



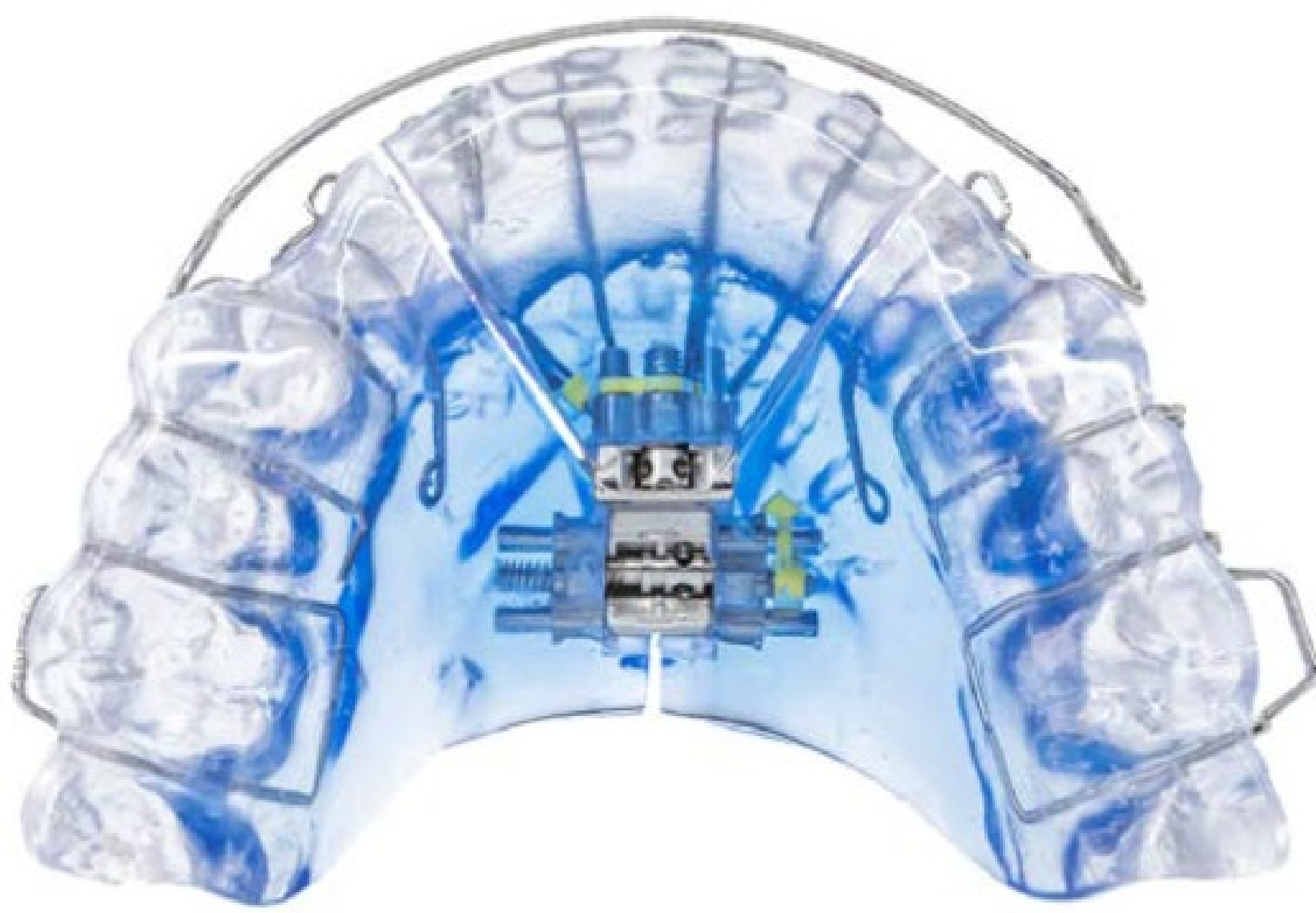
# Complete Airway Repositioning and/or Expansion (CARE): A Novel Oral Appliance Therapy for Headaches Administered by Dentists



