Functional electrical stimulation (FES)-based rehabilitation can improve health and decrease rehospitalizations and their associated costs following spinal cord injury (SCI)

Health after SCI

Physical activity is critical to maintaining good health. Well-known effects of regular physical activity include important positive impact on minimizing the risks of cardiovascular and respiratory diseases, musculoskeletal disorders and conditions, diabetes and mental health disorders, to name only a few.

As the lifespan of individuals with SCI continues to increase thanks to advances in health care, the **primary causes of death among the SCI population are complications associated with lack of physical activity/mobility**.

Changes in body composition after SCI result in disproportionately more fat than muscle mass and a propensity toward **obesity** (Gupta, White, & Sandford, 2006). This increases risks for other diseases including cardiovascular disease and diabetes (Flank, Wahman, Levi, & Fahlstrom, 2012). Even within the acute phase several weeks after injury, skeletal muscle atrophy is one of the most prominent changes associated with SCI and can be quite severe (Gorgey & Dudley, 2007) (Modlesky, Bickel, Slade, Meyer, Cureton, & Dudley, 2004). Results suggest that skeletal atrophy and/or increased intramuscular fat as a percentage of skeletal mass may be linked to glucose intolerance, insulin resistance and later on **type II diabetes** (Gorgey & Dudley, 2007) (Elder, Apple, Bickel, Meyer, & Dudley, 2004). The incidence of type II diabetes characterized by high blood glucose levels and insulin resistance is also elevated in SCI patients relative to the general population (Cragg, Noonan, Dvorak, Krassioukov, Mancini, & Borisoff, 2013).

Cardiovascular disease is elevated among the SCI population compared to the able-bodied population (Cragg, Noonan, Krassioukov, & Borisoff, 2013) and has become a leading cause of death in SCI patients (Bauman & Spungen, 2008) (Thietje, Pouw, Schulz, Kienast, & Hirschfeld, 2011) (Myers, Lee, & Kiratli, 2007).

Musculoskeletal complications related to reduced bone loading include increased incidence of **osteoporosis** and **fractures** (Craven, Robertson, McGillivray, & Adachi, 2009) (Battaglino, Lazzari, Garshick, & Morse, 2012). Respiratory function is also reduced in high-level SCI due to paralysis of thoracic and abdominal muscles. Infections including **pneumonia** are not uncommon (Thietje, Pouw, Schulz, Kienast, & Hirschfeld, 2011) (Soden, Walsh, Middleton, Craven, Rutkowski, & Yeo, 2000) and are a major cause of rehospitalization (DeVivo & Farris, Causes and Costs of Unplanned Hospitalizations Among Persons with Spinal Cord Injury, 2011). **Urinary tract infections** are very common (Soden, Walsh, Middleton, Craven, Rutkowski, & Yeo, 2000) (DeVivo & Farris, Causes and Costs of Unplanned Hospitalizations Among Persons with Spinal Cord Injury, 2011) and **septicemia** or sepsis, a serious and life-threatening immune response to an infection, is a common cause of death (Thietje, Pouw, Schulz, Kienast, & Hirschfeld, 2011) (Soden, Walsh, Middleton, Craven, Rutkowski, & Yeo, 2000).

Finally, **pressure ulcers** (injuries to the skin and underlying tissue resulting from prolonged pressure on the skin) are common and can require expensive hospitalization (DeVivo & Farris, Causes and Costs of Unplanned Hospitalizations Among Persons with Spinal Cord Injury, 2011). Aside from the effects of immobility itself, conditions including bowel incontinence (and associated bacteria), those affecting blood flow such as vascular diseases and even spasms that create friction and shearing can all exacerbate the development of pressure ulcers.

Health care and other costs associated with SCI

Severely decreased mobility after SCI and the chronic and acute medical conditions that can arise from it such as cardiovascular disease, diabetes, respiratory dysfunction, osteoporosis and pressure ulcers all place an increasing economic burden on individuals, their caretakers and health care systems. Given an expected lifespan now very close to that of able-bodied peers, and although SCI is not as frequent as other types of diseases and injury, the costs can be staggering (Cao, Chen, & DeVivo, 2011) (DeVivo, Chen, Mennemeyer, & Deutsch, 2011) (St. Andre, et al., 2011) (DeVivo & Farris, Causes and Costs of Unplanned Hospitalizations Among Persons with Spinal Cord Injury, 2011).

