Application Issues for Robotics

Markus Wirz and Ruediger Rupp

Abstract

This chapter covers the various aspects related to the application of rehabilitation robots. The starting point for developing any novel therapeutic device should be the specific requirements of the users. Users in this case are patients with neurological conditions but also therapists. Both claim different requirements, which need to be united. Modern neurorehabilitation is grounded in the premise that activity is beneficial. Robots are valuable tools to apply intensive active training in terms of the number of repetitions and task specificity. The complexity of robotic devices is mainly determined by the residual functions of the patient. In patients with muscular weakness, a simple weight support system might be sufficient, whereas in patients with severe paralysis, actively driven exoskeletons with multiple degrees of freedom are necessary. Robots must comply with general regulatory and safety standards. Robotic devices have to be adjustable to a wide range of anthropometric properties and to the amount and the characteristics of their impairment. The user-friendliness of the robot's human-machine interface consisting of the mechanical, the control, and the feedback interfaces determines whether a device becomes integrated in the rehabilitation program or not. An inherent advantage of the more complex rehabilitation robots is their ability to use angular and force sensor signals for assessment and documentation. These are important to objectively control the course of the training, to legitimate and shape the training, and to document progresses or deteriorations. In the future, devices

R. Rupp SCI Center, Heidelberg University Hospital, Schlierbacher Landstrasse 200a, Heidelberg, 69118, Germany

M. Wirz (🖂)

Spinal Cord Injury Center, Balgrist University Hospital, Forchstrasse 340, Zurich, CH-8008, Switzerland e-mail: mwirz@paralab.balgrist.ch

which allow the continuation of a robotic therapy at home will further enlarge the range of applications.

Keywords

Patient and therapeutic requirements • Complexity vs. usability • Customization • Regulatory and safety issues • Human–machine interfaces • Robotic assessments • Home application

2.1 Introduction

This chapter focuses on aspects which need to be considered when technologies are applied to subjects. Technical devices are developed in order to support humans in many ways. Tower cranes are able to lift and manipulate heavy loads. Submarine robots work in an environment which is not compatible with human life. Smart controllers inflate airbags within split seconds in order to protect the driver of a car. There is also a long list of technical devices which have been applied in medicine, e.g., infusion pumps, blood pressure measuring devices, or electric stimulators for the treatment of pain. One kind of machines is driven by the force of the person using it, e.g., strengthening apparatus. These are considered as passive devices. Other systems include electric drives or other actuators, e.g., pneumatic devices, and can apply supporting, assisting, or resistance forces. Such actuated devices are referred to as active systems. Devices can act on their own by means of a controller which follows predefined algorithms, e.g., for the surveillance of vital functions such as heart rate monitors. Not only in daily life is the technology becomes smarter but also in the field of treatment and rehabilitation. After an accident or a disease, highly sophisticated devices are applied. These devices help the human physician to draw meaningful conclusions out of a number of figures or to eliminate muscle trembling during a subtle surgical intervention. The focus of this chapter is set on rehabilitation technologies including robotic devices which became established within the last decade for patients with neurological conditions, e.g., spinal cord injury or stroke. These robotic assistive devices enable to start a functional and

goal-oriented training earlier as compared to the conventional approaches. In addition, an intensive application of adequate afferent feedback and a high number of repetitions of functional movements support the rehabilitation of function such as walking or arm use. Robots not only perform movements repeatedly, but they allow the introduction of task variation and provide feedback in order to maintain an adequate level of challenge for the patient. The issues discussed may partially also be valid for other types of rehabilitation and assistive technologies.

The starting point for developing any new device should be the specific requirements of subjects. Subjects in this case are patients with neurological conditions, and it is intended that they will profit from a more effective way of training, meaning that they achieve their individual goals within a shorter period of time. Subjects are also therapists who, by using robotic devices, experience physical relief and can use assessment systems - which are less prone to subjective influence - for quantification of functional improvements. Patients and therapists claim different requirements which need to be united in a meaningful way. Those requirements should be in the focus as opposed to technical feasibility which does not always comply with a rehabilitative demand. This may be different if robots are in the developmental stage; however, the potential clinical application has to be borne in mind throughout the whole developmental process.

Besides the specifications which are framed by patients and therapists, there are several technological issues and principles regarding the clinical application of therapeutic robots. Both aspects will be covered in the next sections.

2.2 Human Issues

2.2.1 Patient

The clinical presentation of a spinal cord injury (SCI) or a stroke comprises motor weakness or complete paresis, complete or partial loss of sensory function, and a more or less pronounced derailment of the vegetative functions [1-3]. The latter include lack of bladder and bowel voiding function, lack of blood pressure adaptation as a response to upright position (orthostatic hypotension), etc. Patients in the early stage after such an event generally have a poor condition which needs to recover to a certain extent before intensive rehabilitation can be initiated. Beside the vegetative symptoms, patients have a reduced vital capacity which may become evident in upright standing and during exercise. Also in the acute phase after stroke, patients' stability in terms of circulation, mood, and motivation is impaired. Robotic devices should account for those instable situations in such a way that subjects can be evacuated from the device within a short period of time. Fittings must be designed that they can be removed quickly, and the whole device must be removable in order to get access to the patient or to transport an unconscious patient from the device without constraints. Patients with SCI have a marked propensity to faint once they are elevated in an upright position. The possibility to position patients horizontally when the blood pressure starts to drop is therefore crucial. After a traumatic SCI, the spine becomes instable in most cases. In addition, extremity fractures can occur. Rehabilitation therapists must make sure that the musculoskeletal system is stable enough to tolerate the applied load and forces, as with robotic devices which are used to train walking function. This holds also true in cases where fractures and instabilities have been treated surgically. The partial lack of sensibility has to be taken into account when a patient with a neurological condition is trained. After every training session, the spots where forces are exchanged between the robotic device and the patient have to be inspected visually. Any

sign of strain must be documented and carefully controlled. Robotic devices enable intensive and long training sessions with a large number of repetitions. Some patients may react to that amount of workload with signs of overload, e.g., joint swelling, increased spasticity, or pain. In older patients with a known history of osteoporosis, the training intensity has to be set carefully. The repeated stress on bony structures may result in a fatigue fracture.

