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Final Narrative Report

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New Jersey Commission on Spinal Cord Research - Final Narrative Report

1) Original Aims of the Project

Walking upright is one of the defining features of humans. The inability to walk due to spinal cord dysfunction has profound effects on patients, both physiologically and psychologically. Physiological complications associated with the loss of walking include a significant loss of muscle mass due to disuse atrophy and a significant reduction in bone mineral density resulting in severe osteoporosis, especially of the long bones of the lower extremities. (Cameron & Calancie, 1995; Chow et al., 1996; Garland et al., 1992; Gefen, Gelmann, Herbison, Cohne, & Schmidt, 1997; Gordon, 1995; Gordon & Mao, 1994; Keating, Kerr, & Delargy, 1992; Lieber, 1986; Lieber, Friden, Hargens, & Feringa, 1986; Lieber, Johansson, Vahlsing, Hargens, & Feringa, 1986; Needham-Shropshire, Klose, Tucker, & Thomas, 1997; Ragnarsson & Sell, 1981; Rodgers et al., 1991; Saltzstein, Hardin, & Hastings, 1992; Szollar, Martin, Parthemore, Sartoris, & Deftos, 1997; Wilmet, Ismail, Heilporn, Welraeds, & Bergmann, 1995) Additional significant complications include an increased risk of pressure ulcerations, deep venous thromboses, and compromised cardiovascular endurance due to lack of regular exercise. Finally, the psychological impact of the loss of ambulation can be quite profound and result in a significant negative impact on sense of well being and sense of control over one's life. (Dijkers, 1999)

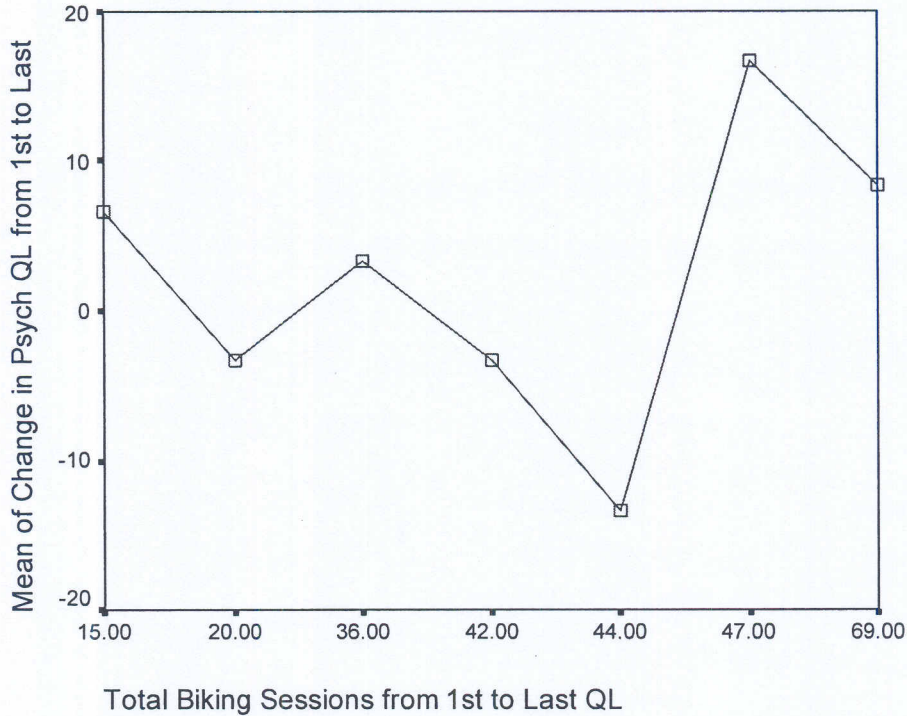
Functional Electrical Stimulation (FES) of the lower extremities has been found to reverse many of the complications associated with the loss of ambulation. Briefly, patients with lower extremity paralysis are placed on a cycle ergometer. Electrodes are placed on the thighs, hamstrings, calves, and other appropriate muscle groups and attached to a signal generator that systematically stimulates muscle contraction so that pedaling the cycle is achieved. Of note, stimulation of muscles through the use of skin electrodes is painful and is limited to patients who are insensate. While patients have no volitional control of their legs, studies in adults indicate increases in muscle mass and bone mineral density, as well as in cardiovascular endurance. However, no studies have been done in children to examine these effects.

