ASSESSING PHYSICAL ACTIVITY IN OROFACIAL PAIN PATIENTS

by

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CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

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has been approved by the Examining Committee for the thesis requirement for the Master of Science degree in Oral Biology at the June 2014 graduation.

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ABSTRACT

ASSESSING PHYSICAL ACTIVITY IN OROFACIAL PAIN PATIENTS
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ABSTRACT

Introduction: Current models of healthcare highlight the importance of regular physical activity for maintaining good health and for disease prevention. Regular physical activity in patients with chronic pain is associated with improved physical and psychological functioning and reduced pain severity. However, associations among physical activity and functioning have not been assessed in orofacial pain patients. **Aim**: The primary aim of this study was to assess physical activity levels in newly diagnosed Orofacial Pain patients. Physical activity was assessed using self-report measures and a physical activity tracking device (Fitbit Flex 2). The secondary aim was to explore relationships among physical activity and pain severity, fatigue, sleep quality, anxiety, and depression. **Methods**: Participants were newly diagnosed orofacial pain patients (n=25). Participants completed study self-report measures at initial clinic visit and wore a portable activity monitor (Fitbit Flex 2) daily until returning to the clinic for a follow-up visit. **Results**: Overall, participants were compliant with use of the activity tracker. Physical activity in study participants was not associated with pain severity, age or fatigue (p's>0.05). The majority of the sample (76%) was overweight or obese, exceeding the national average.

Discussion: There were no correlations between any subjective data and the objective data. There was a large portion of the study had elevated BMI, which is consistent with the general population. There was no correlation between perceived activity and actual physical activity as measured by the portable tracking device.

Conclusions: The results of this study demonstrated the feasibility of portable activity monitors for assessing physical activity in orofacial pain patients. Future research may need to incorporate an intervention to increase physical activity.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

BMI:	Body Mass Index
CDC:	Center for Disease Control
COP:	Chronic Orofacial Pain
FSI:	Fatigue Symptom Inventory
GAD-7:	Generalized Anxiety Disorder questionnaire (7 items)
ISI:	Insomnia Severity Index
NPDS:	Naval Postgraduate Dental School (NPDS).
OPC:	Orofacial Pain Center
PCS:	Pain Catastrophizing Scale
PHQ-9:	Patient Health Questionnaire (9 items)
PPAS:	Paffenbarger Physical Activity Scale
TSK:	Tampa Scale for Kinesiophobia

I. Review of the Literature

Pain is defined "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such[1] [2]." Chronic pain is defined as pain that persists past anticipated healing. Normal healing is expected to occur within 3 months for acute injuries [3] . It is widely estimated that 100 million Americans suffer from chronic pain at a cost of 560-635 billion dollars annually [4]. Data from the 2010 to 2014 National Health Interview Survey (NHIS) indicates military veterans are more likely to suffer from pain conditions than non-military counterparts [5]. In a study of soldiers returning from Afghanistan, 44% reported chronic pain and 15.1% reported using opioids in the past 30 days [6]. The issues with chronic pain, especially in relation to veterans, has been a hot topic in politics and the news. In April of 2018 the U.S. Court of Appeals for Veterans Claims ruled that pain, without any underlying disability, may be a valid reason for awarding VA compensation benefits. This ruling recognizes that pain alone is an illness, and not the result of a diagnosed disease, and is recognized as a cause of disability.

Chronic pain patients appear to have many shared traits. Some of the most common of these traits include poor sleep quality, depression and anxiety. Chronic pain may also be debilitating, decreasing function and the ability to perform simple, everyday tasks. Another interesting trait of chronic pain is the reduction in pain thresholds, meaning less stimulus is needed to cause pain. For example, palpating an area such as the masseter muscle normally would not elicit pain. However, in a chronic pain patient this sensation on the skin may elicit a painful response.