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## INTRODUCTION

- Temporomandibular Joint Dysfunction (TMD) is a common problem that exacerbates headaches and significantly decreases quality of life
- CARE (Vivos Therapeutics; Denver CO) is a series of oral appliances that stimulate palatal expansion via applying gentle pressure at the dento-palatal junction
- Via palatal expansion mandibular adjustment and repositioning as well as muscle relaxation decreased tension at the temporo-mandibular joint is possible
- Dentists proficient in the use of CARE deploying it to patients for headache relief have reported significant anecdotal improvements in their patients
- Investigators sought to evaluate claims of headache improvement with CARE use via a database review



**Figure 1.** The Daytime-Nighttime Appliance- A CARE system with Class 1 FDA registration for jaw expansion and tooth alignment

## METHODS & MATERIALS

- IRB exemption determination made by WCG IRB (Protocol ID 20222934)
- Investigators conducted a retrospective review of the Vivos Airway Intelligence Service database- a prospectively collected, real-world database of patients who underwent CARE treatment
- Included patients 18 years of age and older undergoing treatment for headaches with available pre-treatment HIT-6 scores as well as interval or post treatment HIT-6 scores after completing at least 6 months of therapy
- Demographics, treatment information, and HIT-6 scores were reviewed
- Descriptive statistics were generated and statistical significance was assessed via related-samples Wilcoxon Signed rank test

**HIT-6™ (VERSION 1.1)**  
HEADACHE IMPACT TEST™

This questionnaire was designed to help you describe and communicate the way you feel and what you cannot do because of headaches. To complete, please circle one answer for each question.

- When you have headaches, how often is the pain severe?  
Never Rarely Sometimes Very Often Always
- How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?  
Never Rarely Sometimes Very Often Always
- When you have a headache, how often do you wish you could lie down?  
Never Rarely Sometimes Very Often Always
- In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?  
Never Rarely Sometimes Very Often Always
- In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?  
Never Rarely Sometimes Very Often Always
- In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?  
Never Rarely Sometimes Very Often Always

Columns: COLUMN 1 (6 points each), COLUMN 2 (8 points each), COLUMN 3 (10 points each), COLUMN 4 (11 points each), COLUMN 5 (13 points each)

Total Score: Higher scores indicate greater impact on your life. Score range is 36-78.

