Movement Rehabilitation and Assistance After Spinal Cord Injuries

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Abstract—**In the past, spinal cord injuries have been viewed as a life long injury, often causing patients to be wheelchair bound for the remainder of their lives. Relatively recent advancements in understanding of these injuries, such as an understanding of neuroplasticity, have allowed this viewpoint to change. Patients suffering from spinal cord injuries are now able to seek multiple different forms of recovery and rehabilitation. With the increased understanding of the relationship between physical movement and neuronal axon regeneration, treatments such as over ground gait training and body weight supported treadmill training have developed. More recently, advancements in robotics have lead to the creation of exoskeletons to either supplement or replace these therapies. The goal of this paper is to review and critique these recent robotic advancements in order to determine their feasibility, safety, and remaining improvements required for their integration into rehabilitative methods or as a potential assistive device. It is concluded that these robotic methods have significant potential in improving patient outcomes, as well as acting as a life long assistive device; however, there are still significant advancements required for frequent and independent use.**

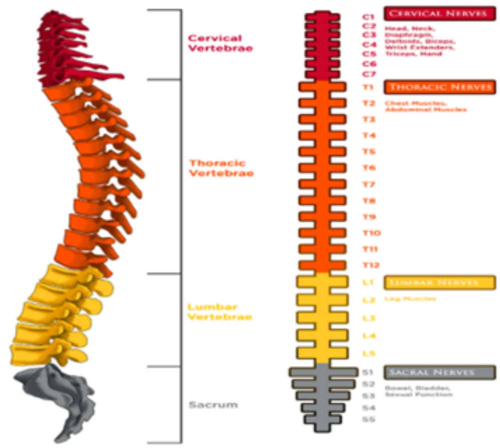

Fig. 1. Diagram of Spinal Cord Components[3]

I. Introduction

Spinal cord injuries can happen for a variety of reasons, and the impacts of said injuries can often result in massive changes to the quality of life of the patient[1]. Whether the trauma be from a stroke or a physical mechanical injury to the brain and/or spinal column, the treatment methods can be quite similar. Movement rehabilitation and gait retraining are a big area of focus in the topic of spinal cord injury, and this paper will delve into detail on current and recent research being done in the field of spinal cord injury movement rehabilitation. The focus is to compare conventional gait training methods—overground walking, and BWSTT (body weight supported treadmill training)—with more recent robotic intervention solutions, and hybrid methods. Results from different studies involving therapies completed in different manners will be compared, and factors such as improvement parameters of the patients undergoing treatment will be discussed. The goal is to determine if robotic exoskeletons used for gait training result in significant rates of improvement and overall performance compared to older and more conventional methods of gait training, to test the hypothesis that exoskeletons are financially feasible as a potential rehabilitation solution in the medical industry. A comprehensive review of different exoskeleton solutions currently used in clinical and research settings will also be a primary focus.

It is first important to understand the interactions within the body and brain at the occurrence of a spinal cord injury. In a significant spinal cord injury, what was previously thought to be irreversible dysfunction occurs through the interruption of neural pathways[2]. This is usually induced through mechanical damage to the structure of the spinal column resulting in breaks between the links of communicable and controllable neural channels at a certain vertical location within the spinal cord. Depending on the vertical location of the damage, the macrophysical outcome differs. Please see Fig. 1 for a descriptive structure of the spinal cord.

Paraplegia is diagnosed at an injury location of T1, and quadriplegia is diagnosed at an injury location of C3[3]. Following this, different severities of injuries occur at different discrete locations along the spinal cord. Where it becomes interesting is with the introduction of a relatively recent concept called neuroplasticity. Neuroplasticity is the ability of the brain to restore and regenerate broken and damaged neural connections[4]. What was before thought to be irreversible damage is now understood to be no longer irreversible. This is where gait training comes in. Most substantial spinal cord injuries will have an impact on the gait of the patient, and the aforementioned conventional training methods with the addition of newer robotic exoskeleton methods serve the purpose of aiding mechanical motion while simultaneously accelerating the rates of neuroplasticity in the body—allowing for the damaged connections to slowly recover.

II. Market Analysis

The WHO estimates that per annum globally, anywhere between 250,000 and 500,000 people suffer from significant spinal cord injury[5]. This is a notable number of individuals whose quality of life could see great improvement through properly administered forms of rehabilitation. This creates demand to continue the study and development of increasingly

Fig. 2. Conventional Overground Walking Gait Training[7]

impactful and efficient robotic methods of gait training and spinal cord recovery.

With regards to the global exoskeleton market, it received a 310 million USD valuation in 2019, and is projected to reach 5.73 billion USD by 2027[6]. This represents majorly significant growth, and further research and development in the area of robotic exoskeletons for medical applications is easily justifiable. As medical exoskeleton systems start to further integrate into the market, the affordability will improve over time. This will inevitably lead to more rehabilitation usage in hospitals and clinics and will result in a further slew of scientific research studies revolving around the benefits of using robotic solutions for the treatment of spinal cord injuries.

III. Review and Critique

A. Conventional Methods

1) Conventional Overground Walking: The oldest and most conventional form of gait training is overground walking gait training. This takes on multiple forms, usually with different ways of partially supporting the body weight of the patient. The methods can include simply using a cane for leaning support, or can be more complex and involve the use of a rolling weight-supporting assistive device[7], as seen in Fig. 2.