Patients who experience an impairment of their cognitive function, e.g., distorted self-perception, might not be able to cooperate with a robotic device. Even though some devices use virtual environments which are very like the real world and the control of these environments is intuitive, patients still require the ability to abstract. In order to completely cope with robotic devices and to make use of the numerous ways of training modalities, patients need to have no more than mild cognitive deficits.

The population experiencing a SCI is becoming older [4]. Patients with stroke are typically of advanced age. These subjects are generally not used to working with new information technologies and may be reluctant to train in a robotic device. Without complete confidence in a training device, the success of the intervention is endangered. It is therefore important that patients are able to acknowledge robotic training as an important component on the way to their maximum possible independence. For future generations, who are much more used to computers and robots from their lives before the neurological incident, this item might be less an issue.

2.2.2 Therapist

Usually, the usage of robotic devices is not a subject in basic physiotherapy training. The reason for that is that the field of rehabilitation robotics is growing rapidly, and a large number of new devices are being developed every year. Different robots are available, and to date no standard devices are established. However, the proper use of robotic devices is critical for the success of the training. A sufficient period of time should be scheduled for the instruction of therapists. It is important that every therapist does as many oneto-one trainings under supervision of an expert user as needed until she or he is able to apply the device accurately and safely. It is recommended that in a given institution, special safety procedures become defined. It must be ensured that every person who trains with a robotic device has been instructed properly beforehand. The emergency procedures should be trained practically. Liability issues in case of an accident must be clarified. Some devices are easy to use, and a basic instruction is sufficient. However, other devices require extensive training and experience in order to respond to variations and irregularities. It must be evaluated if multiple or only few therapists are assigned to use a device. In the case of a large number of users, a single therapist will never become confident with the device. On the other hand, when only few staff members know how to run the device, experience can be accumulated in a shorter period of time. Additionally, knowledge exchange is easier among a smaller group of users. There are also mixed models where an experienced user does the setup for a given patient during an initial training session. The subsequent trainings will then be performed by a therapist with less specific knowledge, usually the therapist who trains the patient with nonrobotic interventions. If required, the more experienced colleague provides supervision in that phase. The advantage of such a model is that a therapist who knows a patient from the conventional therapy can also perform the robotic training as opposed to a therapist who is skilled using the robot but does not know the peculiarities of the patient.

2.2.3 Principles of Robotic Training

At the current stage, robots do not introduce completely new rehabilitation strategies [5]. Robotic devices rather enhance and amend existing approaches. Electromechanical devices can generate and apply greater forces for a longer period of time and follow more precisely predefined trajectories. In addition, robots can measure far more accurately and free from subjective perception than human therapists. However, robotic devices usually measure forces only in one plane or degree of freedom. A human therapist is able to perceive forces acting in multiple directions, in particular rotational forces. There are also approaches where a patient can train on a robotic device at home without direct supervision of a therapist. In that case, patient and therapist are connected through the internet, allowing the therapist to monitor the progress of the patient and adapt the training protocol [6].

The question pertaining to the principles behind robotic training is the question regarding the principles of neurological rehabilitation. In recent years, there have been many reports on the principles and strategies on which neurological rehabilitation is based [7-13]. Most reports which have been published regarding this topic relate to the stroke population since this is one of the most common conditions for acquired neurological disability. Nevertheless, from an empiric point of view, most of the described principles can be transferred to other groups of patients, e.g., SCI, multiple sclerosis, or Parkinson disease. One major and persistent principle of neurological rehabilitation is that of motor learning [11, 12, 14]. During rehabilitation, patients have to relearn motor tasks in order to overcome disability and limitations in the completion of daily activities. These processes are initiated by task-specific training which supports either true recovery of lesioned areas within damaged neural structures or compensation [11, 15]. Regardless the underlying mechanism, the principles of motor learning apply in both cases [12, 16]. These principles comprise among others: task specificity, goal orientation, meaningfulness, and most importantly, a high amount of practice. Rehabilitation robots allow task-specific training early after a neurological incident. For the training of gait function, robotic devices are applied which support the patient to perform leg movements during walking. At such an early stage, patients cannot stand up independently and are not or only partially able to perform leg movements on their own. Studies have shown that adequate proprioceptive afferent input is critical for training functional tasks, e.g., walking in patients with SCI [17-20]. The reciprocal unloading and loading of the legs as well as hip extension seem to be task-specific afferents for the appropriate facilitation of neural structures which are involved in the control of walking.

Also, devices for the training of upper limb functions are most valuable for the rehabilitation. These robots assist patients to follow task-specific trajectories. There are upper extremity robots which are designed for the use in a very early stage when the patient still lies in his bed for most of the time [21]. A number of devices work in conjunction with a display on which the patient completes meaningful tasks of daily living within a virtual environment [22]. An advantage of such a training using virtual environment is that patients do not focus on the learning of specific movements itself but on the effects of these movements. This so-called external focus is beneficial for the learning of task automatism [23, 24]. Other approaches aim at minimizing the lack of coordination between shoulder and elbow joint during reaching movements [25].

Without the support of electromechanical devices, patients would not be able to start these exercises at an early stage or may get exhausted after a short while and few repetitions. Compared to the human therapist, who might get tired while providing extensive amount of support to patients who are dependent on help for completing taskoriented exercises, robotic devices allow longer training durations and a higher number of repetitions. Studies have shown that augmented exercise results in an improved outcome [26]. However, it seems not sufficient just to repeat a specific movement or completion of a task. Task variability improves the acquisition of that task [14]. Robotic devices which have been developed so far offer numerous ways to adapt and vary training. The introduction of virtual environments wherein the patients take over control enables multiple ways of tasks and task variation within the same robotic setup. Further possibilities to adapt tasks are the number of degrees of freedom which are under control of the patient. The amount of support to control a given degree of freedom, e.g., hip flexion or extension, could be adapted according to the patient's abilities. Robots may not only provide assisting forces but in later stages also resisting forces. Increased resistance perpendicular to a defined trajectory helps to guide a patient through a desired movement path. The changes of movement velocity entail a different level of challenge. Walking within a robotic device allows dynamic walking at a nearly normal walking speed as opposed to walking within parallel bars or other walking aids where speed is markedly slowed down. Walking speed during training is considered important to warrant further improvements [27].

