physical rehabilitation [168]. The main conclusion of the effectiveness of the use of multimedia systems in rehabilitation is that therapy should be tailored to the individual patient and there is no ideal solution for each clinical case.

8. Summary and Conclusions

The article presents state-of-the-art, medical device regulations and prospects for the development of a mechanical design, actuator technology, sensor systems, control systems, and computer methods in medical engineering. Moreover, current technical solutions, as well as forecasts on improvement, for exoskeletons are presented and reviewed. The review presented might be the cornerstone for future research on advanced rehabilitation engineering technology, such as an upper limb bionic orthosis. All significant elements described in the paper are summarised in Figure 7.

At the current level of mechanical technology development, upper limb bionic orthosis should be constructed in a manner that is as close as possible to the construction of the human limb. For this reason, direct matching of joint centres' mechanism should be used. Depending on the application (cheap and quick to construct or light and durable), the materials adapted to standard 3D printing and carbon fibre should be taken into account as the construction materials. Moreover, the brushless DC motors or artificial muscles for conventional and unconventional drives, respectively, are the best choices for selecting direct matching of joint centres.

Control systems should be based on EMG signals as biofeedback because it allows to create a simple and quick-to-learn bionic orthosis management system with machine learning. Most used machine learning algorithms are characterised by high efficiency in medical engineering and do not take much computational power. Requirements regarding sensors in bionic orthoses are not excessive, but they fulfill an extremely important role in control and ensuring patient safety.

The use of bionic orthoses in rehabilitation will significantly shorten the duration of therapy, contributing to better treatment of limbs. For this reason, the development of exoskeletons used for medical applications is essential. The design of this type of robotic orthoses should be efficient, easy to operate, and compact. There is a possibility of coupling the orthosis with a multimedia system, which will probably significantly improve the effectiveness of treatment. These features are necessary to popularise exoskeletons for rehabilitation applications in the future.

The most important elements for bionic orthoses are: control system, drives, and sensors. Depending on the application of the exoskeleton, other goals should be set: precision of movements, light and compact design, or high power consumption. In the case of bionic orthoses used for rehabilitation, the key features are the precision of the exercise and the ability to adjust the power to the level of fatigue/involvement of the patient. These features will shorten the period of medical care for rehabilitated people. Additionally, advanced control systems can oversee the course of rehabilitation exercises.

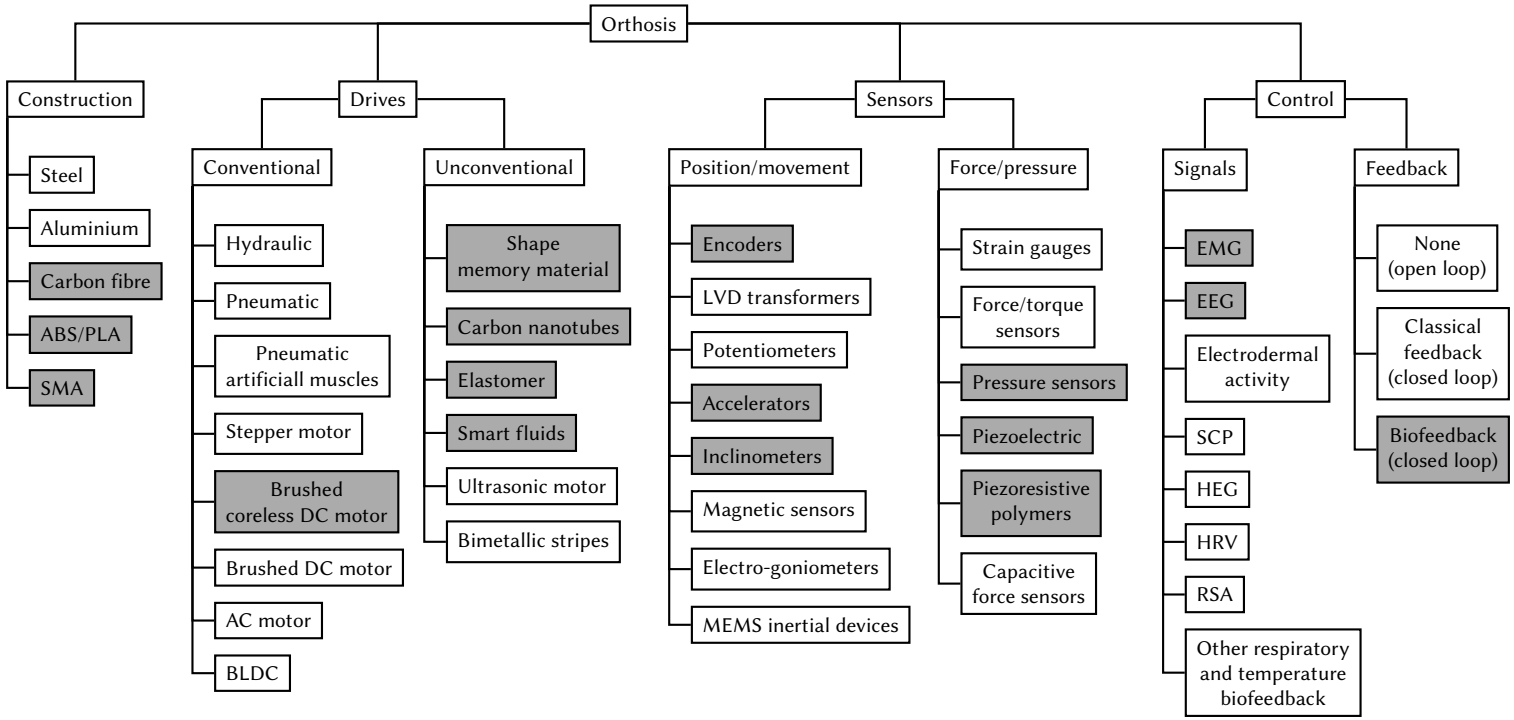

Figure 7. Summary of the main bionic orthosis elements described in the paper. Grey blocks indicate elements that are essential for future development of orthoses.

The biggest challenge in developing a fully usable rehabilitation orthosis is to hybridize all the systems described. That is an issue that requires further research. Without thorough research it is not possible to determine which solutions will be the most effective. An additional challenge is the individualisation of orthosis with the use of scanners and 3D printers. Taking into account the previously mentioned factors, an optimal solution is sought between a personalized and a universal device. According to the reaserch team, there is only one—the development of a universal drive, sensors and control system and the individual selection of mechanical parts. Thanks to this approach, high patient comfort will be possible and costs will be acceptable for rehabilitation clinics.

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