Overground-walking gait training is a rehabilitative procedure in which the patient suffering from spinal cord injury practices walking along flat and even surfaces in the company of a physiotherapist, who is there for both physical and psychological support. The degree to which body weight is supported is determined by the physiotherapist. In general, a patient would start with a higher percentage of supported body weight, and over time and numerous training sessions with the therapist, would slowly decrease the amount of support provided until self sufficient ambulation is achieved. The performance of a patient during overground walking gait training is usually quantified on a numerical scale. The scale varies from study to study depending on the research group performing the therapy, but common scoring is usually

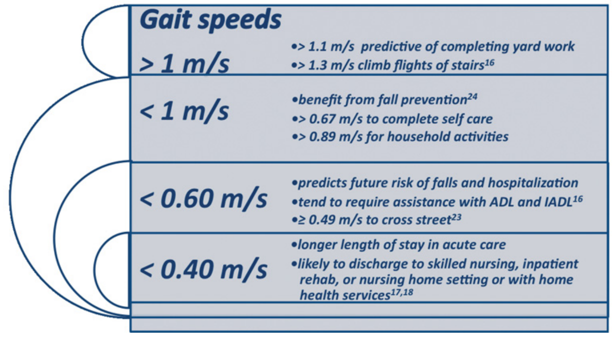

Fig. 3. Gait Speed Values Physical Associations[10]

between 0-5 and 1-10. In a research study on conventional overground walking gait training performed in 2019[8], the following scale was used to assess the performance of each participant:

0 – patient unable to walk and requires the aid of multiple therapists for body weight support

1 – continuous support in both balance and bodyweight from a single therapist is required

2 – intermittent support required from a single therapist for balance or bodyweight

3 – no physical contact from therapist, but verbal support is given, and assistive devices are used

4 – independent ambulation is achieved on flat ground, but aid is required for uneven surfaces and/or stairs

5 – total independent ambulation is achieved on any surface

The 0-5 scale is a very broad and generalized method of observing performance and improvement in overground walking gait training. There are more complex and calculated parameters for numerically observing progress. These metrics include gait speed, walking endurance, step length, and gait symmetry. The most important of these is often gait speed, as it is most representative of improvement over time[9]. Different studies and research groups tend to choose which gait improvement parameters they would like to focus on, but gait speed is often represented in almost every single study done on the subject. Fig. 3 shows a very general association between gait speed and predicted physical condition.

2) Body Weight Supported Treadmill Training: Another method of non-robotic gait training is called body weight supported treadmill training, or BWSTT. In Fig. 4, an image of this training method is taken from a research study done in 2005 comparing BWSTT to conventional overground methods[11].

In the study from which this image was taken[11], partial body weight support is provided using an overhead harness that is fastened to the patient at the hip level. The gait speed is controlled by the speed settings on the treadmill, and the system is designed in such a manner that it allows for the patient to experience a full range of motion to best emulate free walking along solid ground. De-weighting of the patient occurs by adjusting the tension force in the harness. This allows for the researchers and therapists to decide the percentage of body weight that the patient will experience during the training

Fig. 4. Body Weight Supported Treadmill Training[11]

process. The de-weight percentage is dynamically modified throughout the course of the study. In this study, 30% of the patient's body weight is initially removed through adjusting the tension force in the harness[11]. 30% seems to be a common starting value, as they determined that de-weighting by 40% and higher resulted in insufficient heel strike during the walking process. At this point, the patient now weighs 70% of his/her normal body weight. A walking task is performed, and when 10 bilateral heel strikes are achieved, a 5% deduction in the de-weight percentage is performed. The patient now weighs 75% of his/her normal body weight. This process is then repeated in discrete intervals until the patient can walk freely with no support on the treadmill. Gait speed is set through treadmill speed at the highest value tolerable by the patient. Maximum speed is desirable, as it was found that a higher speed in gait training is correlated with a faster and more accurate recovery process for injured patients[12].

Through the careful review of multiple research studies with varying sample sizes that performed a comparison between BWSTT and overground walking gait training, body weight supported treadmill training was not found to be more effective than the conventional method during a training period greater than 3 months. Conversely, gait symmetry and speed were observed to demonstrate a higher rate of improvement in overground walking gait training[11][12]. However, this is not a universally agreed upon result, as there have been studies that show that BWSTT has outperformed overground walking training in certain conditions[13]. The reality is that spinal cord injuries are extraordinarily complex, and one patient may respond differently to a different type of training method than others for a multitude of reasons. A big factor is the mental aspect, as overground walking gait training makes one feel more independent and results in an inflated confidence boost. A positive mental state works miracles in the recovery process from any injury and can totally offset numerical data from a quantitative study. The main takeaway is that both methods are viable ways of re-training gait in an injured patient, and if a non-robotic method is decided upon, it should be up to the physician and physiotherapists discretion as to which method they deem more suitable for the patient in question.

B. Exoskeletons

1) Background: Recently, using robotic methods to both assist with the traditional methods of gait training and in their own right have been developed, with one common type being exoskeletons[14]. There has been a lot of research into using these wearable powered robotic exoskeletons in recent years as a tool for improving walking speed, ability to climb or to improve climbing speed, along other aspects of movement. Outside of these aspects, exoskeletons are also used as an assistive device to help with movement for those that are unable to fully heal, and as such, those who require permanent assistance[14].

Robotic exoskeletons are a relatively new development for rehabilitation applications, with the first exoskeleton being approved for use in the United States by the FDA in 2014[15]. These exoskeletons are coverings for the body with motors and control systems added that are designed to help the user move. There are now several approved robotic exoskeletons in the US in clinical settings, along with some approved for home use including the ReWalk exoskeleton. While these devices often have many restrictions associated with them, such as user weight and height, they allow treatment of quite severe injuries while providing more mobility than wheelchairs for assistive exoskeletons, and potentially faster recovery times and better results for rehabilitative exoskeletons[15].