In order to control movements and for safety reasons, robots are equipped with sensors. These sensors measure positions, velocities, and accelerations on one hand and torques and forces on the other. These signals can be used for a specific feedback for both patients and therapists. Feedback can be provided using various cues such as auditory, visual, or haptic. Based on the forces patients exert on the machine selected actions occur in the virtual environment, e.g., an avatar walks left or right or a virtual hand grasps an object. In such a way, robotic devices act as an interface between the real and a virtual world. The raw signals, however, serve the therapist to survey the level of activity of the patient and to document the progression within a training series. However, to date, only little is known how these figures translate to unsupported activities without a robot.

After all, it is the skill of the human therapist to integrate various signals and expressions and hence to perceive the actual state of the patient. Based on those findings, therapists will shape exercises and set up conditions in a way that patients are challenged and motivated without being overstrained. For therapists and patients, robotic devices offer a useful tool to implement the principles of neurological rehabilitation from the very beginning of rehabilitation and to measure and control the progress.

2.3 Technical Issues

2.3.1 Complexity of Robotic Devices

The main goal of a task-oriented neurorehabilitative training is to enhance neuroplasticity by enabling patients with neurological impairments to perform movements of activities of daily living. A key factor for the success of the training is the number of repetitions and the generation of physiological afferent stimuli [28]. For achieving a meaningful improvement of motor functions by mass practice therapy regimes, supportive devices are beneficial and valuable tools. The complexity of these devices is mainly determined by the residual functions of the patient group in the focus. In patients with minor to moderate impairments, passive devices may be sufficient to enable the execution of relevant tasks. This is especially true for the upper extremity, where passive devices like the Swedish Help Arm (also known as Helparm, Swedish Sling, Deltoid Aide, or OB Helparm), the Freebal device, or the recently commercialized ARMON orthosis (Microgravity Products BV, Rotterdam, Netherlands) are used to reduce or eliminate the effects of gravity and thereby allowing the user to effectively use his weak muscles for performing functional tasks like eating, drinking, or grooming. These devices may also help the patient retain or reestablish important proprioceptive information about the achievable workspace that the impaired limb should be able to reach as recovery progresses. Since the purely passive devices are relatively simple in their construction, they are affordable also for the patients themselves and are easy to use. The main disadvantage of these simple passive devices, which are mainly based on springs or counterweights, is that they basically provide a constant amount of weight reduction regardless of the position of the extremity. Even in positions of the arm, where less or no support is necessary, the patient is supported. Additionally, the desired movement trajectory cannot be predefined, and therefore the user may train a wrong, unphysiological movement pattern. In the worst case, the patient cannot complete a desired movement at all. To overcome this limitation, passive devices are often used during occupational therapy sessions under supervision of a therapist, who actively supports the movements to ensure that a physiological movement trajectory is achieved.

To free the therapist from this physically exhausting and mechanistic work of manually guiding the movements and to perform a therapy in a more standardized way, active robotic devices with integrated actuators have been introduced. The active components of the robots consist nowadays mainly of electric motors or pneumatically driven actuators in combination with spindles, gears or bowden cables. Within the class of active devices, there are technically more simple devices, which are mainly based on an end-effector approach, and complex devices, in which several degrees of freedom (DOF) of several joints are actively driven independently.

The end-effector-based systems use dedicated hand grips or footplates and guide the movements of the hand or foot in space [29–31] (Fig. 2.1). Their main advantage is their easy setup since no technical joints of the device have to be aligned with the anatomical joints of the human body. Furthermore, they only use one or two drives per extremity to generate a two-dimensional planar motion. However, the movements originate from the most distal segment of the extremity, and therefore - though the kinematic movement pattern looks similar to the physiological situation - the kinetics of the generated movements may not be perfectly physiological [32]. However, this seems to be crucial for the success of the therapy [20]. Additionally, in end-effector-based robots, only information about forces and/or position of the most distal part of the extremity is available, which may be too unspecific for control of a physiological kinetic and kinematic movement trajectory. Examples of machines based on the end-effector approach for the upper extremity are the MIT Manus [33] approach and for the lower extremity the gait trainer [34] (Fig. 2.1).

A physiological movement of all joints of an extremity can only be achieved by the use of active drives, which support the movements of every DOF of a dedicated joint. Additionally, an individualized setup of a joint and movement phase–related resistance is only possible with actively driven exoskeletons. Locomotion robots are often constructed as actuated exoskeletons which operate in conjunction with a system for partial body weight unloading and a moving treadmill [35–38]. Since active components form the most expensive parts of a robotic device, usually a compromise between costs and functionality in terms of

Fig. 2.1 The gait trainer GT I assists the patient during gait training using an end-effectorbased approach combined with a system for partial unloading of the body weight (Photo courtesy Reha-Stim, Berlin, Germany. Used with permission)



perfectly following a given trajectory has to be made. Therefore, robotic locomotion training machines are mainly generating movements in the sagittal plane, whereas movements in the frontal or transversal plane are restricted to passive movements. A general challenge of the application of exoskeletons is their proper adjustment and alignment to the anatomical constraints of the different types of joints. Due to their mechanical complexity, the exoskeletons are often time-consuming in their initial setup and in everyday applications. Examples for actively driven exoskeletons are the Lokomat and Lopes devices for the lower extremity [18, 19] and the ARMIN and RUPERT devices for the upper extremity [39, 40].

Though actively driven, exoskeletons represent the state of the art of robotics technology they still leave room for improvement. Most of the systems are operating in an open-loop position control mode, which means that the actively driven joints follow predefined reference trajectories. Hence, the patient's movements are supported even during phases where the voluntary force of the patient would be sufficient. In these cases, the robotic device does not help, but hinders a patient to perform a movement task. Therefore a closed-loop "assist-as-needed" control scheme should be implemented into the active devices to challenge the patient as much as possible and to provide support, when and where it is needed [41]. Special focus should be put on the fact that a physiological movement does not consist of a highly reproductive movement pattern, but contains some variability [42]. Therefore, robotic devices should also incorporate a control scheme that does allow for small deviations from

the reference trajectory, e.g., like the nonlinear control scheme of the "force fields" implemented in the T-/Pneu-WREX device [43] or an impedance control scheme of the Lokomat [44]. In this way, a true cooperative robot-assisted therapy will become reality.

Nevertheless, all motor-driven orthotic devices only generate muscle movements in a passive way. However, from the results of pilot studies, it may be concluded that an additional activation of muscles by externally applied electrical currents leads to a better outcome [45, 46]. Therefore, the combination of functional electrical stimulation and an actively driven exoskeleton may enhance neurorehabilitation in the future. From a technical viewpoint, this combinatorial approach causes additional problems since two force generating systems – the muscles and the external drives – contribute to the same movement, and appropriate, robust control schemes have to be developed and tested.

