

# ACADEMY OF SPINAL CORD INJURY PROFESSIONALS

## Effects of the Cough Stimulator on Family Caregiver Burden of Subjects with Tetraplegia



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### ABSTRACT

**Background:** Patients with spinal cord injury (SCI) suffer from a high incidence of recurrent respiratory tract infections including bronchitis and pneumonia due to their inability to cough and clear secretions. The plight of the caregiver however is often given much less attention.

**Objective:** To evaluate caregiver burden (CB) in family caregivers of tetraplegics before and after use of the Cough Stimulator (CS).

**Design:** Questionnaire (Caregiver Burden Inventory, CBI) administered to family caregivers of tetraplegic subjects at the 6-month, 1- and 2-year mark following use of the CS. Questionnaire A was assembled with a focus on the Respiratory Care Burden Index. The CBI survey (Questionnaire B) was composed of 24 questions on five subscales: time-dependence, developmental, physical, social, and emotional burden. Each question was rated on a five-point scale (0-Never, 1-Rarely, 2-Sometimes, 3-Quite Frequently, 4-Nearly Always) with a higher score suggesting higher burden. Ease in raising secretions and incidence of acute respiratory tract infections were also evaluated in tetraplegic subjects before and after use of the CS.

**Participants:** 15 family caregivers completed the CBI before and at the 6-month, 1-year and 2-year timepoints following use of the CS. SCI subjects had significant clinical improvements in terms of restoration of an effective cough and ability to manage airway secretions with use of the CS. Restoration of expiratory muscle function with use of the CS also resulted in less CG stress, less interference with other CG responsibilities, greater control of their subjects' breathing problems, and improvement in quality of life. Results of the CBI demonstrated marked reductions in caregiver burden in all 5 dimensions. Overall caregiver burden fell from 43.4 pre-implant to 32.4, 31.7, and 26.5 at the 6-month, 1-year and 2-year timepoints (p<0.01, for each).

**Conclusion:** CB in family caregivers of tetraplegic subjects was very high but improves significantly with use of the CS.

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**Non-Financial Disclosure Statement:** Dr. DiMarco holds two United States Patents for technology related to the content of this work: Method and Apparatus for Electrical Activation of the Expiratory Muscles to Restore Cough (5,999,855); Bipolar Spinal Cord Stimulation to Activate the Expiratory Muscles to Restore Cough (8,751,004).

### INTRODUCTION

The impact of cervical spinal cord injury (SCI) on the individual affected is usually quite devastating as these subjects suffer from severe motor and sensory deficits resulting in severe mobility impairments. In addition, their plight is compounded by autonomic deficits including bowel, bladder and sexual dysfunction, respiratory and genitourinary infections, chronic pain, skin breakdown and psychological disorders. Also, critically important but given much less emphasis, is the loss of respiratory muscle function, resulting in dyspnea and the inability of these subjects to generate an effective cough. Following discharge from the acute hospital setting or from a rehabilitation center, patients with SCI are often cared for at home by family members. These family caregivers (CGs), however, are often untrained and unprepared to undertake the multiple needs of SCI patients. Consequently, caregiving of SCI patients often imposes a multi-dimensional toll and significant burden on the CG. In the present study, we hypothesized that restoration of expiratory muscle function and restoration of an effective cough via the cough stimulation system (CSS) which has been shown to improve respiratory secretion management, reduce the incidence of respiratory tract infections and improve subject quality of life, would also impart a significant improvement in CB and quality of life of the family CG.

### METHODS

**Caregiver Participants:** n=15

**Outcome Measures:** Questionnaires related to Caregiver Life Quality, were collected.

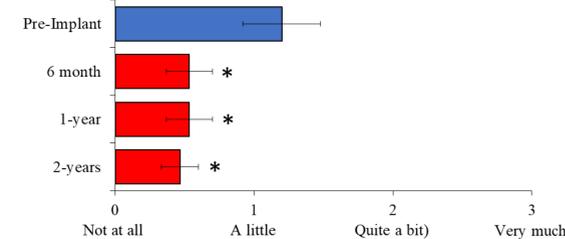
**Data Analysis:** Data obtained prior to implantation were compared with data obtained after implantation of the CS using a nonparametric analog (Dunnnett test) to the standard repeated measures analysis of variance. The internal consistency of the CB index was assessed by Cronbach's  $\alpha$  coefficient. A value of 0.70 and above was considered satisfactory. Results are reported as means  $\pm$  SEs. Statistical significance was assumed at  $P \leq 0.05$ . This alpha level was chosen as a correction for inflated type I error rates due to multiple comparisons.