2) VariLeg: Several different exoskeletons have been developed that assist with spinal cord injuries. The first exoskeleton being reviewed in this paper is VariLeg, which was initially developed in 2016. This exoskeleton was developed in response to other exoskeletons at the time of development being limited in their walking speed along with their ability to support normal tasks like stair climbing. VariLeg was developed with the hope that restoring some walking functionality could assist patients with secondary complications, such as increased depression and social stigmatization. VariLeg's key novel innovation is the introduction of variable mechanical stiffness actuation to drive the knee joint which is based on how humans are able to adapt their joint stiffness for different walking scenarios. VariLeg was intended for users with motor complete SCI and as such was designed as an assistive exoskeleton instead of a strictly rehabilitative one. The exoskeleton had the goal of performing daily mobility tasks, like climbing stairs, so had to support the body weight of the user[16]. Needing to support the full body weight while driving the user's legs seems to explain the large size of VariLeg compared to other slimmer exoskeletons.

The design of the exoskeleton can be seen in Fig. 5. The exoskeleton is designed to have three degrees of freedom in each leg, with 2 active and one passive. The active degrees of freedom control the hip and knee while the passive degree of freedom is responsible for the ankle. The creators decided to use a passive joint instead of active for the ankle since walking does not need ankle push off making a passive joint sufficient while also serving to reduce complexity and weight[16]. This

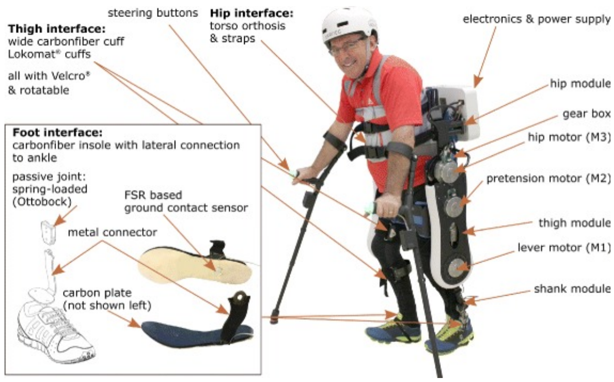

Fig. 5. Diagram of VariLeg components[16]

seems like a reasonable choice as any increased weight on the feet can become extremely tiring to user, as seen from the trend towards lighter shoes, while also reducing battery demand. As batteries are expensive, heavy, and require replacement this would seem to be an extremely good design choice if the passive joint is sufficient, although the authors do not comment on the battery benefits from this choice. The exoskeleton is capable of 1 to 2 hours of operation[16], which is useful for providing mobility when needed but seems that it would be too short to be a daily driver for the user. As such, improving the battery technology or reducing the energy usage should be a top priority for the authors. The exoskeleton makes use of a combination of custom designed upper thigh cuffs to prevent unwanted rotation of the user's thigh along with several commercially designed cuffs and orthosis for the rest of the structure. Commercial force sensitive resistors are in the shoe inserts to detect ground contact. The crutches include a custom designed handle which is how the user inputs commands to drive the exoskeleton[16].

The main novel improvement introduced for VariLeg is the variable stiffness actuator. This system was designed to be as close as possible to the stiffness range of the human knee, with behaviour such as high stiffness during push off, and was estimated by using an EMG-based model. By using this variable stiffness, the authors claim both energy benefits as well as providing a safer system by softening impacts. The system using two motors, one to set the equilibrium position of the shank and one to pretension the spring, along with a potentiometer to measure the angle between the thigh and shank. The authors chose to have the maximum stiffness at equilibrium, 392 Nm/rad, be significantly lowered than the maximum human knee stiffness to keep the weight and torque required within reasonable range[16]. The authors choice in attempting to emulate the human knee as close as possible would seem to be a logical choice. It would presumably put less strain on the patient's body while also being easier to learn, as the movement would be similar to the patient's already learned gait prior to injury. While the compromise the authors chose is not ideal, it does seem reasonable in context, especially as the patient's injury is in the spinal cord and as such their knee itself should already be providing some degree of stiffness.

VariLeg utilized the Failure Modes and Effects Analysis to identify and assess the different types of risks, considering the perspectives of the user, support staff, and the engineer. The authors implemented safety layers in each level of the machine, that is for the software, electronics, and mechanical levels. Software safety included redundant sensors, comparing motor input commands to sensor feedback, disallowing joint angles that would lead to overstretching, monitoring battery levels, and limiting angular velocity and torque. On the electronics side, safety features were built around the motors with having independent power to the motors and the computers to allow immediate motor shutdown and two independent emergency motor shutdown buttons. When power is cut off, the exoskeleton would collapse resulting in supporting staff being required to guide the user softly to the ground. The mechanical safety layer made use of mechanical end stops to prevent joint overstretching and external handles for staff assistance[16]. The authors included many safety layers, particularly at the software level, but it is surprising that it was chosen to limit angular velocity and torque at the software level instead of or with extra limits at the electrical and mechanical levels. Using current limiters and mechanical safeties that would break and physically separate the motor in case of over-torquing could provide additional safety to the user. Requiring support staff in case of failure resulting in power being cut to the motors is a useful safety feature, but does mean the system would not be suitable for home use for individuals that either live alone or are frequently by themselves. However, as the system is a lab prototype with the eventual goal of home use rather than being currently intended for it does mean that at the moment this would not be an issue. A final safety layer that the authors used was to have the staff present extensively trained, both with instructions and with practicing on a unimpaired user to gain practical experience[16]. This does provide a useful last safety layer but again suffers from not being applicable to the eventual end goal of daily home use.