Physiological changes in the CNS, caused by chronic pain, can be visualized using functional neuroimaging studies. This allows researchers to see structural changes associated with chronic pain, such as gray matter volume and density changes, as well as specific areas of the brain that are involved in the processing of pain, such as the prefrontal cortex and cingulate cortex [7-9]. These neuro-plastic changes taking place up and down the CNS are the result of Central Sensitization and is the cornerstone for understanding chronic pain conditions. Central Sensitization is defined as state of hyper-excitement of spinal and supra-spinal structures of the CNS due to an amplification of neural signaling [10]. These CNS changes include both increases in pain input to the brain, and a decreased pain inhibition, or endogenous pain modulation.

Central sensitization is characterized by a reduction in pain thresholds previously mentioned and an increase in the receptive field, or the painful area [11]. There is a host of syndromes associated with central sensitization [12] (Please see Figure 1).

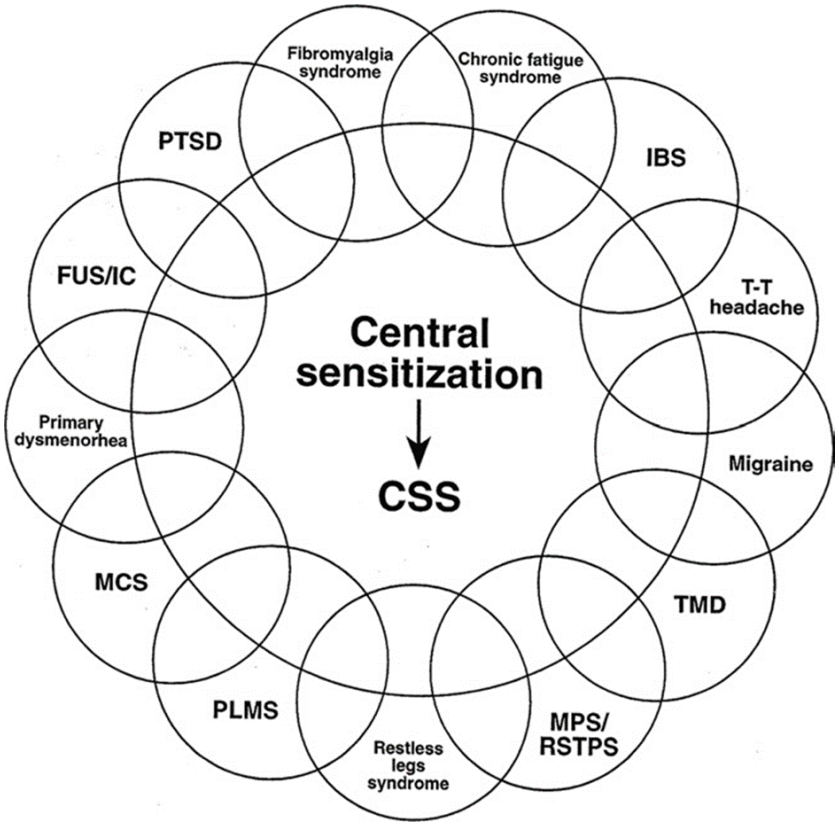

Figure 1. Multiple pain conditions associated with central sensitization.

These complex pain disorders include fibromyalgia, irritable bowel syndrome, chronic headaches, and TMD. These conditions share common characteristics of chronic pain, are co-morbid to each other and all lead to a decreased quality of life [13]. Because these central sensitization disorders are multifactorial, managing these patients presents many challenges. These patients are likely to be refractory to standard treatment, are already on multiple medications, and have undergone the vicious cycle common with chronic pain patients that includes poor affect, stress, anxiety, poor sleep quality, elevated BMI and decreased function [14].

Chronic Orofacial Pain (COP) is commonly associated with central sensitization and is considered one of the central sensitivity syndromes. Approximately 10% of adults and up to 50% of the elderly suffer from chronic orofacial pain [15, 16]. COP, like other

chronic pain conditions, is strongly linked to poor sleep quality [17], mood disturbance, autonomic nervous system dysfunction [18, 19], and decreased release of endogenous opioids [20].

