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Post Market Study of the Carpal-Aid Device

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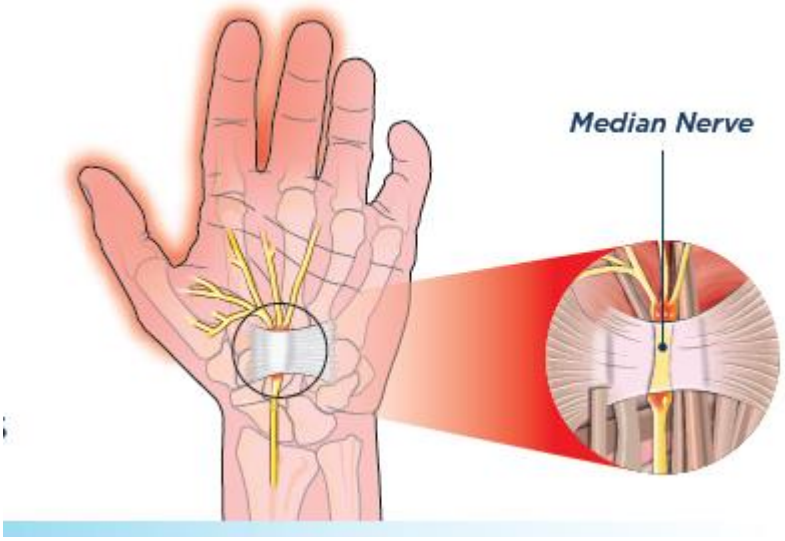
1. INTRODUCTION

The Carpal-Aid device is a non-sterile, single use, adhesive bandage that is placed on the palm of the affected hand. The device is worn at night while the patient sleeps and during the day as needed. The device is designed to be worn on intact skin and should not be placed over an open wound or abrasion. Carpal-Aid is designed to lift up the skin on the palm relieving pressure on the median nerve, thereby relieving carpal tunnel syndrome. (See figure below).



The present study will assess customer/patient satisfaction of using the Carpal-Aid device. The study will be overseen by orthopedic surgeons who have experience treating carpal tunnel syndrome. Patients will present to the investigators for consent and follow up.

This is a non-invasive home use study that requires no long term follow up. The Carpal-Aid device meets the FDA Classification description for limb orthosis (21 CFR 890.3475, product code IQI) and is Class I, Non-significant risk device, 510(k) exempt. This device is listed with the FDA (Registration 3009766183) and full GMP compliance is maintained.

Summary of the Investigational Plan

This section provides an overview of the protocol and investigational plan for the Device clinical study. A complete copy of the protocol is provided in Attachment V-C for reference.

1.1 Study Objectives

1.1.1 The primary objective is to evaluate the performance of the Carpal-Aid device during home use. The following outcome will be measured:

- Pain as reported daily using VAS pain scale

1.1.2 The following Secondary Objectives will be evaluated as well.

- Quality of life as measured by baseline and 30 day
- Improved sleep as measured by sleep survey
- Patient compliance with wearing the device
- Patient satisfaction with the device as measured by customer survey.

1.2 Study Design

This prospective, multicenter, observational study designed to evaluate the ability of the Carpal-Aid device to provide functional support for patients suffering from carpal tunnel syndrome.

2. INVESTIGATIONAL PROTOCOL AND FOLLOW-UP

2.1 Objective & Purpose:

The study will evaluated 30 subjects for 30 days of device use. The study will enroll as many subjects as necessary to gather data on 30 subjects through 30 day follow up. The primary objective of this study is to evaluate relief of carpal tunnel syndrome as evidenced by an overall reduction in pain. All subjects will be enrolled within approximately 6 months.

Data will be collected on subjects who have consented to nightly use and wear of the Carpal-Aid device. The physician will identify appropriate candidates based on the inclusion and exclusion criteria identified in this protocol. Subjects must consent to participate in the study prior to first wear of the device.

2.2 Patient Population

Subjects self-presented to physicians with complaints or symptoms of carpal tunnel syndrome. Subjects were considered for enrollment if they meet the following criteria:

2.3 Inclusion/Exclusion Criteria

Inclusion Criteria

- Willing to consent to participate in study
- Self-reported pain and symptoms consistent with Carpal Tunnel

- Willing to return for follow up
- Willing to complete daily diary
- 18 years or older

Exclusion Criteria

- Previous intervention for Carpal Tunnel (surgery, braces, or injection)
- No open wound on treated hand
- No bone spur or deformity on treated hand

2.4 Regulatory Requirements

The Device clinical study was conducted in accordance with the investigational plan, the Informed Consent Regulations (21 CFR 50) and the Institutional Review Board Regulations (21 CFR 56). Sponsor initiated this study to provide clinical data for the Device. New England IRB approved the current Device clinical study on September 4, 2013 and the first subject was enrolled on September 30, 2013.

2.5 Statistical Methods

The study was designed to evaluate the device performance and patient satisfaction in "real world" conditions. As such, the study was not powered to provide scientific evidence of clinical efficacy.