The system was tested with two users who had never used a powered mobile exoskeleton before and who were suffering from motor complete spinal cord injury for at least one year. The users trained in three sixty minute sessions a week over the course of four months with the eventual goal of competing in the 2016 CYBATHLON. The users completed the training with no adverse effects, including no falls. They were able to comfortably take a maximum step length of 50cm with a maximum walking speed of 0.2m/s[16]. For comparison, the average human has a step length of 68 to 76cm[17] and an average walking speed of 1.4m/s[18]. As a result, the study showed a step length fairly comparable to an unimpaired human but significantly slower walking speed. At CYBATHLON 2016, one user was able to compete and was able to successfully complete 3 of 6 obstacles, resulting in 5th place at the competition being beaten by one commercial product and three research prototypes. However, the authors did not have time to test using the variable stiffness actuator to adjust joint stiffness during walking and instead used fix stiffness for this[16].

The authors noted several challenges they still needed to overcome, such as fully utilizing the variable stiffness actuator and using a more suitable controller. Other issues with the design pointed out by the authors included issues with the insole, with the users frequently having their foot slipping out of the shoe and suspecting that the insole is too stiff resulting in the users being unable to stiff their body weight when needed. These issues identified by the authors, along with the issues pointed out earlier such as battery improvements and suggested safety feature changes, are key areas of improvements for the author. However, the system provides significant promise with its fairly good results in the CYBATHLON, especially considering that at the time of participation there were still several areas the authors intended to improve or could not test. In comparison to exoskeletons that will be further discussed below, such as the ReWalk exoskeleton that won at the CYBATHLON competition[19], VariLeg both provides some significant advantages but some crucial disadvantages. For advantages, VariLeg is able to overcoming much steeper inclines than other exoskeletons, overcoming 20 degree inclines compared to other systems being limited to 8 degrees or under at the time. VariLeg also targeted daily living tasks while many other exoskeletons often targeted other areas such as rehab[16]. However, as demonstrated at the CYBATHLON event, there are several other exoskeletons that perform better in the obstacle scenarios encountered at the event. Further, VariLeg suffers from slow training times as pointed out by the authors[16].

Another study was done on the VariLeg exoskeleton in 2019, aiming to improve exoskeleton usability for patients through modifying the pilot attachment system on VariLeg[20]. The authors designed the new system based on qualitative user feedback based on the initial VariLeg system and then tested with both paraplegic and healthy subjects to more accurately evaluate the change in user safety and comfort. The authors introduced iterative design changes to VariLeg in order to gradually create an entirely novel pilot attachment system. For testing, the authors were able to use the two patients that VariLeg was initially used with along with 5 healthy patients, whom could provide feedback on the ergonomics that the original patients could not provide due to their spinal cord injury preventing feeling in the legs. The authors evaluated the performance of their novel system through user questionnaires, including having users rate the Ekso GT exoskeleton for comparison, along with a discomfort heat map. The new system made use of different upper body attachments depending on where the patient injury was to accommodate different patients unique scenarios along with an adjustable pelvic plate. The new thigh and shank components made use of compliant thermoplastic cuffs with padding. Lastly, the foot attachment was redesigned to allow shoes to be mounted onto the exoskeleton[20]. These changes would all appear to significantly enhance the VariLeg exoskeleton. In particular, redesigning the foot attachment would seem to be an important part of this redesign, as one of the main issues with the original design, which particularly made incline climbing difficult, was the patient's foot sliding out. The effects of the author's changes seemed to have panned out in reality, as both of the original patients only voiced continued issues about the design outside of the attachment system after the redesign. The authors do note, however, that the new system is still not capable of independent home use as the system still requires someone to assist the patient with entering and exiting the exoskeleton. In terms of usability, both patients rated the original design of the attachment system extremely low, with a SUS score of 22.5/100 compared to the Ekso GT average score of 83/100, but one patient rated the new design as better than the Ekso design and the other as significantly worse[20] than the Ekso design. This would seem to indicate that the new system has significant potential, as the Ekso system is a commercial design so should be expected to be better, but still has significant refinement needed to be easily usable for all types of patients. The authors do note, however, that the comparison to the Ekso design would need to be done with caution as the patients were only able to use the Ekso exoskeleton in a single brief session[20]. This study seems to succeed in its goal of showing the potential of modifying the attachment system in exoskeletons along with the benefits of incorporating user feedback. Specifically, it shows that VariLeg, when combined with the benefits discussed in the initial paper presentation the exoskeleton, has significant potential. The potential issues with the paper, such as small sample size and patients being biased to suggestions they presented are considered by the authors[20], and as such there is little to critique that has not already been discussed by the authors. However, one area the paper lacks in which could provide more useful info would be more analysis and detail on why the two paraplegic users responses varied so wildly, although this is not directly a critique of the exoskeleton improvements proposed.

3) ReWalk: Another exoskeleton, which has gained popularity for rehabilitative use, is the ReWalk exoskeleton. The ReWalk exoskeleton is a commercial powered exoskeleton used both for personal use at home and has also been used in clinical settings, and is controlled by the user changing their center of gravity which then causes the system to step, with the system attempting to mimic the natural gait of the legs[21]. An image of this exoskeleton can be seen in Fig. 6, for a visual reference to compare to the VariLeg exoskeleton discussed before.

A study published in 2019 that ran from 2014 to 2018 attempted to determine if training with the ReWalk exoskeleton could improve the strength of neural pathways in patients, along with investigating its use in a home setting[23]. The study included patients with spinal cord injury from at least a year prior and whom used a wheelchair as their primary method of movement, along with uninjured patients for comparison[23]. Initially the ReWalk 2.0 was used before eventually changing to the ReWalk 5.0. The authors made use of 4 different procedures in order to determine the effectiveness of the exoskeleton: standing upright, transferring into and out of the exoskeleton, standing balance, and walking[23].