However, such hybrid systems offer the possibility that not only a training of restricted or lost motor function can be performed but that the same system can also be used for substitution of permanently lost motor functions [47]. To achieve this functionality novel, lightweight drives and multichannel, dry electrode concepts have to be introduced.

2.3.2 Regulatory and Safety Issues

Robotic training devices and all of their subsystems including software are medical products and therefore have to comply with the International Standard IEC 60601–1, which has become the global benchmark for medical electrical equipment. Compliance with the IEC 60601–1 International Standard and/or the relevant national versions does not equal medical device approval. However, it is a recognized step towards medical device approval in nearly all markets across the world. As a result, many companies view compliance with IEC 60601–1 as a de facto requirement in most markets for product registration, "CE" "UL" "CSA" marking, contract tenders, and defense against claims in the event of problems, etc. The biggest upgrade in the third edition of the standard published in 2005 [48] is that it requires a manufacturer to have a formal risk management process in place which complies with ISO 14971. The following, not exhaustive list summarizes the most important standards that apply in particular to therapeutic robotic systems:

- IEC 60601–1–1: Medical electrical equipment

 general requirements for basic safety and
 essential performance
- IEC 60601–1–2: Medical electrical equipment – electromagnetic compatibility
- IEC 60601–1–4: Medical electrical equipment – programmable electrical medical systems
- IEC 60601–1–6: Medical electrical equipment – usability
- ISO 13485: Medical devices quality management system
- ISO 14971: Medical devices application of risk management to medical devices

In parts, also the "ISO 9241: Ergonomics of human-system interaction," which contains substandards for user-centered design, applies to the design of robotic devices. It has to be emphasized that devices used in clinical applications do not necessarily need to be certified. However, if these noncertified machines are intended to be used in human applications, then in additional to the application to an ethical committee, a special insurance has to be procured, which covers the risks of adverse events caused by the application. By all means, a risk analysis according to ISO 14971 is mandatory to obtain ethical approval. In addition to the safety, manufacturers have to prove in clinical testing that the device is efficient in order to introduce the device in the European and American market. Since therapeutic robots are highly innovative products, in most cases, no data can be taken from literature which prove their efficiency. Therefore, clinical trials, preferably with a controlled and randomized study design, have to be performed. This fact has to be considered especially by small- or medium-sized companies, because a proper efficacy study may cause additional costs in the range of the device development before the introduction of the novel device to the market.

Within the framework of the IEC 60601, no dedicated substandard for robotic training devices has yet been introduced. Thus, the potential risks of harming the patient by the robotic training or the device itself have carefully to be considered. In general, active orthotic devices inherently bury the risk of causing severe injuries to the musculoskeletal system, e.g., bone fractures, capsule injuries, ruptures of muscle fibers, etc. This risk has to be minimized by a joint-related limitation of the maximum torque, which may be generated by the drives. Since a model-based estimation of the drives' torques is often not precise, enough redundant force or torque sensors have to be foreseen to ensure that the applied forces in every DOF stay in a safe range. In case the reference trajectory cannot be followed with maximum torque, the robot may either switch off, halt the movement, or limit the applied torque to a safe amount. In case of end-effector-based robotic systems, only the net force of several joints can be measured, which may lead to false-switch-off episodes of the machine or in the worst case to an exceeding of safe torque limits.

The most apparent adverse events of robotic devices in particular of active exoskeletons for locomotion training are skin erythema [49]. Though skin erythema is not a life-threatening condition, it may severely affect the compliance of the patient since the training may be interrupted a few days to allow for healing. Therefore, the main focus of the mechanical design of robotic devices has to be put on the parts that are in direct contact with the patient. It is highly recommendable to avoid the occurrence of shear forces in the orthotic components with direct skin contact by design, in order to minimize the risk for skin erythema in case of misalignment of the human and the machines joint centers.

Depending on the onset of training after a CNS lesion and the cardiovascular status of the patient, episodes of presyncopes or syncopes may occur during verticalization for locomotor training. For adequate handling of a patient in this case of a medical emergency, safety mechanisms for quick evacuation of an uncooperative patient are necessary. Despite the automatic deactivation of the device in case of excessive torques, several emergency stops or enabling mechanisms have to be foreseen [50]. This will allow to check for attendance of the therapist or to give the patient the opportunity to stop the training at will. The latter is especially important if the patient performs the training on his own without supervision of a therapist.

Finally, the best safety concept of a machine is useless if it does not work properly due to defective mechanical or electrical components. Thus, highly qualified technical support has to be available to perform regular checkups and maintenance of the device.

2.3.3 Customization

Human beings vary to a great degree in their anthropometric data like size and weight and body proportions like length or widths of extremities. In order to perform the training in 95% of the population with one device, the machine has to be adjustable to a large degree and in many ways. This means that, e.g., in a locomotion exoskeleton, the length of the shank and thigh, the width of the pelvis, and the position of the trunk in all three directions must be adaptable to the individual patient. Also the continuous increase of the body mass index of the population of industrial countries represents a challenge for the level of adaptability of orthotic and robotic devices.

In addition to the differences in the properties of the body segments, the amount of impairment of neurological patients varies to a high degree. This applies not only to individuals within the same patient group but also between different patient groups. For example in incomplete SCI persons, the individual motor deficits may vary between subjects to a high degree, ranging from an isolated drop foot on one side to an almost complete loss of motor function in both legs. In stroke survivors, an increased spastic muscle tone may restrict the successful application of a robotic training. In traumatic brain injury, cognitive restrictions may occur additionally to the physical impairments, which reduce the cooperativeness of the patient to a minimum. All these patient-related factors require an individualized setup of either the mechanical components of the machine or the training paradigms including feedback modalities. Since a regular therapy session is for personnel resources reasons limited to 45–60 min, every effort has to be made to keep the changeover time at a minimum. In reality, it takes one therapist about 5 min to prepare an endeffector-based robotic system to a patient and about 10–15 min in case of an exoskeleton. Much more time has to be reserved when the system is initially being set up.

Ideally, a machine would automatically adapt to different patients or not need any type of adjustment, since technical solutions have been provided which do not need manual interventions. Surprisingly, up to now, not a lot of effort has been made into this direction.