Categorical variables are summarized using counts and percentages. Continuous variables are summarized using mean and standard deviation. Student T-test were applied were possible to determine statistical significance of data gathered.

2.6 Subject Enrollment and Follow-up

Three (3) investigational sites participated in this clinical study. The investigational sites were all orthopedic private practice. All centers were experienced in diagnosis, treatment, and management of carpal tunnel syndrome. NAMSA selected these sites based on their practice experience, experience in participating in clinical studies, and ability to enroll subjects.

This clinical report summarizes the available data for all subjects who consented to participate in the study and completed 30 day follow up.

2.7 Subject Enrollment

A total of thirty (30) subjects were enrolled in the clinical study. A total of 27 subjects completed 30 day follow up. Of the 30 subjects that consented to participate in the study, 2

subjects did not return for initial clinical visit and device overview. One (1) subject received devices, but did not return for 30 day follow up.

Table B1 shows the subject enrollment per investigational site. All the investigational sites used the same clinical protocol.

Table B1 Subject Enrollment per Investigational Site

Site Number	**Center**	**Principal Investigators**	**Number of Subjects Enrolled**
01	Clinical Research Source, Inc.	Robert Kalb, MD	6
02	Sunrise Medical Research	Richard Linn, MD	22
03	Alabama Orthopedic Center, PC	Robert Sorrell, MD	2

2.8 Discontinuation and Protocol Deviations

Two enrolled subjects did not return for initial clinical visit. One subject did not return for 30 day follow up. These two subjects were contacted numerous times and return visits were scheduled. Yet, they did not keep their appointments. The subject that received devices was also contacted and repeated 30-day follow-up visits were scheduled however the subject never kept the appointment. The site did speak to these subjects and they did not report any adverse events.

There were no protocol deviations reported for any subjects.

2.9 Follow-up Rates at 30 Days

Table B2 shows the follow-up rates for subjects. These rates demonstrate that the investigational sites complied with the clinical protocol. A sufficient number of subjects were evaluated to adequately characterize the safety and feasibility of the Device System.

Table B2 Follow-up Rates at 30 Days

Interval	**Follow Up Requirements (n = 30)**	
Follow Up	**Clinical Visit**	**Daily Diary**
Enrollment	100% (20/20)	Not Applicable
30 days		
Completed	93% (27/30)	93% (27/30)
Out of Window	0	0
Refused	3	3

2.10 Subject Characteristics

The subject characteristics are presented in this section to describe the study population. The study population accurately reflects the general carpal tunnel syndrome population.

The demographic, pain assessment, sleep quality, and medications were collected and analyzed.

Overall, subjects were comparable to reported historical controls for most demographic and clinical characteristics.

2.11 Demographics

Table B3, shows the demographics of the study population. Overall, more significantly women were enrolled than men. This reflects the actual rate of physician office visits by women compared to men for preventive health and non-life threatening conditions.

Table B3 Demographics of Study Population

Demographics		
Age, years ± SD	51	16.9
Male, n (%)	2*	8%
Weight, kg ± SD	81.5	20.1
Pregnant, n (%)	2	10%
White Non-Hispanic, n (%)	16	57%
Black, n (%)	3	11%
Hispanic, n (%)	9	32%
Asian, n (%)	0	0

*n=26, sex was not reported for 2 subjects

2.12 Medical Conditions and History

The prevalence of selected medical conditions was analyzed to describe the study population and determine whether the study population was comparable to historical data. Almost half of all subjects (48%) reported preexisting medical conditions and were taking medication.

Two (2) subjects were pregnant and in their 3rd trimester during participation in the study. Both subjects reported having Carpal Tunnel Syndrome before pregnancy.

Table B4 shows the prevalence of preexisting conditions or past medical histories. A complete list of medications is provided in Appendix 2.

Table B4 Summary Medical History in Study Population

Pre-existing Medical Conditions	n	%
Pre-existing Condition	15	55.56%
Arthritis	4	14.81%
Hypertension	5	18.52%
Hypothyroidism	2	7.41%
Hypercholesterolemia	6	22.22%
Diabetes	3	11.11%
GERD	2	7.41%
Pregnant	2	7.41%
Other	6	22.22%

Many subjects also had a history of carpal tunnel syndrome.

3. DATA PRESENTATION AND ANALYSES

3.1 Primary Endpoint Analysis

Analysis of both safety and feasibility outcomes was performed for the Per Protocol population and the As Treated population. This section describes the different analyses that were performed and the subjects included in each analysis.

3.2 Safety Analysis

There were one reported adverse events in the study. Subject (02-002) reported device discomfort and rubbing, but this did not result in any additional medical care or intervention. Although this event is device related it is mild. The subject stopped wearing the device and the adverse event resolved.

3.3 Efficacy Analyses

Efficacy analysis was performed by calculating the number of subjects who perceived a reduction in pain from Day 1 to Day 30 of wearing the Carpal Aid device. A table of device success in pain reduction and improved sleep quality is listed below (Table C5). This table also identifies the preexisting medical conditions for each subject.