The study measured several outcomes, such as walking speed and spasticity, with a physical therapist not involved in the experiment measuring the latter. The study also measured balance and strength of sensory and motor pathways to determine the neurophysiological outcomes, which was the goal of the study[23]. An interesting analysis that the study performed was both testing during training but also testing

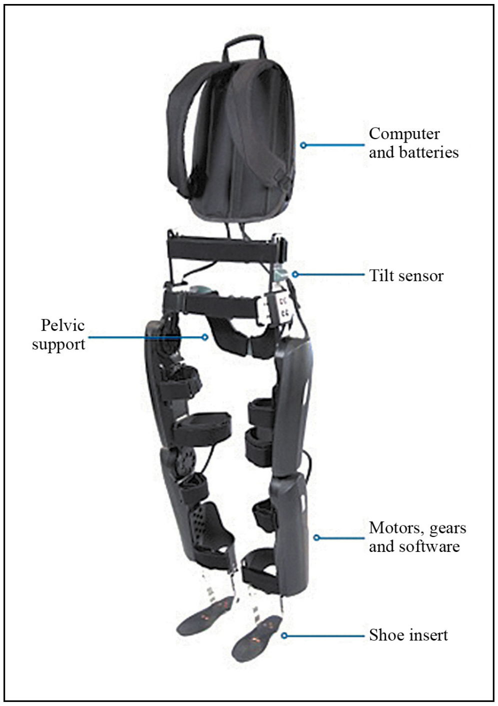

Fig. 6. Image of ReWalk Exoskeleton[22]

with breaks and 2-3 months after testing finished to determine if skills were retrained[23]. Checking these break outcomes should help to verify the effectiveness of the exoskeleton, especially considering the goal of the study of determining if neural pathways are changed. Notably, this was something that was lacking in the VariLeg studies mentioned earlier.

Initially, the study included twelve participants, however one dropped out of the program too early for their data to be included and one suffered an unrelated injury several weeks into the program resulting in only some data included for them. Of the twelve, 8 patients had a follow-up session to determine if training was retained. Training included 14 pauses of at least 7 days across the patients, with the pauses being due to a combination of patient and trainer injury along with holidays. These pauses, along with the revisit after 2-3 months, were used to test if training was retained. The result was no decrease in walking distance or average number of uninterrupted steps during training and after also found no decrease in sitting balance and walking[23]. These results would seem to show that the author's training program was able to provide neuropathic change for the patients, indicating that exoskeletons can used be used for rehabilitative rather than strictly assistive purposes independently of other methods. It would be interesting to see if the changes are still observed after a longer period, as the pauses and revisits were only on the timeline of weeks to months. Observing for a longer period could also be interesting for helping to establish a maximum effect for the patients from the exoskeletons. One area the study does not delve into that may help establish if these effects are from learning how to use the exoskeleton itself or a general recovery would be having the patients also use other exoskeletons. Revisiting the same exoskeleton may be simply due to patients already knowing how to use the ReWalk exoskeleton rather than actual improvements. In turn, having the patients try another exoskeleton, after a period of learning the differences in the control scheme, could potentially indicate a true change as one would expect if the same results are shown in an entirely new system than the results must be independent of the exoskeleton used.

The study found that participants were able to walk at an average speed of 0.4m/s, with no consistent difference between incomplete and complete spinal cord injury patients[23]. In comparison to VariLeg, this average speed was about double the maximum speed attained in their study of 0.2m/s[16] but still significantly lower than the average walking speed of uninjured individual of 1.4m/s[18]. However, VariLeg only included two patients and had a shorter training period of 4 months[16] so it is difficult to determine if this is an issue with VariLeg itself or just the extremely small sample size and limited training time. The study also found that three patients who were able to walk without the ReWalk exoskeleton, two from before the study and one from after, were able to initially walk farther in the 6 metre walking test with less effort than with their period aids. However, one of the patients made gains with walking without ReWalk after the study ended and another of the three found only a minor difference[23]. It is worth considering that the gains without the ReWalk exoskeleton that the authors noted for the one patient after the study could be due to their time in the exoskeleton helping heal their neural pathways. To this extent, even though it would seem that the ReWalk exoskeleton did not show an actual improvement in the patient at face value it is possible unobserved changes did occur. It would be interesting to see future studies on if this was the case, as it would support the goal of using exoskeletons to heal neural and motor pathways.

In comparison to VariLeg, it is interesting to note that this study on ReWalk reported some injuries, particularly skin abrasions[23], while VariLeg did not have these issues[16]. This would seem to indicate that the design of the VariLeg exoskeleton puts less pressure on the patient, which would presumably result in greater comfort over the longer term. The authors of the study noted that, in comparison with the Ekso exoskeleton, they found patients continued to improve for the duration of the study to an average of 1359 steps per hour, while Ekso plateaued around 1000 steps per hour. As the authors did note though, this could be due to the longer duration of their study compared to the Ekso study[23]. These results may also be from the small sample sizes of these studies, and as such these variations could simply be due to wildly varying patient needs over any direct difference in the exoskeletons. The authors of the paper themselves also seem to note this, as they directly mention the considerable variation in their patients progress and recommend clinicians closely track each patient[23].

Another study also published in 2019 analyzed the effect of changing the control software of the ReWalk exoskeleton without changing any hardware. The study consisted of 15 motor complete spinal cord injury patients of at least 6 months since injury and were divided into two groups, 5 using the initial control software of the ReWalk exoskeleton and 10 using the updated software[22]. Of these 15 patients, 13 completed the study with two leaving the study due to personal issues. This study consisted of three 60 minute sessions a week for at least 8 weeks[22], making it significantly shorter than the other ReWalk study already discussed[23], although with a similar sample size, but comparable in time to the VariLeg study[16]. This study found that found that the group using the original control software had a velocity of 0.1m/s and the second group a velocity of 0.3m/s, a significant improvement over the first group. To this extent, along with similar improvements in other metrics, the study concluded that changing the control software to more precise kinematic control provides significant improvement[22]. It is interesting to note that the numbers published in this study for the second group are inline with the numbers reported in the first study discussed[23]. As it would appear both studies were using the same version of ReWalk, these numbers aligning would provide further evidence that the results of both studies are indeed accurate rather than being corrupted by bias, such as the small sample size. It would be useful if this study had indicated what the changes in the control software from the first version to the second version were. To this extent, it would be interesting to analyze which aspects of the software changes provided the most benefit. This information could help narrow down where future research into software control algorithms should take place to provide the most change.