**Study approved by:** The Institutional Review Board at MetroHealth Medical Center, the Food and Drug Administration (IDE G980267) and the National Institutes of Health (NIH)

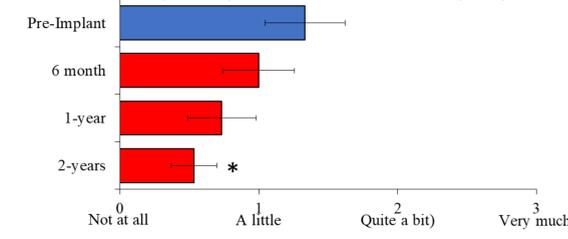
### RESULTS

#### Questionnaire A: Respiratory Care Burden Index

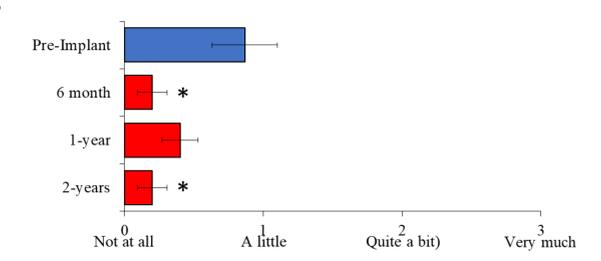
**1.** To what extent did providing assistance with managing the airway secretions of the person you care for cause you stress?



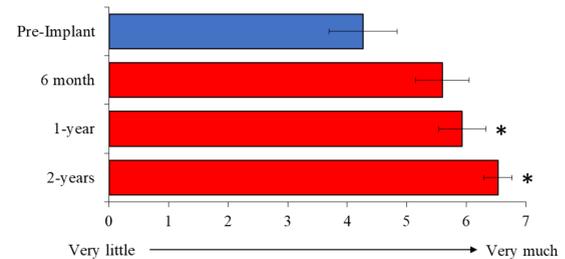
**2.** To what extent did providing assistance with managing the airway secretions of the person you care for interfere with your personal activities?



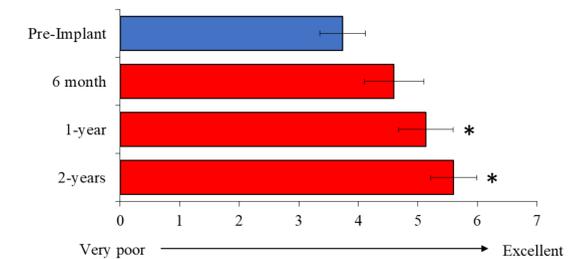
**3.** To what extent did you feel a sense of fear or panic when providing care?



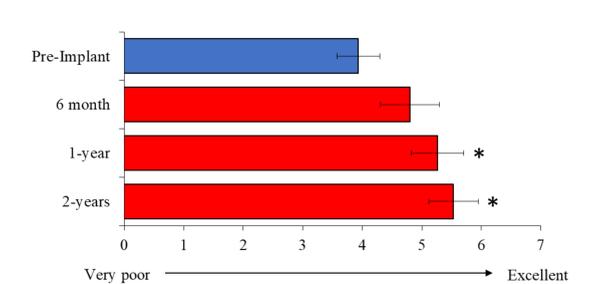
**4.** To what extent did you feel in control of the breathing problems to whom you provide care?



**5.** How would you rate your satisfaction with your personal life since the last visit?



**6.** How would you rate your overall quality of life?



### SUMMARY AND CONCLUSION

**Conclusion:** Use of the CS by cervical SCI subjects results in restoration of an effective cough with significant clinical benefits. While caregiver burden is very high in primary family caregivers, they derive marked improvement in caregiver burden and quality of life within 6-months of implementation of this device which was sustained long-term at the 2-year timepoint.

