

**Orthopaedic Section of the APTA
Grant Program
Final Report Form**

Date: June 19, 2017

Name of Investigators: Rogelio A. Coronado, Kristin R. Archer, Clinton J. Devin

Name of Grant: Early Postoperative Exercise after Anterior Cervical Discectomy and Fusion: A Pilot, Randomized Controlled Trial

Award Period: June 1, 2016 to May 31, 2018

1. Summary of accomplishments in the past year:

Over the past year, we have dedicated significant effort and resources to participant recruitment/enrollment and data collection. We aimed to enroll and randomize a total of 96 participants after anterior cervical discectomy and fusion (ACDF) over the 2-year period. Our initial projection was to enroll 75% of our sample (n = 72) by July 15, 2017. Currently, we have enrolled and randomized 29 participants after ACDF and successfully completed data collection (e.g., up to 6-month follow-up) for 22 participants. We have not reached our initial goal for participant recruitment for two reasons. First, two of three primary surgeons at VUMC who perform ACDF surgeries have relocated to other institutions in the past year. Second, there have been adjustments to insurance plan, namely BCBS of Tennessee, which we suspect have impacted patient decision-making for undergoing ACDF. Regardless, we have made significant efforts to approaching all patients at VUMC considering ACDF for enrollment. This year, we presented preliminary data on the feasibility and safety of the early home exercise program at the Combined Sections Meeting of the American Physical Therapy Association (APTA).

2. Provide a one-paragraph summary of results or abstract suitable for posting on the Orthopaedic Section website. (The following abstract was presented at the 2017 Combined Sections Meeting of the APTA):

Purpose/Hypothesis: Anterior cervical discectomy and fusion (ACDF) is the most common surgery for cervical spine conditions. Poor outcomes after ACDF have been linked to impaired muscle functioning from postsurgical disuse and deconditioning. Postoperative exercise can counteract the effects of deconditioning and promote an increase in self-efficacy. To date, no study has determined whether performance of an early home exercise program (HEP) is safe and efficacious for improving ACDF outcomes. The purpose of this case series is to describe the clinical efficacy and safety of an early HEP performed within the first 6 weeks after ACDF surgery.

Number of Subjects: Five consecutive patients (mean \pm SD age = 53.0 \pm 12.4 years, 4 females) who underwent ACDF surgery.

Materials/Methods: Patients were given a 6-week HEP to be started immediately following hospital discharge after ACDF. The HEP intervention included daily walking, deep breathing, distraction techniques, cervical (limited to 30 degrees) and upper body range of motion, cervical and shoulder isometrics, abdominal strengthening, and shoulder theraband exercises. Compliance (e.g. days completing exercise) and adverse events during the 6-week exercise phase were monitored using a diary log and weekly calls with a physical therapist. Patient-reported outcomes for neck and arm pain (Numeric Rating Scale), disability (Neck Disability Index), and physical and mental health (SF-12) were assessed preoperatively, after completing the HEP (6 weeks after surgery) and at 6-month follow-up. Self-efficacy (Pain Self-Efficacy Questionnaire) was measured at baseline, 6 weeks, and 6 months after surgery. Minimal clinically important differences were used to determine meaningful change in pain (2.6 points), disability (7.5 points), physical (8.1 points) and mental health (4.7 points), and self-efficacy (11 points). Safety was assessed with radiographic imaging at 6 months.

Results: After surgery and the early HEP, a majority of patients reported meaningful change in disability (4 patients at 6 weeks; 5 patients at 6 months), arm pain (4 patients at 6 weeks and 6 months), neck pain (4 patients at 6 weeks; 3 patients at 6 months), and self-efficacy (3 patients at 6 weeks and 6 months). Two patients reported meaningful change in mental health at 6 weeks and 6 months. Only 1 patient reported meaningful change in physical health at 6 months. No adverse events were reported during the 6-week exercise phase. The average number of days performing exercises was 33 days (79% of the 6-week period) with a range of 27 to 37 days (64% - 83%). Radiographic imaging did not show any signs of abnormal healing after fusion.

Conclusions: The findings of this case series suggest that an early HEP can be safely implemented immediately after surgery and may positively affect ACDF outcomes.

Clinical Relevance: These data support the early implementation of exercise after cervical spine fusion surgery with potential long-term benefits and no apparent safety concerns. Future trials will determine the effectiveness of an early HEP after ACDF.

3. Attach a list of your publications published or accepted during the past year, or currently being written. Send reprints when available. List presentations made and abstracts accepted for presentation based on this work. Indicate with an asterisk (*) those publications support by Orthopaedic Section funding.

Publications:

1. *Coronado RA, Devin CJ, Van Hoy EE, Haug CM, Vanston SW, Aaronson OS, White DK, Archer KR. Feasibility and safety of an early home exercise program after anterior cervical discectomy and fusion: a case series. Manuscript in preparation.