Treatment for these conditions can be difficult in light of the multidimensional aspects already discussed. As such, the treatment should have a multidimensional approach. Another way to look at this is to address these conditions as an illness and not just a disease. Evaluating both the objective findings (disease), of which there may be little, and the subjective experience (illness) may provide better therapy responses. Acute pain responds well to the biomedical model, but this approach may not be effective in managing patients with chronic pain [21]. Addressing the pain as an illness, to include addressing the pain in the context of its multiple co-morbidities, is the basis of the Biopsychosocial model. This model has demonstrated efficacy in the treatment of chronic pain and other chronic diseases [22].

Effective treatment of orofacial pain conditions involves the use of multiple modalities to address the primary pain complaint to include pharmacologic, physical and behavioral interventions. Using the biopsychosocial model, a better outcome is achieved by addressing not only the pain complaint itself, but various comorbidities linked to chronic pain allowing the patient to better manage if not alleviate their pain complaint while concurrently improving function and quality of life.

It is in light of this model that the role of physical activity is viewed as a possible modifying factor in treating chronic pain conditions. Physical activity affects all aspects of the biopsychosocial model. Multiple studies have evaluated the beneficial health effects of physical activity as well as the detrimental effects of a sedentary lifestyle [23-

26]. The benefits extend to improved mood, increased self-esteem, and increased social interactions [27, 28]. Numerous studies have evaluated the link between sedentary behavior and declining health standards to include all-cause mortality [29], cardiovascular disease [30], cancer incidence and mortality [31], and type-2 diabetes in adults [32, 33]. Other studies have found significant and direct correlations between frequency and intensity of physical activity and long-term health outcomes [34, 35]. The phrase credited to Dr. James Levine of the Mayo Clinic, "Sitting is the new Smoking" is quickly becoming a popular adage for proponents of regular physical activity. Dr. Levine also stated that "sitting is more dangerous than smoking, kills more people than HIV and is more treacherous than parachuting. We are sitting ourselves to death," in a July 2014 interview published in The Los Angeles Times [36, 37]. His views are based on years of research exploring the relationships among sedentary behavior, physical activity, and long-term health outcomes [38, 39]. Interestingly, the concept of physical activity as a necessary part of maintaining good health has been recognized for thousands of years dating back to Susruta in 600 BCE and later with Hippocrates and Galen [40].

Physical activity is also associated with a reduction in pain severity in patients with a variety of pain conditions. A 2012 study on the effects of an exercise program for women with fibromyalgia showed significant improvement in bodily pain as well as self-esteem [27]. A study assessing physical activity in adolescents receiving orthodontic care found that children with higher baseline physical activity levels reported less pain perception and used less analgesics than adolescents with lower baseline physical activity levels [41]. The associations among physical activity, pain perception, and analgesic use are consistent with established pain physiology. It is well-established that physical

activity increases expression of the body's natural endogenous opioids to include serotonin and norepinephrine [42, 43]. This same process is utilized pharmacologically in antidepressants to address mood disorders and in medications to address chronic pain.

In a study with post-menopausal women [44], members of the intervention group each received a pedometer and were asked to increase their steps from baseline by 500 per week. This resulted in decreased levels of anxiety, depression and insomnia. Another study found walking prevented the onset of cervical pain in sedentary workers [45]. These studies have been completed in samples with well-studied chronic pain problems like back pain and fibromyalgia. Regular physical activity has been associated with reduced pain and improved overall functioning in patients with chronic pain such as low back and fibromyalgia [36, 46-50]. Other studies have demonstrated the effect physical activity has on endogenous opioids involved in descending pain inhibition [51]. Regular physical activity also has demonstrated psychological benefits in patients with chronic pain by increasing self-esteem, reducing distress, and improving physical functioning [52-54]. Physical activity has the added benefit of improving sleep quality [55] with a strong bidirectional relationship between improved sleep quality and decreased pain severity [56]. However, there are no published studies describing the exercise habits or regular physical activity in chronic orofacial pain patients.