One study has concluded that lifetime direct costs for a person injured at age 25 vary by severity of injury from 2.1 to 5.4 million dollars (Cao, Chen, & DeVivo, 2011). Although studies of the costs associated with SCI in European countries are more limited, two have shown that the direct costs of health care associated with SCI are much higher than that of many other injury-related categories whereas the incidence of SCI is much lower than that of other injury categories (Polinder, et al., 2005) (Meerding, Mulder, & van Beeck, 2006).

Charges for goods and services are commonly used to qualify health care costs. DeVivo, et al (2011) found that overall mean annual health care charges after the first year were close to $80,000. The authors believe this estimate, based on actual goods and services provided, is likely lower than the costs that would be associated with optimal care. While it is possible some people receive more than necessary, it is more likely people receive less than they should due to financial or insurance limitations.

A study specifically of US veterans (St. Andre, et al., 2011) found annual health care costs to be around $45,000 to $50,000. These cost estimates reflect direct Veterans Administration (VA) expenditures for patient care either at VA facilities or at non-VA facilities but paid for by the VA. Cao, et al (2011) found annual health care charges following the first year post-trauma to range from around $33,500 to $150,500 per year depending on injury severity.

Recent studies with updated and more accurate data have shown that the **cost of inpatient care is second only to the cost of attendant care** when it comes to long-term health care cost (DeVivo, Chen, Mennemeyer, & Deutsch, 2011). When assessing the sources of the approximately $80,000 in annual charges, the authors found that rehospitalization charges accounted for one fourth of all annual health care charges (approximately $22,500 per year). Attendant care accounted for slightly more than half or approximately $46,000.

In another study of the charges associated with individual unplanned hospitalizations for various causes among a population with SCI (DeVivo & Farris, Causes and Costs of Unplanned Hospitalizations Among Persons with Spinal Cord Injury, 2011), although urinary tract complications were the most common reason for hospitalization followed by skin complications, the mean charge for skin complications was approximately $76,000 whereas that for urinary tract issues was only $24,000.

The average charges per stay associated with causes related to the musculoskeletal system, cardiac system or respiratory system were approximately $69,000, $46,000 and $30,000, respectively.

Skin conditions and complications, primarily pressure ulcers, are a leading cause of rehospitalization among patients with SCI (DeVivo, Chen, Mennemeyer, & Deutsch, 2011) (St. Andre, et al., 2011) (DeVivo & Farris, Causes and Costs of Unplanned Hospitalizations Among Persons with Spinal Cord Injury, 2011) (Stroupe, et al., 2011) and they are among the most expensive (St. Andre, et al., 2011) (DeVivo & Farris, Causes and Costs of Unplanned Hospitalizations Among Persons with Spinal Cord Injury, 2011).

Another study of veterans (Stroupe, et al., 2011) compared annual health care utilization and costs between veterans with SCI with and without pressure ulcers. Patients with pressure ulcers averaged nearly 52 more total inpatient days than those without and their health care costs were approximately $73,000 higher.

In the study of DeVivo and Farris (2011), skin complications had the longest mean length of stay (approximately 20 days), meaning not only high hospital costs but many days missed from potential employment. Thus, in addition to rehospitalization direct costs, the indirect costs particularly of lost employment due to these secondary or co-diseases, conditions and infections are an important consideration as well. The vast majority of skin complications (95.8%) were pressure sores.

DeVivo and Farris (2011) also found that psychosocial complications such as depression contributed to approximately 7% of rehospitalizations. The authors suggested that prevention of mental health issues could reduce the number of hospitalizations due to other causes and thus the overall cost of health care.

Finally, many studies have found a low or decreased quality of life (QOL) associated with SCI (Boswell, Dawson, & Heininger, 1998) (Budh, 2007) (Stevens, Caputo, Fuller, & Morgan, 2008) (Craig, Tran, & Middleton, 2009) (Lidal, Veenstra, Hjeltnes, & Biering-Sorensen, 2008). Standardized QOL questionnaires (World Health Organization,

1997) (Ware & Sherbourne, 1992) produce a self-assessment of health status reflecting an individual's perception of his/her health and well-being. Research has shown that many parameters of QOL clearly affect physical and mental health (Centers for Disease Control and Prevention, 2000) (Gandek, Sinclair, Kosinski, & Ware Jr., 2004) (McHorney, 1999) (Selim, et al., 2009). In fact, the self-assessment has proven to be a stronger predictor of morbidity and mortality than many other conventional and objective measures of health (Dominick, Ahern, Gold, & Heller, 2002) (DeSalvo, Bloser, Reynolds, He, & Muntner, 2006). Thus, improving QOL in patients with severely limited mobility is expected to have a direct impact on actually improving their physical and mental well-being, thus decreasing the long-term costs of health care both for the patients and their families/caretakers as well as for the national health care system.