4) Ekso Bionics: Ekso Bionics is a fifteen year old company who produces several different exoskeletons, with one of their focuses being on rehabilitation for spinal cord injuries[24]. There has been numerous studies done on the exoskeletons developed by Ekso Bionics, although many of these studies focus on multiple sclerosis and stroke patients. As this paper is focused on rehabilitation and assistance for spinal cord injury patients, these papers are not being reviewed. However, future study in the effect of Ekso Bionics exoskeletons for spinal cord injury patients may find it useful to study these papers. Some aspects may crossover such as skin injury issues and secondary benefits resulting in walking for those who are otherwise wheelchair bound, as many of these patients are also unable to walk independently[25]. An image of the Ekso GT exoskeleton can be seen in Fig. 7.

Fig. 7. Image of Ekso GT Exoskeleton[26]

A study published in 2017 that ran from 2014 to 2016 aimed to determined the safety and feasibility of the Ekso Bionics exoskeletons for patients with varying levels of spinal cord injury. The study was conducted in 9 rehabilitation centers across Europe in 8 week sessions and began with 60 patients, of whom 52 patients completed the training. The study used two different exoskeletons from Ekso Bionics, the Ekso and the Ekso GT, with 8 and 44 participants for each respectively and found minimal difference in the results between the two groups[27]. With a total of 52 patients, this study is the largest study being reviewed today although still is an extremely small study, especially compared to the amount of spinal cord injury patients in the world. One interesting note about this study compared to the other studies reviewed is it includes both recent and chronic injury patients, whereas the other studies tended to only include chronic injury patients. Of the original 60 participants, most of those who dropped out did so due to unrelated reasons but there were 3 who did due to ankle swelling from using the exoskeleton[27]. This is an interesting result about the Ekso Bionics exoskeletons, as the other studies reviewed so far have not had any patients dropping out due to injury while training. However, the comparatively small sample sizes of the other studies may explain this as it may be possible they just happened to not have these issues rather than any differences in the exoskeleton designs. Larger studies would need to be conducted on the other exoskeletons to determine whether this is the case. The authors analysis that the injuries sustained were due to overuse after having minimal movement outside a wheelchair[27] would be in line with this thought process.

The study found that patients with recent injuries displayed improvement in all tested areas while those with chronic injuries displayed improvement in the TUG and BBS metrics. The authors note that these results could be explained by normal recovery in this time period for those results differing for recent vs chronic injures. They further note that the chronic group also displaying improvement in the TUG and BBS metrics may mean the use of the exoskeletons increases balance[27]. It is interesting that the some studies discussed for the VariLeg and ReWalk exoskeletons did note improvements in walking speed for their chronic patients while this study does not. A reasonable guess for why this is the case may be that this study was only for a short period of time of 8 weeks while these other studies were for long periods of time, as such noticeable improvement may take significant training time. This study concluded that the Ekso Bionics exoskeletons were safe to use, although noting attention should be paid to overuse and to skin injuries[27], which is in line with the other studies reviewed for VariLeg and ReWalk.

Another study published in 2019 analyzed the ability of the Ekso Bionics Ekso GT exoskeleton to be integrated into clinical rehabilitation for stroke and spinal cord injury patients over a period of 6 months. The study included a total of 25 patients of whom 7 were incomplete spinal cord injury patients[28]. Within the context of this paper, only the results for the spinal cord injury patients will be reviewed. Therapists in this study noted that it was difficult to get patients into and

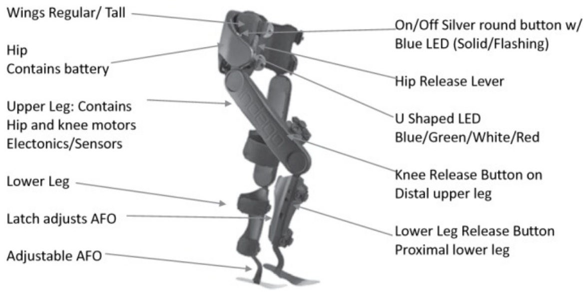

Fig. 8. Diagram of Indego exoskeleton[29]

out of the exoskeleton, although this improved with time[28]. This is consistent with the other studies reviewed today for both the Ekso Bionics exoskeletons and for other exoskeletons, indicating the industry as a whole is struggling at creating an easy to put on system. To this extent, it is important for future research for powered wearable exoskeletons to be done on creating easier harness systems if these exoskeletons are to be eventually used independently at home. The study noted that therapists at the end of the 6 month period were generally in favour of incorporating the exoskeleton into clinical practice while patients generally thought their time was well spent and able to move better afterwards[28]. The authors noted that the goal of this study was to determine if it is feasible to integrate exoskeletons into existing clinical practice instead of replacing traditional methods. They came to the conclusion that it is both feasible and appears to provide overall assistance to patients. However, currently only a small subset of clinical patients were able to use the exoskeleton, specifically 4% for spianl cord injury patients[28]. This study was unique in comparison to the other studies reviewed, as the other studies focused on use of the exoskeleton in and of itself rather than with traditional methods. This is an interesting aspect for rehabilitative use that should be further investigated, particularly through comparison of the Ekso GT to other exoskeletons like ReWalk and VariLeg.