Also, the machine has to provide the possibility for setup of a large variety of training paradigms in order to broaden its fields of application. Most importantly, the function that is trained has to be the same as the one which should be improved. Recent developments in robotics for the lower extremities take this prerequisite into account and offer the possibility for training of stair climbing [22].

Nevertheless, it has to be kept in mind that practically none of the robotic devices are able to generate a fully physiological movement since not every DOF is equipped with an actuator and therefore cannot be controlled independently.

2.4 Human–Machine Interface

The user interface is a crucial part of a robotic therapy system since it determines to a large degree whether a device is regularly integrated in the rehabilitation program of neurological patients or not. Since the robotic systems are designed by research and development engineers, the user interfaces they design tend to be complicated and are not intuitive to understand. This is a general problem of the human–machine interface in almost every technical product intended to be operated by users with different technical expertise and nontechnical professional background. Therefore, the ISO 9241–210 standard, which refers to "Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems" may be a good starting point to continuously improve the human-machine interface of a technical system. The ISO 9241–210 standard defines the framework of an iterative approach to involve end users during all stages of development of a product and explicitly includes parts which are important for any type of assistive technology.

It has to be emphasized that in rehabilitation robotics the term "end user" includes therapists as well as patients. Therefore, their feedback should be addressed very carefully by developers and implemented into novel designs for increasing the acceptance.

2.4.1 Mechanical Interfaces

Special attention must be paid to the mechanical interfaces between robot and patient. At the points where the robot is attached to the patient, high forces are transmitted depending on the mode of operation, i.e., either a robot assists the performance of movements or applies resistance forces. Force vectors have to be in accordance to the joint axes to allow pure rotational moments. The fixations of the robot have to be soft and mold to fit the respective part of the body in order to prevent the occurrence of pressure lesions or abrasions of the skin. In contrast to that requirement, the interfaces must transmit the forces without loss, e.g., by deformation or loose fit. This will ensure appropriate monitoring and modeling of the forces which exert on the patient. This is especially important pertaining to the assessment features of robotic devices. Fixations have to be adaptable to a wide range of anthropometrics. The usage has to be unambiguous and easy. This is of importance in the case when a patient has to be removed from the device quickly.

2.4.2 Control and Feedback Interfaces

An important component of the robotic system is the control interface, which is used by the therapist to set and adapt the most important therapy parameters like speed, amount of support or range of motion, and the feedback interface, which is used to provide the patient with information about the current status and the progress of the training. The control interface has to provide a very intuitive graphical user interface, which can be handled by an operator during the therapy. Special focus has to be put on the limitation of the number and the selection of an appropriate size of the control elements on the screen or on the operator panel to avoid faulty parameter settings. A general requirement of the robotic device often demanded by therapists is a high degree of "transparency," i.e., all of the machine parameters and options are accessible. However, a balance has to be found between maximal adjustability and easy handling. A possible way to meet both claims could be the common implementation of a standard and an expert mode together with the possibility for individualization of the graphical user interface.

Additionally to the graphical user interface, the input device is of crucial importance, since keyboards and mice are not easy to handle while having the patient in the focus, which often results in mismatch of parameter settings. Therefore, touch panel-based interface systems are a proper choice, in particular if the system is operated by a patient without supervision.

Since most of the robotic machines are equipped with sensors, which provide feedback about the current state and performance of the patient, the implementation of an automated adaptation scheme would free the therapist from continuously adjusting the relevant parameters of the therapy. In some cases, such an adaptation scheme may allow a robotic therapy without the need for continuous supervision by a therapist. However, in this condition, an adequate feedback has to be provided to the therapist and the patient so that both are informed what the machine is doing and to give them the confidence that both have the machine under control and not vice versa.

At the current stage of knowledge, the benefit of any neurorehabilitative approach seems to be based on the enhancement of spinal as well as supraspinal neuroplasticity. In order to enhance the supraspinal neuroplasticity, the patient has to be provided with an adequate feedback of his current performance, in particular in patients with sensory deficits. This is also most important for increasing motivation. Comparable to the situation in the control interface, the number of dynamic feedback parameters presented to a patient at a time has to be carefully chosen, since a patient is only capable to influence one or two parameters simultaneously. The feedback parameters have to be individualized, chosen according to the main functional deficit and the most severe impairment respectively. In case of the lower extremities, this might be a joint angle of a dedicated gait phase like swing or stance phase. The feedback should be provided in an absolute scale so that patients are able to compare their current status to their status at the end of the last therapy session. Also, feedback modalities other than visual may provide a more effective way to enhance the perception of the patient [51].

2.4.3 Assessment and Documentation

Rehabilitation robots are not only equipped with motors but also with multiple sensors. The signals deriving from these sensors are used to control the operation of the robots but can also serve as feedback and to measure certain biomechanical properties. Angular sensors can measure range of movement, force, or torque transducers' voluntary strength of muscle groups (Fig. 2.2).

Combined signals can assess resistance against passive movements and where in the movement arc resistance occurs. Changes in resistance can be attributed to impaired muscular tone or spasticity. Assessments are important to control the course of the training, to legitimate training and to document progresses or deteriorations. Measurement results can be used to monitor the

widely used tests such as the manual Ashworth scale (MAS) are under debate and may be improved if tested using a robot [56].

Although only few studies addressed the issue of the quality of assessment recorded by rehabilitation training robots, it can be stated that these devices measure practically and reliably. Appropriate measurements whose results can be transferred into daily functions need to be defined.

2.4.4 Continuation of a Robotic Therapy at Home

Due to increasing economical restrictions in the health care system, the length of primary rehabilitation is getting shorter, i.e., in the US Model Spinal Cord Injury System, the mean initial rehabilitation period of incomplete patients was 89 days in 1975, which continuously decreased to 28 days in 2005 [57]. It can be expected that this trend will continue in the future and lead to even shorter rehabilitation periods.

With the help of robotic locomotion, the sufficient intensity of task-oriented gait training can be sustained in the clinical setting, whereas a dramatic reduction of the quantity and quality of the training occurs after the discharge from the rehabilitation unit. This is especially true if patients return to their home in rural areas.