Our aim was to examine the use of FES in children who have suffered a loss of ambulation due to spinal cord dysfunction and as a result are insensate in the lower extremities. We hoped to examine the effect of FES on muscle mass and bone mineral density in order to determine if FES can reverse or forestall the decrease in each. We also sought to examine the effects of regular exercise using FES on the psychological well-being of children with spinal cord dysfunction.

2) Project Successes

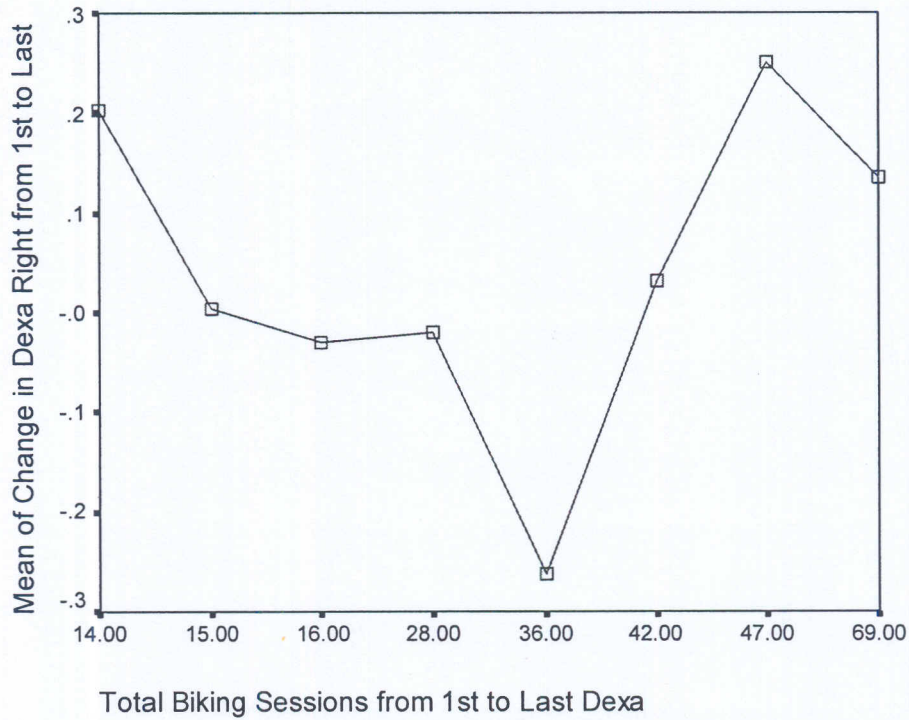
The main success of this project was seen in the delight of the children who were able to participate on a regular basis. They reported enjoying the ability to exercise like their non-injured peers. An improvement in psychosocial quality of life was reported by 57% of the participants who completed the PedsQL questionnaire pre- and post-intervention. The two children who exercised the most regularly reported the greatest increase in quality of life across the intervention period (see Figure 1, below).

Figure 1. Change in quality of life from first to last PedsQL questionnaire by number of biking sessions.



In a population of children who would be expected to have a decrease in bone mineral density over time due to lack of exercise, 63% of our participants either maintained or increased bone density from the beginning to the end of their exercise period (see Figure 2 below). Also, although the level of spinal cord injury of all of the children who biked regularly placed them at risk for dysreflexia, no children experienced any episodes of dysreflexia during their biking sessions.

Figure 2. Change in bone mineral density from first to last dexa scan by number of biking sessions.