5) Indego: Another popular commercial exoskeleton is the Indego exoskeleton by Parker Hannifin. Parker Hannifin sponsered a clinical trial in 2014 to 2015 across 5 rehabilitation centers in the United States in order to obtain FDA clearance for Indego. A study in 2017 analyzed the results of this trial in order to analyze safety and feasibility of the device for rehabilitative use for the 32 patients who completed the trial. The trial consisted of 3 sessions per week over 8 weeks for a total of 24 sessions[29], which is in line with most of the clinical trials discussed in this paper. The design of the Indego exoskeleton can be seen in Fig. 8. In comparison to VariLeg which uses external controls[16], the Indego controls are self contained and uses changes in the center of pressure to change mode[29], similar to the ReWalk exoskeleton with its center of gravity control[21].

There were 66 adverse events reported[29], which is higher than that reported for other studies of similar size. Of these events, most were skin irritation or bruising and resolved over the course of the study through additional padding[29]. This resulted in the final product presumably being comparable to the issues reported with the Ekso Bionics and ReWalk exoskeletons, which are its competitors in the commercial space. Indego did report one moderate injury of an ankle sprain[29], which is more severe than those injuries reported in the other studies reviewed. As it was just a single moderate injury its possible it was not an indication of any issue with the device. As with the other studies reviewed, the speed to enter and exit the exoskeleton improved with practice.

The study noted significant improvement in all measured metrics, with a final walking speed of 0.37m/s[29]. This is significantly better than the speed VariLeg achieved of 0.2m/s[16] while comparable to those reported for the other commercial exoskeletons. This indicates that commercially available exoskeletons have their ability to train walking speed much more fine tuned than the research prototype of VariLeg. However, this would be expected of commercial developments and similar developments could potentially be seen with VariLeg if it were to benefit from the same funding commercial projects receive. At the end of the study, all patients still choose to use external stability aides, although two chose what the authors consider less restrictive devices while 8 chose crutches and the remaining 24 chose a rolling walker[29]. These are comparable results to what other exoskeletons reported, although as some, such as VariLeg, integrated the controls into the crutches those devices only use crutches. As two patients chose to use less restrictive devices, it would be increasing to see if further training could result in patients using no external devices. This would be a significant development towards long term at home assistive use.

6) Overall Exoskeleton Critique: Research on using robotic exoskeletons for gait training and long term assistance for patients with spinal cord injury has shown promising results, with generally significant improvements to patient outcomes. However, the studies so far have had small sample sizes, with the largest study reviewed today having only 52 subjects, which makes it difficult to draw definitive conclusions about the general usefulness of these devices. Despite this, the research reviewed does consistently show positive results which is a strong indication of the usefulness of exoskeletons pending further research. Outside of this, exoskeletons suffer from high prices, particularly for those intended for home use. For example, the ReWalk exoskeleton, which is one of those approved for home use, retails for $71000 US dollars[30]. In comparison, powered electric wheelchairs generally retail for less than $10000 US dollars[31]. With this high of a price difference, it makes comparisons to standard wheelchairs, like the ReWalk study mentioned earlier that showed a 3.3 times improvement compared to manual wheelchair propulsion, less useful as fairly fast electric wheelchairs can be had for significantly lower prices[23].

With the high prices of current devices, a major hurdle that the industry still needs to overcome is in lowering the cost of these devices for the average consumer can afford them. In the meantime, they do still show promise for those that can afford them for home use, with one major advantage over the cheaper wheelchairs being in gaining full control of one's body again compared to being confined to a wheelchair, along with use in clinical settings where rehabilitation centers can afford their high cost. These exoskeletons also tend to be fairly bulky, which can make their use in confined spaces such as smaller homes quite difficult. To this extent, another hurdle that the industry needs to overcome is in reducing the bulkiness of these devices to allow a wider range of use, which will likely gradually happen as battery and motor technology improves.

Current exoskeletons also suffer from short operating times, with most limited to 1 to 2 hours of continuous use. While this is sufficient for rehabilitative use, as clinical sessions tend to be no longer than this, it presents a significant hurdle for home use. Despite this short operating time, current exoskeletons still do present significant secondary benefits for patients. As noted in the VariLeg study, many patients report that even short periods of standing and walking help with issues such as depression[16]. It is also worth noting that even with current limitations, these exoskeletons still gave patients some ability to walk again which many are completely unable to do otherwise[16]. It would be interesting to see exoskeletons in the future sacrifice operating time for slimmer units, as longer battery life typically means larger batteries, in order to determine if patients benefit more from longer use periods or from lighter and easier to use units.

A slimmer unit would allow far easier operation in home environments which may mean more tasks that patients can perform. Current designs also suffer from being difficult for patients to enter and exit, with no current designs being capable of patients independently entering or exiting. This presents a significant hurdle for the industry to overcome for assistive exoskeletons for at home use. To this extent, it would be interesting to see if a slimmer lighter unit may also be easier for patients to enter and exit. One other aspect that none of the exoskeletons studied in this review has attempted to use is to see if it would be feasible for exoskeletons to use an external power source. This would reduce the significant weight of the battery units while permitting unlimited operation time but at the cost of a physical tether. This is one possible area of future study in the field of powered over ground exoskeletons. Another issue noted in studies for independent use of the exoskeletons is the lack of fall detection in current units. Recent developments in wearable technology, such as in the Apple Watch, has allowed cheap solutions for remote fall detection[32]. Future exoskeletons could incorporate this technology in order to solve this hurdle for independent home use of assistive exoskeletons.

C. Hybrid Methods

1) Lokomat: A partially robotic hybrid gait training method also exists. Lokomat is a gait training system that can be described as a cross between a BWSTT system and an exoskeleton[33]. In Fig. 9, a depiction of the Lokomat system being discussed can be seen.

