Medical and Rehabilitation Innovations
Functional Electrical Stimulation Ergometer
(FES Bike)
BACKGROUND

Functional Electrical Stimulation Ergometers, or FES bikes, allow users to cycle by applying electrical stimulation to peripheral nerves that control the larger lower extremity muscles of gluteus, quadriceps, and hamstrings. This process simulates and creates active exercise for a disabled worker who would otherwise be unable to do so.

Spinal cord injury (SCI) patients with complete and incomplete tetraplegia/paraplegia are associated with significant cardiovascular deconditioning, muscle atrophy, change in muscle morphology, osteoporosis from bone demineralization, and decreased range of motion from contractures. The aforementioned conditions predispose SCI injured workers to obesity, diabetes, cardiovascular disease, metabolic syndrome, and worse overall health outcomes over time.

The clinical hypothesis behind FES bike utility involves the presumptive health benefits associated with exercise. This includes reducing the risk for diabetes, cardiovascular diseases and osteoporosis, and increasing muscle strength and endurance. Other potential benefits include improving the overall health of SCI injured workers while decreasing both the long-term medical complications and the cost of care associated with chronic SCI conditions.

A number of published studies and research articles have looked at the benefits of FES bikes on a limited number of clinical endpoints. These suggest some therapeutic benefits to physical conditioning, and increasing aerobic capacity and muscle volume or muscle cross-sectional area. However, to date there has not been any definitive study that demonstrates improved health outcomes, such as weight reduction (change in BMI), lipid reduction, prevention of cardiovascular disease or reduced overall bone density, in adult SCI patients utilizing FES bikes.

LITERATURE SUMMARY

The following summarizes the current conclusions from the medical literature to date.

1. In SCI with complete motor loss below the level of T12, FES bikes may not be effective since these SCI patients do not respond to stimulation due to lower motor neuron injury.\(^1,2\)
2. FES bike use appeared to be a feasible alternative to upper body exercise for SCI patients and required 4-8 hours per week of FES cycling to reach the recommended weekly exercise caloric expenditure.\(^2\)
3. 30 minutes of FES cycling per day, three times per week, for 10 weeks improved muscle mass, endurance, and glucose tolerance. There was no significant difference in bone or fatty tissue.\(^3\)
4. High volume FES cycle training partially reversed bone loss and increased total bone mineral density in the distal femoral epiphysis but no changes were seen at the tibia. Participants worked up to 5 sessions per week of 60 minutes/session with 76.6% compliance.\(^4\)
5. High volume FES cycle training increase cardiopulmonary fitness and bone parameters of paralyzed limbs in tetraplegia; however, if training is not maintained, these improvements are lost.\(^5\)

6. In Tetraplegia at C4 and above, there are limited options for any cardiovascular workouts or exercises other than FES bikes.\(^2\)

**PARADIGM OUTCOMES’ POSITION**

FES bike use has been shown to increase aerobic capacity and muscle mass in those with SCI and upper motor neuron injury. The current indication for FES bike utility most supported by the literature is the potential for aerobic exercise benefit on the overall health of SCI patients.

Paradigm supports the use of FES bikes in the following candidates:

1. Injured worker with tetraplegia at C4 and above.
2. Injured worker with tetraplegia (complete or incomplete) or paraplegic with permanent inability to use upper extremities for strength and endurance.
3. Injured worker with paraplegia above T12 who has demonstrated enduring commitment to active involvement in a high intensity upper extremity exercise program and will further benefit from or require increased aerobic capacity and conditioning.

If a candidate meets one of the above categories, then the following needs must be addressed before approving the purchase:

1. No medical contraindications.
2. The injured worker has been evaluated for and properly trained to use a FES bicycle by an expert professional therapist.
3. Those who may qualify should prove they have the ability to use the equipment at the intensity of exercise demonstrated to be effective. Only those who reach and tolerate the exercise intensity and frequency consistent with research protocols have been shown gain in measurable parameters.\(^6\)
4. The injured worker should be able to use the FES bicycle equipment in the home-based setting safely and at an intensity and frequency consistent with research protocols—at least a half hour per day, 3 to 5 days per week.
5. Candidates should exhibit a history of compliance with treatment that would predict compliant and safe use of the device, that is, they should be cooperative in all therapies and performing at a level consistent with their physical capacity.
6. Candidates should have the physical resources to accommodate this piece of durable medical equipment. Their residence should be able to readily and safely accommodate an FES Bike.
7. Candidates should not have any contraindications to use, such as cardiac disease, critical respiratory disease, ventilator-dependency, advanced age, exercise induced illness, fixed contractures, severe osteoporosis with risk for pathological fracture, or skin breakdown in areas that would be stressed.
8. The candidate’s health status needs to be routinely monitored by a rehabilitation physician since FES, although researched, may have unintended negative consequences.
In addition, bone, muscle, skin and joint integrity should be fully re-checked on an annual basis.

9. The Paradigm Medical Director shall review the attending physician’s “letter of medical necessity” to ensure that all guidelines for use are being followed.

Summary

Help: There appears to be an aerobic exercise benefit for tetraplegics and under some special circumstances for paraplegics.

Hope: Use of the device may help reduce the risk of osteoporosis pressure ulcers, cardiovascular disease and diabetes.

Hype: There is presently no evidence to support claims of spasticity reduction or neurologic recovery.

ENDNOTES

References

6. “Functional Stimulation for SCI.” Deborah Backus, PT, PhD, and Candace Rae Tefertiller, MPT, ATP. May 2007; Physical Therapy Products

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