Studies support the need to prevent secondary complications to decrease health care costs and improve quality of life in patients with SCI.

FES cycling health benefits in patients with SCI

FES by definition is the electrical stimulation of nerves that innervate muscles, typically in the extremities, to enable those muscles to perform a function. It is commonly applied to patients with partial or total paralysis from events including SCI, stroke and traumatic head injury as well as to treat multiple sclerosis (Ratchford, et al., 2010) (Multiple Sclerosis Trust, 2014) (National Multiple Sclerosis Trust). Its role in treating other diseases and conditions affecting the neuromuscular system is a subject of important research.

FES cycling employs FES of leg, arm and possibly trunk muscles (for posture and tone) to enable **active cycling in which the muscles are doing work**. This is in direct contrast to passive cycling in which the crank or a therapist moves the patient's legs or arms mechanically with no or minimal muscle contractions.

The active therapy has numerous demonstrated health benefits delineated below whereas the passive therapy does not. In fact, **active therapy utilizing FES cycling** has many of the health benefits associated with regular physical activity in the general population including **increasing muscle mass and strength, decreasing fat, minimizing glucose intolerance and insulin resistance and thus overall minimizing the risks for cardiovascular disease and diabetes.** Among the SCI population, it has the added benefit of **reducing the incidence of pressure sores** likely due to increased muscle mass in the gluteal region, increased local circulation and decreased spasticity.

A review of FES cycling studies found consistent improvements in skeletal muscle and cardiovascular measures, metabolic responses and aerobic fitness (Hamzaid & Davis, 2009). Another review of FES cycling systems and clinical applications supported the potential for FES cycling to reduce secondary complications in patients with paralysis (Peng, et al., 2011). The review cited: improved cardiopulmonary function including increased blood flow to the lower extremities; improved muscle function including decreased spasticity, increased strength and endurance; increased insulin sensitivity; and a near elimination of pressure sores due to increased capillary density, blood circulation and muscle mass of gluteal soft tissue.

These results are seen in numerous studies, a few of which are delineated below.

In a case study of a patient classified as a C-2 American Spinal Injury Association (ASIA) Grade A, tetraplegic with assisted ventilation and no substantial recovery in the first five years after traumatic SCI, scientists conducted a regimen of lower extremity FES cycling over a three-year period post-injury. It reversed osteoporosis, increased muscle mass, decreased spasticity, dramatically decreased medical complications and reduced by more than 90% the incidence of infections and the use of antibiotic medications. The health gains allowed the patient to return to work (McDonald, Becker, Sadowsky, Jane, Conturo, & Schultz, 2002).

A regular lower extremity FES cycling regime has been shown to decrease spasticity compared to passive therapy with leg movement only by ergometer (Krause, Szecsi, & Straube, 2008). It has also been shown to enhance cardiorespiratory fitness (Hooker & Scremin, 1995) (Russell Berry, et al., 2008) and lower extremity circulation (Nash, Montalvo, & Applegate, 1996) while increasing insulin-stimulated glucose uptake (Mohr, Dela, Handberg, Biering-Sørensen, Galbo, & Kjaer, 2001) (Jeon, et al., 2002) (Griffin, et al., 2009).

Even up to more than 20 years after injury, lower extremity FES cycling can partially reverse inactivity-associated changes seen in exercise performance capacity and skeletal muscle (Mohr, et al., 1997). Importantly, in this study, **reduction in the frequency of training from three times to once per week was not sufficient to improve glucose tolerance or the insulin response relative to baseline levels.**

Finally, in **a comprehensive study of 45 people with chronic SCI, twenty-five underwent an FES cycling rehabilitation regimen. They were compared to 20 controls matched for age, gender and SCI injury level, severity and duration who received passive stretching typical of the chronic phase of SCI** (Sadowsky, et al., 2013). This study included a large sample number with strong controls and comparison of FES cycling relative to other physical activity. Researchers evaluated a change in neurological function (motor, sensory and combined motor-sensory scores) as well as QOL and functional independence.