A force control system is used to operate motors that drive the femur and shank areas of the exoskeleton body. Much like traditional BWSTT gait systems, harnesses are used to de-weight a patient by adjusting the tension force in the lines. The patient walks along in a stationary manner on a treadmill system. With a severe injury, the exoskeleton motors are used to apply mechanical force to the patients tibial and femoral sections of the legs to help propel motion forward. In the Lokomat system, the patient is initially de-weighted by 50%. Similar to BWSTT methods, the de-weight percentage is reduced over time until the walking tasks can be completed under full body weight conditions[34]. Ambulation level of the patient is analyzed by using the Walking Index SCI II score—a scale developed for gait training patients with spinal cord injury[34]. An FIM (functional independence measure) score is also used during analysis of performance. FIM consists of categories such as social interaction and cognitive activity during the training process[34].

Fig. 9. Lokomat Exoskeleton/BWSTT Hybrid System[33]

When compared to conventional overground walking gait training methods, a study performed in 2012 found statistically significant evidence suggesting a better performance and recovery over time in patients using the Lokomat system[35]. The result was determined by measuring higher scores in both the FIM (functional independence measure) and the walking index score in the Lokomat test subjects compared to the control group.

Another study involving Lokomat was published recently in 2021[36]. This study was interesting, as it focused on the psychological impact and energy cost of robotically assisted gait training methods by doing a comparative study between a stationary exoskeleton system (Lokomat) and an overground walking exoskeleton system–Ekso GT. During the training process, observed metrics consisted of oxygen consumption, heart rate measurements, walking economy, metabolic equivalent of task, and carbon dioxide production[36]. In Fig. 10, a side by side comparison of a test subject undergoing measurements during both training methods can be seen.

After examining experimental data, it was determined that both the metabolic equivalent of task values and the metabolic response values were lower in the subjects performing Lokomat stationary assisted walking in comparison to the overground Ekso GT method. On top of that, the results of the overground exoskeleton demonstrated higher mental effort, discomfort, and fatigue scores during gait training. Conversely, Lokomat test results showed vast improvement in muscle relaxation in comparison. Walking economy was improved in

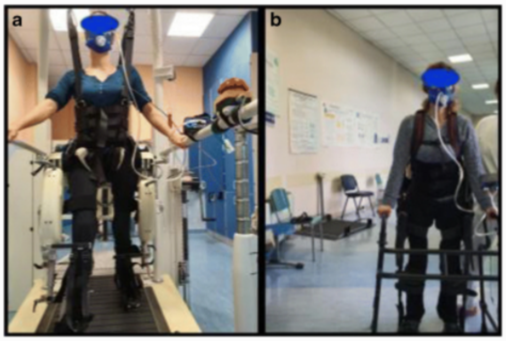

Fig. 10. Lokomat Stationary Exoskeleton vs Mobile Ekso GT[36]

both methods compared to a standard conventional overground walking training–likely due to reduced skeletal loading from the exoskeleton support structure–and both robotic methods resulted in all test subjects scoring significantly high in positive emotion and mental satisfaction. In terms of gait improvement results such as change in gait speed over time, both robotic methods seemed to show similar improvement in performance.

2) Overall Hybrid Method Critique: Robotic hybrid methods seem to offer promising results in the gait training process. Although the research study[36] seemed to show higher fatigue, mental effort, and discomfort in the overground walking robotic method (Ekso GT), this isn't necessarily a bad thing. Often training under fatigued circumstances can benefit the rate of improvement as it is more representative of normal ambulation. The important parameters are those of gait improvement; namely, gait speed. Both methods demonstrated similar improvement scores over time and as such, it cannot be definitively concluded which method is more beneficial. An important takeaway is that both methods are beneficial to patient recovery, and the chosen system could theoretically be selected based on the individual circumstances pertaining to each respective patient. Different patients have different personal needs. One patient could be farther ahead in the recovery process naturally, and could be better suited for a more fatiguing training program using an overground walking system, whereas a patient with a more severe injury or who happens to be in worse physical shape could benefit from starting slower with the stationary ambulation practice from the Lokomat system. These decisions would be at the discretion of the researchers, physicians, and physiotherapists in charge of the training and testing processes.

IV. Conclusion

In conclusion, various robotic methods to assist with traditional rehabilitative methods for spinal cord injury have been tried. One particular area of promise is the use of exoskeletons to supplement traditional methods or to provide long term assistance to those with permanent disabilities. However, before exoskeletons can reach extremely wide spread use some issues still remain to be solved including reducing the extremely high price point of these devices, particularly for home use, and showing larger performance improvements relative to traditional methods. For home use, exoskeletons still suffer from being difficult to maneuver in tighter spaces, requiring assistance for entering or exiting the device, and lack fall detection for independent use. The first of these issues still require significant research to be done, but is likely to be assisted by general technological improvements such as recent advances in battery technology. Some research has been done into making the devices easier to enter and exit, but is still an area requiring significant improvement. Lastly, recent advances in fall detection technology, such as on the Apple Watch, may be useful for exoskeleton researchers and developers for adding fall detection to these devices. Other than direct benefits, exoskeletons for over ground gait training have shown significant secondary benefits, such as in decreasing depression. Outside of the independent use of exoskeletons, hybrid approaches such as the Lokomat provide potential promise. However, current studies are mixed on if these hybrid systems and BWSTT as a whole, provide significant advances compared to traditional over ground gait training. To this extent, exoskeletons for over ground gait training may provide more promise, along with having shown significant secondary benefits due to patients experiencing an activity similar to feeling as if they are able to walk normally. Ultimately, integration of robotic exoskeletons into both BWSTT and over ground gait training have shown great potential for patient outcomes.

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