Note: There was one outlier in the data, the child who biked 36 hours and showed a comparatively sharp decrease in bone mineral density. As it was beyond the scope of this project to measure other factors that contribute to bone mineral density, such as calcium and vitamin D intake, degree of spasticity, etc., we do not know what accounted for this result.

We believe this work supports the conclusion of the group at Shriners Hospitals for Children that has shown that FES cycling appears to be an option that may have positive health benefits for children with spinal cord injury (Johnston, Lauer, Smith, & Betz, 2007; Johnston, Smith, Oladeji, Betz, & Lauer, 2008). Given the issues we faced with access to the exercise equipment when housed at our site, we believe this is a viable method for providing exercise to children with spinal cord injury. However, the equipment needs to be readily accessible in the home environment in order to be of maximum benefit.

3) Project Challenges

The main challenge encountered in this project involved recruitment and retention of participants. This was due to our inability to provide transportation to Children's Specialized Hospital. Our plan was that participants would exercise 3 times per week for 9 months, for an average of 12 sessions per month. Given the level of funding, it was not possible to include transportation to CSH in the project budget. Great effort was put into recruitment of children to participate in this project. The need to arrange their own transportation negatively affected these efforts, and it was extremely difficult to find families who were able to commit to this schedule. While the children who exercised on the FES bike reported that they enjoyed using it and were delighted at the prospect of exercising like their non-injured peers, it was very difficult for them to come in for the exercise sessions on a regular basis. The group mean for months of participation was 6.2 months; however, the range was from 1 to 9 months. The mean number of

sessions per month, based upon the number of months each participant exercised, was 5.6 sessions; however, the range was from 2.5 to 8.4 sessions per month. Hence, the majority of participants either exercised for a short period of time and then stopped, or exercised sporadically over the 9 month period. For example, one participant exercised 3 times during the first month and then stopped, while one participant exercised for 8 months but had a mean of only 2.5 sessions per month with a range from 1 to 4 sessions. The most dedicated participant exercised for a total of 69 sessions over the entire 9 months, with a mean of 7.7 sessions per month with a range of 6 to 11 sessions. The child with the second highest number of sessions (47 over 9 months) showed the greatest increase in reported quality of life, as well as the greatest increase in bone mineral density in the right distal femur. This suggests that both time and consistency are of great importance if an intervention of this type is to be effective.

4) Implications for future research and/or clinical treatment.

There is evidence from research conducted at Shriners Hospitals for Children that FES cycling, when used regularly by children with spinal cord injury, contributes to increased bone mineral density in the hip, femur, and tibia (Johnston et al., 2007). However, participants in this study stayed in house for two weeks and then went home with the exercise equipment. Compliance at 6 months was greater than 90% (Richard Lauer, personal communication). Combined with these results, our experience has shown us that the best way to recruit and retain children in a program of this type is to eliminate the transportation issue and provide them with FES cycles in their homes. This involves an additional cost of \$15,000 to \$20,000 per child. The only other solution, which has yet to be tested, would be to provide transportation at least three times per week between home and the intervention site for each child. This would be less efficient and could lead to even greater cost than providing the children with their own bikes. In order to study the effects of FES cycling on bone mineral density, we also think it is important in future research to consider measures of other factors that are known to affect bone mineral density, such as calcium and vitamin D intake, and degree of spasticity.

As a result of this study, Children's Specialized Hospital continues to provide FES cycling clinically to patients as part of both the inpatient and outpatient spinal cord therapy programs.

5) Plans to continue this research, including applications submitted to other sources for ongoing support.

In the future, we plan to work with a small group of interested families in order to seek funding from foundations or the families' insurance companies for cycles to be placed in the home. This will allow us to gather much more valid and consistent data on a greater number of children.

6) List and include a copy of all publications emerging from this research, including those in preparation.

None to date. We are planning to pursue options for writing up and publishing our results.

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