Goal of the present study

This project will assess physical activity in orofacial pain patients seen in the Orofacial Pain Center (OPC) at the Naval Postgraduate Dental School (NPDS). Participants in this study will be newly diagnosed patients with chronic orofacial pain (COP). Potential participants will be identified during the standard orofacial pain exam

at his/her initial clinic visit and invited to participate in this study. Participants will be assessed on primary study variables via self-report measures at baseline and will wear a physical activity tracking device to measure physical activity for two consecutive weeks.

Specific Aims

This project has two primary goals. **First**, to measure physical activity levels in newly diagnosed orofacial pain patients using both self-report measures and a physical activity tracking device. **Second**, improve understanding of the associations among physical activity and psychological, behavioral and physiological characteristics will help identify specific pathways associated with reduction in pain severity and improvement in physiological resilience over the course of standard orofacial pain care. Recent published work suggests strong associations among psychological factors and pain severity in patients with chronic pain conditions [57, 58]. Further, evidence suggests that psychological distress, poor sleep quality, and fatigue may act as barriers of beneficial effects of physical activity on pain severity and treatment efficacy.

II. Material and Methods

Participants. Study participants were patients reporting for initial examination at the NPDS OPC in Bethesda, MD. All patients were DEERS eligible, meaning they were associated with Department of Defense as either active duty members, retired from active duty, or family members of active/retired service members. All patients had completed the standard Orofacial Pain department questionnaires packet prior to their examination (see Table 1).

Inclusion criteria: To be eligible for this study, the potential participant had to be at least 18 years old and be DEERS eligible. The patient will have a history of orofacial pain greater than 3 months. Potential participants will also have a present pain severity of at least a 3/10 on a 0-10 visual analog scale with 0 being no pain and 10 being the worst pain at time of consent. Lastly, potential participants will be local for the duration of the study to ensure the return of the physical activity monitoring device.

Exclusionary criteria: The only exclusionary criteria was that the subjects could not be below 18 years of age.

Study Procedures. Written informed consent was obtained from eligible and interested participants in accordance with IRB/HIPAA guidelines. Patients were screened for study eligibility by the OPC providers prior to the start of his or her initial treatment appointment. Eligible patients interested in study participation were consented at the end of the initial treatment appointment. Once consented, the study participant completed study specific self-report measures (see Table 2), and were given the physical activity tracking device and instructed on how to use the device. All participants were instructed to wear the device until they reported for their follow-up appointment, which is usually 3-4 weeks. All devices were wiped thoroughly with Cavi-Wipes disinfecting towelettes per product instructions prior to use and upon return by the study participant.

Table 1. Standard OPC intake measures

Measure	Purpose
OPC Exam Form	General dental and medical history, history of main complaint and current examination
Patient Health Questionnaire-9 (PHQ-9)	Depression screening

Generalized Anxiety Disorder (GAD-7)	Anxiety screening
Pain Catastrophizing Scale (PCS)	Pain catastrophizing screening
Insomnia Severity Index (ISI)	Sleep dysfunction screening
NAVMED 6600/3 Dental Health Questionnaire	Current dental status and oral health routine

Self-report measures

The following measures are part of the standard OPC clinical assessment and are completed by all new patients. These measures are listed in Table 1. The data from these measures will be used in the proposed study.

OPC Exam Form- This is a 2 part form. Part one is a subjective questionnaire completed by the patient prior to arrival at the clinic and used by the Orofacial Pain provider to assess the chief complaint. Part two is an objective analysis completed by the provider during the exam to assess the chief complaint, possible secondary causes and aggravating factors. (This form is standard of care)

Generalized Anxiety Disorder GAD-7. The GAD-7 [59] is a 7-item measure used to assess the presence of symptoms of generalized anxiety over the previous two weeks. The GAD-7 is a widely used assessment instrument and has demonstrated good psychometric properties in clinical and research applications [59].

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 [60] is a 9-item measure of the presence and severity of depressive symptoms over the previous two weeks. Test-retest reliability, internal consistency, and convergent validity have been established [60].