Though systematic experimental investigations are missing, it may be concluded from review of the literature that long-term, mid-intensity locomotion training over several months is more effective than the application of training protocols with high intensity for only a few weeks [58, 59]. However, up to now, only a few robotic training devices exist for home-based locomotion training. A simple transfer of the existing robotic devices to the patients' homes is not possible since most of them are mainly restricted to the application in a clinical setting due to their size, weight, and price. Furthermore, most of the devices have to be operated by skilled therapist.

The main challenges of therapy devices for application in the home environment are safety issues and the self-operation of the device by the users. This is especially true for the use of



Fig. 2.2 Example of a series of force measurements recorded with the Lokomat system. The columns represent the maximum force in direction of unilateral hip flexion during successive sessions from a patient recovering from a Guillain–Barré syndrome (The respective value of healthy volunteers amounts to 74 Nm)

actual state of the patient and to shape the training accordingly. Some improvements may not be perceived by the patient but are accessible for the sensors. Prove of gains are important factors to generate motivation [52]. However, for any assessment, there are basic requirements which have to be met in order to be useful. Assessments have to be practical, reliable, valid, and responsive to changes. The measurement within a robotic device is easy to perform since it can be performed along with training or as a part of the training. Nevertheless, the assessment within a robotic device is restricted to that particular situation; for example, a robot is able to measure the range of motion in the sagittal plane, but its mechanical construction does not allow measuring in the other planes. Appropriate software can record and compare the results to previous measurements or normative values. On the first sight, it seems obvious that a mechanical sensor has a higher accuracy than a human examiner. A reduction of error leads to increased reliability. Still, there are more sources for error, e.g., the instruction of the therapist or pain may influence measurements. Few studies pertaining to this issue affirmed feasibility and reliability [53–55]. The concept of validity states that a given testing procedure aims at measuring a specified property. Regarding range of movement and voluntary muscle strength, there are no controversies as opposed to the measurement of spasticity. Even

10

8



Fig. 2.3 The MoreGait is a pneumatically actuated robot for the training of ambulatory function. The device allows the use at the patient's home

locomotion training devices. Whereas in the clinical environment, the therapy is supervised by trained therapists, in the home environment, a safe operation without the need for supervision has to be guaranteed.

Only a few studies exist which describe the development and application of dedicated homebased robotic training systems [6, 60]. In locomotion robotics, a key method to minimize the risk of injuries is to put the user in a safe training position, like a semirecumbent position of the body in the MoreGait device (Fig. 2.3).

From the available results of real home-based training, it may be concluded that a safe application without a high risk for serious adverse events is feasible and that the outcomes of the training are in the same range than of systems used in clinics.

Nevertheless, a certain amount of supervision is necessary to assess the current status of the patient, to individually adjust therapy parameters to the patient's progress, and to help patients in solving small hardware problems. Here, internetbased telemonitoring methods are a cheap and effective tool for transfer of sensor data and diagnostic trouble codes of the machine to a centralized location, e.g., a large rehabilitation center or an outpatient clinic. Personal video conferences between a therapist and users or among different users are very valuable to keep patients motivated and to share experiences.

A very promising way of performing a homebased therapy, especially in patients with minor motor and cognitive deficits, is the use of conventional gaming consoles like Nintendo's Wii or Microsoft's Xbox in particular with the kinect option. The latter allows for full body movement analysis, and therefore a joint-specific therapy without the need for dedicated markers or sensors fixed to the body. The main advantage of using such type of technology is the nonlimited availability and the low price.

The gaming console–based training relies mainly on the feedback principles of the external focus, which is beneficial for the learning of task automatism. This form of training is motivating and provides the possibility for giving feedback about the current state of the functional impairment and the improvement over time to the user. However, up to now, only a few studies exist which evaluate the effect of a console-based training [61]. Furthermore, it has to be investigated in the future if the already implemented option for an internet-based multiplayer mode may be used for supervision of home-based training by a qualified therapist.

2.4.5 Financial Aspects

In the long run, every novel therapeutic or diagnostic procedure will only become a standard if a financial benefit for the health care or the welfare system can be achieved. This does not necessarily mean that the novel method has to be inexpensive; the maybe most prominent counterexample is MRI, which is a cost-intensive diagnostic method but which saves a lot of money by providing the basis for a major improvement in clinical decision-making.

The costs for the application of a robotic training device are composed of the device's costs, costs for personnel and their training, cost for infrastructural alterations, and cost for technical support. The costs of the device are mainly based on its complexity: the more complex, the more expensive. The price of a system is, to a large degree, dependent on the number of actuators it contains, since not only actuators but also sensors for safety issues have to be foreseen. Most of the people outside the neurorobotics field believe that - like in industrial robots - fewer personnel are necessary to perform a given therapy regime. This may be true for the lower extremities, where up to three therapists are needed to perform conventional body-weight-supported treadmill training. However, this does not apply to upper extremity training settings, where only one therapist is needed to perform manual training. By any means, one therapist is necessary to supervise the robotic training therapy.

The justification for implementing robotic training machines into clinical routine is mainly based on the fact that, in the given time frame for primary rehabilitation, the patient achieves a higher level of independence by the use of robotic therapies [62], which, in turn, may save costs for care and prevent secondary complications.

Nevertheless, in most countries, the robotic training sessions are not regularly compensated by insurance companies or sickness funds. Here, additional efforts are needed in the future from industry as well as from health care providers to give every patient with a motor disorder the chance to profit from such training.

2.5 Conclusion

For the successful development, application, and integration of robotic systems, engineers, clinicians, and end users have to work closely together. The devices' specifications should be founded on rehabilitative goals and neurophysiological knowledge. The characteristics of robotic devices should comply with the demands of patients and therapists. In order to justify the costs of rehabilitation robots, they should allow for adaptation to a wide range of patients with respect to anthropometrics but also with respect to different grades of capabilities reflecting the actual state of rehabilitation. In the beginning, supporting forces are required; in later stages, a device may apply resisting forces in order to challenge patients appropriately at every level. The setup and operation of robots should fit in a clinical setting. Signals from sensors enable sophisticated feedback modalities and the surveillance of training progression.

Robotic devices are very useful enhancements of rehabilitation interventions, offering additional training as well as measurement options. Studies suggest that an advantage of therapy by robotic devices, compared with conventional therapies, may be an increase in repetitions during training. Robot-assistive training devices therefore allow a massed practice therapy paradigm, which is intensive, frequent, and repetitive and accords with the principles of motor learning. They offer, for the first time, the possibility to systematically investigate dose-outcome relationships since the variability and the physical constraints of therapists and their limitations in terms of guiding movements of several joints simultaneously can be overcome.