2. Coronado RA, White DK, Bird ML, Buchowski MS, Aaronson OS, Cheng JS, McGirt MJ, Devin CJ, Wegener ST, Archer KR. Physical activity and function after lumbar spine surgery. Manuscript in preparation.
3. Bialosky JE, Beneciuk JM, Bishop MD, Coronado RA, Gay CW, Simon CB, George SZ. Unraveling the mechanisms of manual therapy: modeling an approach. *J Orthop Sports Phys Ther*. In review.
4. Archer KR, Coronado RA, Wegener ST. The role of psychologically informed physical therapy for musculoskeletal pain. *Curr Phys Med Rehabil Reports*. In review.
5. Archer KR, Ehde DM, Coronado RA, Vanston SW, Koyama T, Phillips SE, McGirt MJ, Spengler DM, Aaronson OS, Cheng JS, Devin CJ, Wegener ST. Fear of movement and pain self-efficacy as mediators for a targeted postoperative rehabilitation intervention: changing behavior through physical therapy. *J Pain*. In review.
6. Simon CB, Valencia C, Coronado RA, , Wu SS, Dai Y, Farmer KW, Moser MW, Wright TW, Fillingim RB, George SZ. Post-operative shoulder pain recovery patterns for a high-risk subgroup defined by genetic and psychological predisposition: analysis of sensory, emotional, and functional domains. *Pain*. In review.
7. Coronado RA, Bird ML, Van Hoy EE, Huston LJ, Spindler KP, Archer KR. Do psychosocial strategies improve rehabilitation outcomes after anterior cruciate ligament reconstruction? a systematic review. *Clin Rehabil*. In review.
8. Cook CE, Coronado RA, Graham JE, Bettger JP. The influence of rehabilitation discharge destination on 30-day rehospitalization rates among older adults receiving lumbar spinal fusion surgery. *The Spine J*. In review.
9. Coronado RA, Seitz AL, Pelote E, Archer KR, Jain NB. Are psychosocial factors associated with patient-reported clinical measures in patients with rotator cuff tears: a systematic review. Accepted for publication in *Clin Orthop Relat Res*.
10. Bishop MD, Coronado RA, Hill A, Alappattu MJ. Where we have been and where we are going: a content analysis of manuscripts published in the *Journal of Women's Health Physical Therapy* from 2005-2015. Accepted for publication in *J Womens Health Phys Ther*.
11. Hill RJ, McKernan L, Wang L, Coronado RA. Changes in psychosocial well-being after mindfulness-based stress reduction: a prospective cohort study. *J Man Manip Ther*. 2017; 25(3):128-36.
12. *Coronado RA, Simon CB, Lentz TA, Gay CW, Mackie LN, George SZ. Optimism moderates the influence of pain catastrophizing on shoulder pain outcome: a longitudinal analysis. *J Orthop Sports Phys Ther*. 2017;47(1):21-30. PMID: 27819191.
13. Yang AJ, Coronado RA, Hoffecker L, Gao C, Saurwein K, Shoreman D, Hoffberg AS, Akuthota V. Conservative care in lumbar spine surgery trials: a descriptive literature review. *Arch Phys Med Rehabil*. 2017; 98(1):165-72. PMID: 27576191.
14. Banks SD, Coronado RA, Haislip L, Abraham CM, Conrad BN, Morgan VL, Archer KR. Thalamic functional connectivity in mild traumatic brain injury. *Arch Phys Med Rehabil*. 2016; 97(8):1254-61. PMID: 27085849.

15. Valencia C, Coronado RA, Simon CB, Wright TW, Moser M, Farmer K, George SZ. Pre-operative physical therapy treatment was not predictive of post-operative pain and disability outcomes: a prospective study. *J Pain Res.* 2016; 9:493-502. PMID: 27462174.

Presentations:

1. *Clinical efficacy and safety of an early home exercise program after anterior cervical discectomy and fusion: a case series. Poster presentation at the American Physical Therapy Association Combined Sections Meeting, San Antonio, TX, February 2017.
 2. *A randomized trial of early home exercise versus usual care after anterior cervical decompression and fusion for degenerative cervical spine conditions. Grant progress report presentation at the Cervical Spine Research Society Annual Meeting, Toronto, Ontario, Canada, December 2016.
4. Provide a budget, using the original approved budget. Indicate total funds spent to date per major categories. If there was $\geq 25\%$ deviation (greater or less spent) of use of funds for any of the budget category, please BRIEFLY indicate the rationale.

See attached budget summary as of 4/30/17. Budget variation from the initial plan was due to the allocation of resources to recruitment efforts (i.e., research personnel) and the low total enrollment. The estimated costs for recruitment were higher than anticipated as we needed to cover efforts to recruit at 3 different clinical sites to try and boost enrollment.

5. Objectives for the next year:

Our objectives for this year are to 1) continue efforts for participant recruitment as outlined in our original timeline, 2) maintain a high (>85%) follow-up rate with our current participants at 6 months, 3) generate preliminary data analyses to be used for an upcoming NIH NIAMS R21 submission, and 4) submit our feasibility and safety manuscript to a peer-reviewed journal by August 2017.

Signature:  _____

Date: June 19, 2017