The benefits were dramatic. A significantly higher percentage of FES subjects demonstrated improved motor function and sensation on the measures evaluated and their improvements were statistically significant as well. The FES group demonstrated **muscle mass on average 36% higher** than controls and **intra/inter-muscular fat 44% lower**. In addition, hamstring and quadriceps **muscle strength was 30 and 35% higher**, respectively, in the FES group. In contrast to the general belief that increasing muscle strength in a spastic muscle increases spasticity, **spasticity and the daily dosage of anti-spasticity medications were successfully reduced** rather than increased in FES subjects despite the increase in muscle strength. Finally, the FES group demonstrated

significantly higher QOL in the physical domain and significantly higher daily function measures.

Numerous other studies conducted within the last four years, the majority specifically using the RT300 FES ergometer, have demonstrated improvements in QOL (Dolbow D. , Gorgey, Cifu, Moore, & Gater, 2012) (Dolbow D. , Gorgey, Moore, & Gater, 2012) (Dolbow D. R., Gorgey, Ketchum, & Gater, 2013) (Castello, Louis, Cheng, Armento, & Santos, 2012). Given that QOL has been found to be a **very strong indicator of morbidity and mortality**, improving the QOL of SCI patients can rationally be expected to improve their actual physical and mental well-being and potentially contribute to decreasing the lifetime costs of health care.

Increasing muscle mass and circulation in the lower extremities while decreasing spasticity are all ways to **combat pressure ulcers**, one of the leading causes of rehospitalization among individuals with SCI and **by far the most expensive**. Further, the **RT300 system accommodates trunk, back and abdominal stimulation**. FES of lower back muscles has also been **shown to reduce or even prevent the occurrence of pressure sores** (Vanoncini, Holderbaum, & Andrews, 2010).

Finally, the benefits of FES cycling have also been recorded in children ages five to 13 years old and may contribute to reduced risk for cardiovascular diseases, insulin resistance, glucose intolerance and Type II diabetes as they progress to adolescence and adulthood (Johnston, Modlesky, Betz, & Lauer, 2011). Clearly, an early intervention and therapy in young patients has the potential to even more drastically reduce the long-term costs of health care.

Conclusions

The typical SCI population has severely limited physical activity due to a combination of factors including paralysis, transportation barriers and limited access to rehabilitation/wellness facilities. FES cycling has proven health benefits as the literature confirms that **FES systems such as the RT300 FES cycle can improve a number of measures of health including those linked with the most expensive causes of rehospitalization.** Further, these benefits are not achievable with limited physical activity, as is the case in the general population. Able bodied individuals can remain in relatively good health with a minimum level of activity unlike those with SCI.

It would be nearly impossible to maintain a FES cycling regimen of at least three times per week over the course of a patient's lifetime without a home cycle. Therefore, **a home FES cycling system for patients with SCI can make an invaluable contribution to improving the health and QOL of patients and to decreasing the health care costs and rehospitalization associated with the long-term complications of severely limited mobility**.

In further support of the justification for funding a home-based FES cycling system, research has shown that exercise **adherence rates to a home-based FES lower**

extremity cycling program were nearly double the exercise adherence rates in the able-bodied population (Dolbow D. , Gorgey, Ketchum, Moore, Hackett, & Gater, 2012).

Finally, the **cost of the RT300 system for home use is a small fraction of the cost of a single hospitalization for a pressure ulcer**. In other words, preventing even one hospitalization for a pressure ulcer would enable a tremendous cost savings for patients and the health care system even after the cost of the RT300 system. Needless to say, given the broad range of health benefits possible with FES cycling, the savings are expected to be far greater than a single visit to the hospital for pressure ulcer treatment.

RT300 provides intense electrical stimulation (currents up to 140mA) to specific muscle groups. It achieves strong, coordinated muscle contractions in arms and legs to create a therapeutic level of patterned neural activity and movement and which would not otherwise be possible in patients with severely limited mobility. RT300 is **NOT** utilized by persons without disease or disability nor will it have any profound effect on a person without disease or disability who is able to achieve activity volitionally.

The percentage of individuals with SCI who achieve the recommended duration and frequency of weekly physical activity is extremely low.

Given that SCI patients who participate in an FES rehabilitation regimen demonstrate improvements in physical and mental condition and in QOL, **good medical practice requires that suitable patients be prescribed FES cycle therapy**. RT300 FES cycling has the potential **to minimize the decline in health** that would otherwise inevitably arise as a result of reduced mobility. In addition, the cost-benefit analysis produces the same conclusion, this time from an economic standpoint. Given that RT300 FES cycling has the potential **to significantly reduce the lifetime costs of health care** for the patients, their caretakers and the health care system, **sound health care management** requires that suitable patients be prescribed FES cycle therapy.

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