

# **Sleep Quality after Arthroscopic Rotator Cuff Repair: Preliminary Results from a Prospective, Randomized Trial**

Anya Hall, Donghoon Lee, John Hayden Sonnier, Ryan W Paul, Richard Eli-Huie Campbell<sup>1</sup>, Bradford S Tucker, Matthew D Pepe, Kevin Blake Freedman<sup>2</sup>, Fotios Paul Tjoumakaris

<sup>1</sup>UVA Medical Center, <sup>2</sup>Rothman Institute

## **INTRODUCTION:**

Sleep disturbance is a significant symptom associated with both rotator cuff tears and arthroscopic rotator cuff repair. Melatonin has been shown to be safe and effective in managing multiple sleep disorders, including secondary sleep disorders, with relatively minor adverse effects, and lack of addictive potential. There is currently no published literature assessing the use of melatonin after orthopaedic surgery, or specifically shoulder surgery. The purpose of this study was to evaluate the effectiveness of melatonin for the reduction of sleep disturbance following arthroscopic rotator cuff repair.

## **METHODS:**

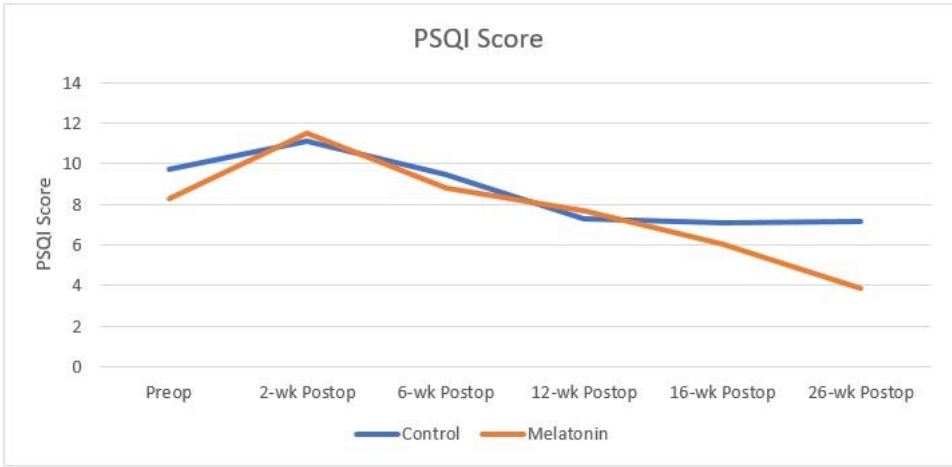
This is a prospective, randomized, patient-blinded clinical trial evaluating patients undergoing arthroscopic rotator cuff repair. Exclusion criteria included history of alcohol abuse, current antidepressant or sedative use, revision rotator cuff repair, severe glenohumeral arthritis, and concurrent adhesive capsulitis. Patients were randomly assigned in a 1:1 ratio to one of two groups: 5 mg dose of melatonin 1 hour before bedtime, or standard sleep hygiene (6+ hours per night, avoid caffeine and naps in the evening). Patients in the melatonin group took their assigned melatonin dose for 6 weeks beginning the day of surgery. Patient-reported outcome assessments (Pittsburgh Sleep Quality Index (PSQI), the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), Single Assessment Numerical Evaluation (SANE), pain medication chart, and melatonin adherence (if in the melatonin group)), were collected preoperatively, as well as at 2, 6, 12, 16, and 26 weeks postoperatively. Numeric variables were analyzed using paired and unpaired t-tests, with significance set at  $P < 0.05$ .

## **RESULTS:**

Fifty-three patients are included in this analysis (25 control, 28 melatonin). Mean age at surgery was 59.8 years for control patients and 61.7 years for melatonin patients, and did not differ between groups ( $P = 0.440$ ). Sex ratio did not differ between groups (7 female/18 male control, 10 female/18 male melatonin,  $P = 0.760$ ). Patients in the control group had no statistically significant change in PSQI scores during the 26-week follow-up period ( $P \geq 0.091$ ). Patients taking melatonin had a decrease in sleep quality (according to PSQI scores) from preop to 2-weeks postoperatively ( $P = 0.002$ ), and a significant improvement in sleep quality from preop to 26-weeks postoperatively ( $P < 0.001$ ) [Figure 1]. Patients in the control group had significant improvement in ASES scores from preop to 12-, 16-, and 26-weeks postoperatively ( $P \leq 0.002$ ), and significant improvement in SANE scores from preop to 16- and 26-weeks postoperatively ( $P \leq 0.007$ ). Patients taking melatonin had significant improvements in ASES scores from preop to 16- and 26-weeks postoperatively ( $P \leq 0.002$ ), and significant improvement in SANE scores from preop to 26-weeks postoperatively ( $P < 0.001$ ). Pointwise comparison revealed no statistically significant differences between groups at any timepoint for ASES, SANE, or PSQI scores ( $P \geq 0.062$ ). Also, there was no difference between groups at any timepoint for change in ASES, SANE, or PSQI scores from baseline ( $P \geq 0.071$ ). Eight of 28 (29%) of patients in the melatonin group missed more than 2 doses of melatonin during the treatment period. Adverse effects to melatonin described by patients during the treatment period include daytime drowsiness ( $n = 7$ ) and headache ( $n = 2$ ).

## **DISCUSSION AND CONCLUSION:**

Melatonin use after arthroscopic RCR leads to a decrease in sleep quality in the first 2 weeks postoperatively, which improves by 26 weeks postoperatively. All patients demonstrated significant improvement in shoulder function, with control patients improving earlier. Patients with significant sleep disturbances associated with rotator cuff repair may benefit from the use of melatonin.



**Figure 1:** PSQI score over time for control patients and patients taking melatonin, where a lower PSQI score represents better sleep quality.