References

 American Spinal Injury Association and International Medical Society of Paraplegia. Reference manual of the international standards for neurological classification of spinal cord injury. Chicago: American Spinal Injury Association; 2003.

- Kelly-Hayes M, Robertson JT, Broderick JP, et al. The American Heart Association Stroke Outcome Classification. Stroke. 1998;29(6):1274–80.
- Alexander MS, Biering-Sorensen F, Bodner D, et al. International standards to document remaining autonomic function after spinal cord injury. Spinal Cord. 2009;47(1):36–43.
- Jackson AB, Dijkers M, Devivo MJ, Poczatek RB. A demographic profile of new traumatic spinal cord injuries: change and stability over 30 years. Arch Phys Med Rehabil. 2004;85(11):1740–8.
- Reinkensmeyer DJ, Maier MA, Guigon E, et al. Do robotic and non-robotic arm movement training drive motor recovery after stroke by a common neural mechanism? Experimental evidence and a computational model. Conf Proc IEEE Eng Med Biol Soc. 2009;2009:2439–41.
- Sanchez RJ, Liu J, Rao S, et al. Automating arm movement training following severe stroke: functional exercises with quantitative feedback in a gravityreduced environment. IEEE Trans Neural Syst Rehabil Eng. 2006;14(3):378–89.
- Floel A, Cohen LG. Translational studies in neurorehabilitation: from bench to bedside. Cogn Behav Neurol. 2006;19(1):1–10.
- Hubbard IJ, Parsons MW, Neilson C, Carey LM. Task-specific training: evidence for and translation to clinical practice. Occup Ther Int. 2009;16(3–4): 175–89.
- Graham JV, Eustace C, Brock K, Swain E, Irwin-Carruthers S. The Bobath concept in contemporary clinical practice. Top Stroke Rehabil. 2009;16(1): 57–68.
- Kalra L. Stroke rehabilitation 2009: old chestnuts and new insights. Stroke. 2010;41(2):e88–90.
- Dobkin BH. Strategies for stroke rehabilitation. Lancet Neurol. 2004;3(9):528–36.
- Krakauer JW. Motor learning: its relevance to stroke recovery and neurorehabilitation. Curr Opin Neurol. 2006;19(1):84–90.
- Oujamaa L, Relave I, Froger J, Mottet D, Pelissier JY. Rehabilitation of arm function after stroke. Literature review. Ann Phys Rehabil Med. 2009;52(3):269–93.
- Hanlon RE. Motor learning following unilateral stroke. Arch Phys Med Rehabil. 1996;77(8):811–5.
- Levin MF, Kleim JA, Wolf SL. What do motor "recovery" and "compensation" mean in patients following stroke? Neurorehabil Neural Repair. 2009;23(4):313–9.
- Curt A, Van Hedel HJ, Klaus D, Dietz V. Recovery from a spinal cord injury: significance of compensation, neural plasticity, and repair. J Neurotrauma. 2008;25(6):677–85.
- Dietz V, Duysens J. Significance of load receptor input during locomotion: a review. Gait Posture. 2000;11(2):102–10.
- Harkema SJ, Hurley SL, Patel UK, Requejo PS, Dobkin BH, Edgerton VR. Human lumbosacral spinal cord interprets loading during stepping. J Neurophysiol. 1997;77(2):797–811.

- Lunenburger L, Bolliger M, Czell D, Muller R, Dietz V. Modulation of locomotor activity in complete spinal cord injury. Exp Brain Res. 2006;174(4):638–46.
- Dietz V, Muller R, Colombo G. Locomotor activity in spinal man: significance of afferent input from joint and load receptors. Brain. 2002;125(Pt 12):2626–34.
- Rosati G, Gallina P, Masiero S. Design, implementation and clinical tests of a wire-based robot for neurorehabilitation. IEEE Trans Neural Syst Rehabil Eng. 2007;15(4):560–9.
- Ferraro M, Palazzolo JJ, Krol J, Krebs HI, Hogan N, Volpe BT. Robot-aided sensorimotor arm training improves outcome in patients with chronic stroke. Neurology. 2003;61(11):1604–7.
- van Vliet PM, Wulf G. Extrinsic feedback for motor learning after stroke: what is the evidence? Disabil Rehabil. 2006;28(13–14):831–40.
- Wulf G, Shea C, Lewthwaite R. Motor skill learning and performance: a review of influential factors. Med Educ. 2010;44(1):75–84.
- Sukal TM, Ellis MD, Dewald JP. Source of work area reduction following hemiparetic stroke and preliminary intervention using the ACT3D system. Conf Proc IEEE Eng Med Biol Soc. 2006;1:177–80.
- Kwakkel G, Wagenaar RC, Twisk JW, Lankhorst GJ, Koetsier JC. Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial. Lancet. 1999;354(9174):191–6.
- Sullivan KJ, Knowlton BJ, Dobkin BH. Step training with body weight support: effect of treadmill speed and practice paradigms on poststroke locomotor recovery. Arch Phys Med Rehabil. 2002;83(5):683–91.
- Prange GB, Jannink MJ, Groothuis-Oudshoorn CG, Hermens HJ, Ijzerman MJ. Systematic review of the effect of robot-aided therapy on recovery of the hemiparetic arm after stroke. J Rehabil Res Dev. 2006;43(2): 171–84.
- Hesse S, Uhlenbrock D. A mechanized gait trainer for restoration of gait. J Rehabil Res Dev Clin Suppl. 2000;37(6):701–8.
- Hesse S, Waldner A, Tomelleri C. Innovative gait robot for the repetitive practice of floor walking and stair climbing up and down in stroke patients. J Neuroeng Rehabil. 2010;7:30.
- 31. Freivogel S, Mehrholz J, Husak-Sotomayor T, Schmalohr D. Gait training with the newly developed 'LokoHelp'-system is feasible for non-ambulatory patients after stroke, spinal cord and brain injury. A feasibility study. Brain Inj. 2008;22(7–8):625–32.
- 32. Hesse S, Sarkodie-Gyan T, Uhlenbrock D. Development of an advanced mechanised gait trainer, controlling movement of the centre of mass, for restoring gait in non-ambulant subjects. Biomed Tech (Berl). 1999;44(7–8):194–201.
- Hogan N, Krebs H, Sharon A, Charnnarong J.: Interactive robotic therapist. US Patent No. 5466213, 14.11.1995.
- Hesse S, Werner C, Uhlenbrock D, von Frankenberg S, Bardeleben A, Brandl-Hesse B. An electromechanical

gait trainer for restoration of gait in hemiparetic stroke patients: preliminary results. Neurorehabil Neural Repair. 2001;15(1):39–50.