Table C5 Subject Specific Change is Pain and Sleep Scores

Subject ID	Age	Gender	Pain Score	Sleep Score	Medical Conditions
					Osteoarthritis
					Hypertension
					Hypothyroidism
01-001	61	Female	5	1	Hypercholesterolemia
01-002	53	Female	-2	-1	
					Diab type 2
01-003	50	Female	1	1	HTN

Subject ID	Age	Gender	Pain Score	Sleep Score	Medical Conditions
					Hypercholesterolemia
					IBS
01-004	66	Female	4	0	
01-005	50	Female	1	0	Osteoarthritis Back
					Osteoarthritis
01-006	65	Female	4	1	Glaucoma
02-001	67	Female	2	3	
					Hypertension
					Hypercholesterolemia
02-002	68	Female	-1	2	Hypothyroidism
02-003	34	Female	-1	3	
02-004	35	Female	5	5	Pregnant
02-005	30	Female	4	2	
02-006	22	Female	1	1	Pregnant
02-007	42	Female	2	0	
02-009	51	Female	1	5	
02-010	58	Female	1	2	Osteoarthritis of the knee
					Hypertension
					Hypercholesterolemia
					Back pain
02-011	91	Female	5	3	Complete hysterectomy
02-012	51	Female	0	2	
02-013	0	Female	1	1	
02-014	44	Female	3	2	
02-015	66	Female	0	0	High Cholesterol
02-016	53		0	0	Seasonal allergies
02-017	58	Female	3	0	
					Diabetes
02-018	46	Male	0	0	Hypertension
02-019	45	Female	2	1	Diabetes
02-020	56		0	-1	
					Choeystitis
					GURD
03-001	48	Male	2	1	Anxiety
					Hypercholesterolemia
03-002	62	Female	1	0	GERD

The majority (70%) of subjects saw an improvement in pain as evidenced by the reduction in pain scores. The average improvement in pain in subjects who reported an improvement was 2.5 points on the VAS scale. Table C6 summarized the population self-reported changes in pain scores.

Table C6 – Summary of Pain Scores

Measure	Pain (n)	Pain (%)
Negative Change	3	11%
No Change	5	19%
Positive Change	19	70%

Some subjects did report that pain relief was only realized while wearing the device. To better understand the daily fluctuation in pain a point plot diagram was created. Figure C1 below identifies each subject (n=19) that reported an improvement in pain from Day 1 to Day 30 and their daily reported pain.

3.4 Secondary Endpoint Analysis

This section describes the different analyses that were performed and the subjects included in each analysis for the following criteria.

3.5 Sleep Improvement

Over half of the subjects (63%) reported positive change in sleep. The average improvement in pain in subjects who reported an improvement was 2.5 points on the VAS scale. Table C7 summarized the population self-reported changes in sleep scores.

Table C7 – Summary of Sleep Scores

Measure	Sleep (n)	Sleep (%)
Negative Change	2	7%
No Change	8	30%
Positive Change	17	63%

3.6 Quality of Life

Twenty-three (23) of the 27 subjects completed baseline and follow up quality of life surveys. An EQ-5D Quality of Life questionnaire was used instead of an SF-30. The EQ-5D was chosen because it is shorter and easier for subjects to complete. The majority (43%) of subjects that complete both baseline and 30-Day Quality of Life surveys reported no change

in their overall quality of life, while 30% reported an improvement. Table C8 summarized the population self-reported changes in sleep scores.

Table C8 – Summary of Quality of Life Scores

Measure	**Score (n)**	**Score (%)**
Negative Change	6	26%
No Change	10	43%
Positive Change	7	30%

3.7 Device Compliance

Of the 27 subjects that completed follow up, 26 recorded device use for 28 – 30 days, for a device compliance rate of 96%. The most common reason for not wearing the device was forgetting to put it on. Subject 02-002 stopped wearing the device after 15 days. This subject also cut the device in an attempt to make it more comfortable. The complete list of subject comments from their daily diary recordings is provided in Appendix 1.

4. **CONCLUSIONS**

The conducted study provides objective evidence that the Carpal Aid device provides relief from Carpal Tunnel Syndrome. 70% of all subjects that wore the device for 30 nights reported a reduction in pain due to CTS. This relief is primarily experienced while actively wearing the device and, if worn at night while sleeping, may improve quality of sleep.

There were no serious adverse events reported in this study and only one mild adverse event. This data supports the safety of the Carpal Aid device.

This study also provides insights into the complexity and influence concominate medical conditions and general “state of mind” may have on perceived CTS pain. As evidenced by self-reported Quality of Life surveys; the majority of subjects, including those with a negative change in pain scale reported no change or improved QOL indicating a general tolerance to all medical conditions.

This study demonstrates that there is no to minimal risk associated with the Carpal Aid device and possibly significant benefit for those suffering from CTS.