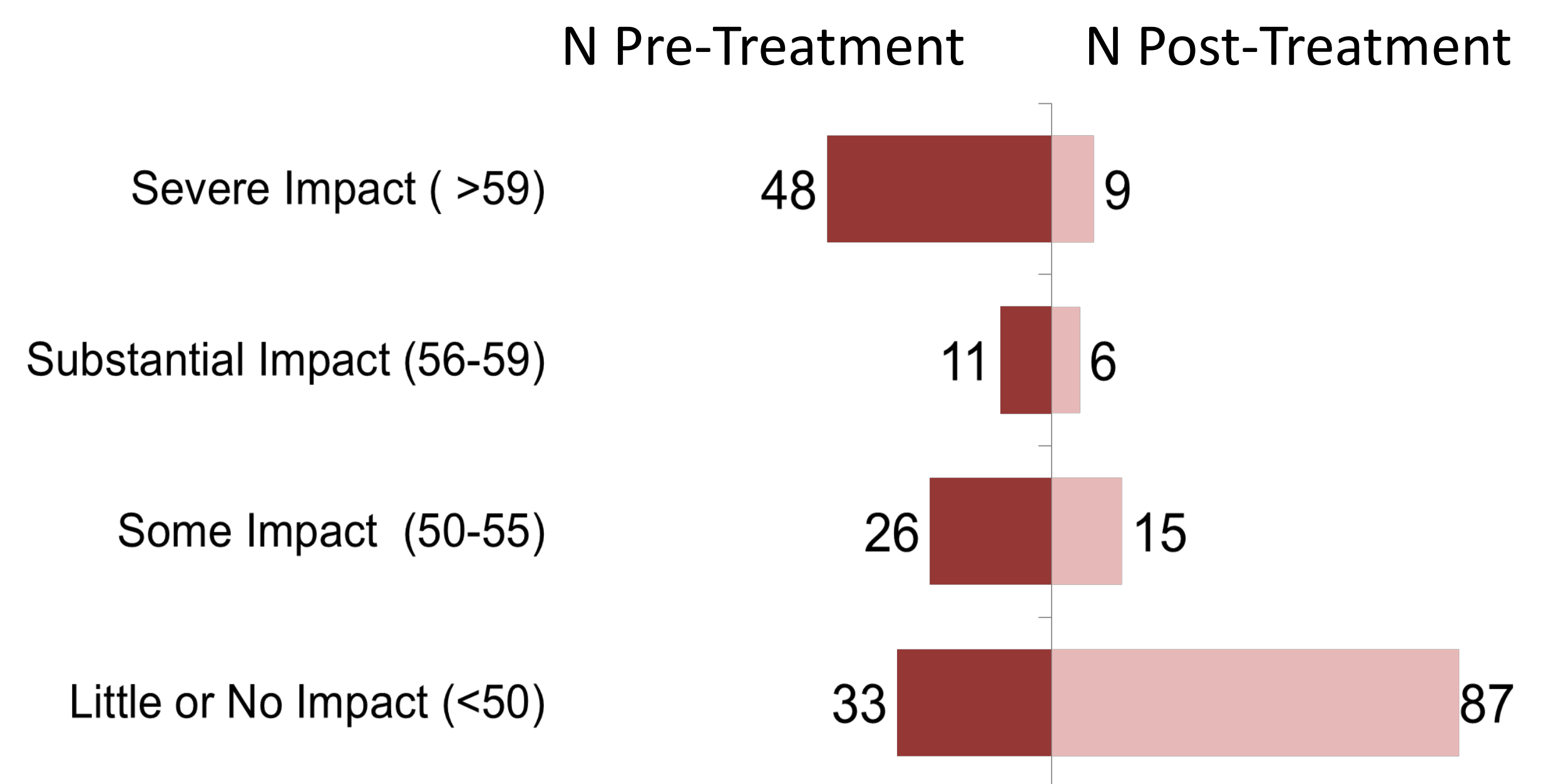
**Figure 2.** The Headache Impact Test (HIT-6) is a brief tool validated to assess the impact of headaches in clinical research and practice

**Table 1. Demographics**

<u>Age- median years (Interquartile Range)</u>	44 (33-54)
<u>Gender #(%)</u>	
Male	43 (35.5)
Female	76 (62.8)
Missing	2 (1.7)
<u>Ethnicity #(%)</u>	
Caucasian	105 (95.5)
Other	5 (4.5)
<u>Pre-Treatment Headache Impact #(%)</u>	
Little or No Impact (<50)	33 (27.3)
Some Impact (50-55)	26 (21.5)
Substantial Impact (56-59)	11 (9.1)
Severe Impact (>59)	48 (39.7)

## RESULTS

- 121 patients were included for review from 4 dental practices across the United States and Canada- demographics in Table 1
- Median treatment duration was 357 days (Interquartile Range 192-722)
- Compliance was high- median 75% compliance with hours worn/night and median 100% compliance with nights/week worn
- Median HIT6 Scores decreased from 56 to 40 for a decrease of 16 or 28.6%, P<.05
- 60.7% of patients decreased their headache impact severity category
- 63.5% of patients who started treatment with at least some headache impact demonstrated clinical cure (final score little to no impact)



**Figure 3.** Patients in each HIT-6 impact category pre and post treatment

## CONCLUSION

- CARE treatment significantly decreases headache impacts
- Study is limited by sample size, selection bias, lack of medical histories especially including prior and adjunctive treatment, and limited courses of therapy
- Larger cohorts and clinical trials are warranted to determine the role CARE might play and how to optimize patient candidacy
- Enhanced medical-dental collaboration is required to optimize this potential opportunity in headache treatment