Pain Catastrophizing Scale (PCS). The PCS [61] is a 13-item measure of catastrophic thinking associated with pain. The PCS yields a total score and three subscale scores assessing rumination, magnification, and helplessness. The PCS has been shown to have

good overall internal consistency (coefficient alphas: total score=0.87, subscales range from 0.66-0.87) [61].

Insomnia Severity Index (ISI). The ISI [62] is a brief instrument that assesses the severity of both subjective nighttime symptoms as well as daytime consequences of insomnia. The ISI is a 7-item measure assessing severity of sleep onset and sleep maintenance difficulty, satisfaction with current sleep pattern, interference with daily functioning, noticeability of impairment from sleep problem, and degree of distress or concern caused by sleep problems. Each item is rated on a 0-4 scale and the total score ranges from 0-28 with higher scores indicative of more severe insomnia. It has been validated for use as a screening tool to detect sleep disturbances in numerous patient populations and is extensively used in research and clinical settings. The ISI has demonstrated good reliability and validity [62, 63].

NAVMED 6600/3 Dental Health Questionnaire. The Dental Health Questionnaire is used to determine the health and physical status of all dental patients.
Reference BUMED INSTRUCTION 6600.12A

The following self-report measures will be completed after the study participant is consented, are not standard forms used in the OPC, and are specific to the aims of the proposed study.

Table 2. Self-report measures for the present study

Measure	Purpose
Demographics and Health History Questionnaire	Demographics and health history
Tampa Scale for Kinesiophobia (TSK)	Fear of movement/activity

Paffenbarger Physical Activity Scale (PPAS)	Weekly physical activity and intensity
Fatigue Symptom Inventory (FSI)	Daily pattern of fatigue

Demographics and Health History Questionnaire. All participants will complete a brief demographics and health history questionnaire after study enrollment. Information recorded here includes ethnicity, race, marital status, job status, as well as questions about dental and medical history, current medications, and current use of non-prescription supplements.

Tampa Scale for Kinesiophobia (TSK). The TSK [64, 65] is a 17-item questionnaire used to assess the subjective rating of kinesiophobia or fear of movement. The TSK has good psychometrics and is used in exercise and disability research studies [64, 66], and was recently validated in a study with chronic orofacial pain patients [67].

Paffenbarger Physical Activity Scale (PPAS). The PPAS [68] is a 4-item measure of perceived physical activity. This measure has several open and closed-ended items that ask the participant to estimate their usual levels of daily physical activity, frequency, and exertion. Participants also list any sports or recreational activities. The PPAS has good psychometrics and is a commonly used measure in exercise research studies [69].

Fatigue Symptom Inventory (FSI). The FSI [70] is a 14-item measure designed to identify fatigue severity, fatigue frequency, perceived interference associated with fatigue, and the daily pattern of fatigue. Participants rate each statement according to how true it has been for them over the past seven days. The FSI has good psychometrics and is widely used in studies of patients with chronic pain and other medical conditions [71].

Objective Measures

Physical Activity Assessment Device

The Fitbit© Flex was utilized to assess physical activity. This device has the ability to track steps, distance, calories burned, active minutes, hourly activity and stationary time [72, 73]. For this study, walking, or steps per day, was used as the measure for physical activity. Studies have demonstrated the Fitbit is easy to use, recognized by the patients and has a moderate validity for tracking steps per day[72, 74-76]. This device was given to the subject with instructions to wear this device throughout the day and night. The subject was to recharge the device every third night. The subjects were asked to return the device at their follow-up appointment, which is normally 3 to 4 weeks.

Every subject was given a subject number. Every subject was given a device that was synchronized to the Fitbit website using the study subject number only. Because the devices are paired to the Fitbit website, all devices were paired to the subject number only. No names or other identifiable information was entered into the Fitbit website.

Body Mass Index

The second objective measure in this study was Body Mass Index (BMI) in order to assess healthy weight of the subjects. The use of BMI is the universal standard for measuring obesity [77]. All patients were assessed using the Inbody 520 [78] to measure body fat percentage.