- Banala SK, Kim SH, Agrawal SK, Scholz JP. Robot assisted gait training with active leg exoskeleton (ALEX). IEEE Trans Neural Syst Rehabil Eng. 2009;17(1):2–8.
- Colombo G, Joerg M, Schreier R, Dietz V. Treadmill training of paraplegic patients using a robotic orthosis. J Rehabil Res Dev. 2000;37(6):693–700.
- 37. Veneman JF, Kruidhof R, Hekman EE, Ekkelenkamp R, Van Asseldonk EH, van der Kooij H. Design and evaluation of the LOPES exoskeleton robot for interactive gait rehabilitation. IEEE Trans Neural Syst Rehabil Eng. 2007;15(3):379–86.
- 38. Mantone J. Getting a leg up? Rehab patients get an assist from devices such as HealthSouth's Auto Ambulator, but the robots' clinical benefits are still in doubt. Mod Healthc. 2006;36(7):58–60.
- Nef T, Mihelj M, Riener R. ARM in: a robot for patient-cooperative arm therapy. Med Biol Eng Comput. 2007;45(9):887–900.
- Sugar TG, He J, Koeneman EJ, et al. Design and control of RUPERT: a device for robotic upper extremity repetitive therapy. IEEE Trans Neural Syst Rehabil Eng. 2007;15(3):336–46.
- Edgerton VR, Courtine G, Gerasimenko YP, et al. Training locomotor networks. Brain Res Rev. 2008;57(1):241–54.
- Kruger M, Eggert T, Straube A. Joint angle variability in the time course of reaching movements. Clin Neurophysiol. 2010;122(4):759–66.
- Wolbrecht ET, Chan V, Reinkensmeyer DJ, Bobrow JE. Optimizing compliant, model-based robotic assistance to promote neurorehabilitation. IEEE Trans Neural Syst Rehabil Eng. 2008;16(3):286–97.
- 44. Duschau-Wicke A, Caprez A, Riener R. Patientcooperative control increases active participation of individuals with SCI during robot-aided gait training. J Neuroeng Rehabil. 2010;7:43.
- Hesse S, Werner C, Bardeleben A. Electromechanical gait training with functional electrical stimulation: case studies in spinal cord injury. Spinal Cord. 2004;42(6):346–52.
- 46. Daly JJ, Ruff RL. Construction of efficacious gait and upper limb functional interventions based on brain plasticity evidence and model-based measures for stroke patients. ScientificWorldJournal. 2007;7:2031–45.
- 47. Schill O, Wiegand R, Schmitz B, Matthies R, Eck U, Pylatiuk C, et al. OrthoJacket – an active FES-hybrid orthosis for the paralysed upper extremity. Biomed Eng. 2011;56(1):35–44.
- IEC, Medical electrical equipment Part 1: General requirements for basic safety and essential performance, IEC 60601 Ed. 3, 2005.
- Borggraefe I, Klaiber M, Schuler T, et al. Safety of robotic-assisted treadmill therapy in children and adolescents with gait impairment: a bi-centre survey. Dev Neurorehabil. 2010;13(2):114–9.

- 50. Toth AN, Nyitrai D, Jurak M, Merksz I, Fazekas G, Denes Z Safe robot therapy: adaptation and usability test of a three-position enabling device for use in robot mediated physical therapy of stroke. In: International conference on rehabilitation robotics ICORR 2009, Kyoto; 2009.
- Koritnik T, Koenig A, Bajd T, Riener R, Munih M. Comparison of visual and haptic feedback during training of lower extremities. Gait Posture. 2010;32(4): 540–6.
- 52. Banz R, Riener R, Lunenburger L, Bolliger M. Assessment of walking performance in robot-assisted gait training: a novel approach based on empirical data. Conf Proc IEEE Eng Med Biol Soc. 2008;2008: 1977–80.
- Bolliger M, Banz R, Dietz V, Lunenburger L. Standardized voluntary force measurement in a lower extremity rehabilitation robot. J Neuroeng Rehabil. 2008;5:23.
- Schmartz AC, Meyer-Heim AD, Muller R, Bolliger M. Measurement of muscle stiffness using robotic assisted gait orthosis in children with cerebral palsy: a proof of concept. Disabil Rehabil Assist Technol. 2011;6(1):29–370.
- 55. Bosecker C, Dipietro L, Volpe B, Krebs HI. Kinematic robot-based evaluation scales and clinical counterparts to measure upper limb motor performance in patients with chronic stroke. Neurorehabil Neural Repair. 2010;24(1):62–9.
- Craven BC, Morris AR. Modified Ashworth scale reliability for measurement of lower extremity spasticity among patients with SCI. Spinal Cord. 2010; 48(3):207–13.
- Center NSCIS. Spinal cord injury: annual statistical report. Birmingham: The University of Alabama; 2007.
- Wirz M, Zemon DH, Rupp R, et al. Effectiveness of automated locomotor training in patients with chronic incomplete spinal cord injury: a multicenter trial. Arch Phys Med Rehabil. 2005;86(4):672–80.
- 59. Hicks AL, Adams MM, Martin Ginis K, et al. Longterm body-weight-supported treadmill training and subsequent follow-up in persons with chronic SCI: effects on functional walking ability and measures of subjective well-being. Spinal Cord. 2005;43(5):291–8.
- Rupp R, Plewa H, Schuld C, Gerner HJ, Hofer EP, Knestel M. MotionTherapy@Home – first results of a clinical study with a novel robotic device for automated locomotion therapy at home. Biomed Tech (Berl). 2011;56(1):11–21.
- 61. Saposnik G, Teasell R, Mamdani M, et al. Effectiveness of virtual reality using Wii gaming technology in stroke rehabilitation: a pilot randomized clinical trial and proof of principle. Stroke. 2010;41(7):1477–84.
- 62. Pohl M, Werner C, Holzgraefe M, et al. Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (DEutsche GAngtrainerStudie, DEGAS). Clin Rehabil. 2007; 21(1):17–27.