Data Analysis Plan

Sample Size Estimation. This study was a pilot study, and thus did not include a powered statistical comparison from which a sample size determination can be derived.

Data Analysis. The primary aim of this study was to establish confidence intervals for activity levels and evaluate the feasibility of using activity trackers to conduct research with orofacial pain patients. For Aim 1, report measures from the activity tracker and from the self-report measure of perceived physical activity were summarized across participants. Data are unlikely to be normally distributed, and so medians with ranges were reported. Objective data in the form of steps per day was collected using the Fitbit Flex. We attempted to identify how physical activity changes with respect to time in order to create better profiles of individual patients. For example, we isolated how physical activity changes as a function of day of the week or days since the start of the study to appropriately adjust our expectations of actual activity in each patient. For Aim 2, we compared the associations among physical activity and the self-report measures assessing perceived pain, psychological (anxiety and depression) and behavioral (fatigue and sleep dysfunction) using Pearson correlations. The pattern of missing data will be described and related to study covariates to help inform future research designs using the activity tracker. The feasibility of using the tracker will be closely monitored, including cases of irretrievable data or days where the subject failed to wear the device.

III. Results

Study Participants. Of the 25 OFP patients enrolled, 25 subjective questionnaires were completed and returned. The majority of the sample were female (n=17, 68%). Just over half were active duty service members (n=14, 56%). The mean age of participants was 41.20 years (SD=13.8) with an age range of 18 to 78. Data from the tracking devices was

downloaded for 17 participants. Of the remaining activity devices, six were returned but were found to not have been synced properly at the initial appointment, and two devices were not returned. All of the subjects resided in either Virginia or Maryland. No adverse events were reported and all of the subjects found the device simple to wear and recharge.

From the 17 subjects that wore activity trackers that were programed and downloaded correctly, the data shows there was little day to day variation in steps per day per subject (see Figures 2 and 3). These figures display day to day step data from two typical study participants. In these figures, the X axis is the day of the experiment, starting from the left. The Y axis is the number of steps measured on the Fitbit. Though it looks as though there are peaks and valleys, there was little significant day to day variation throughout the course of the study.

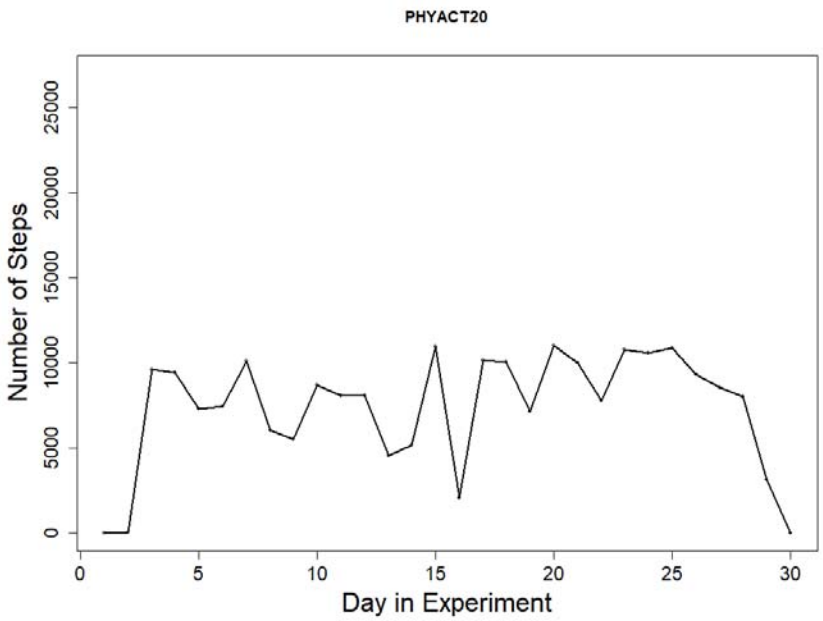

Fig 2. Individual subjects steps measured with the Fitbit Flex 2.

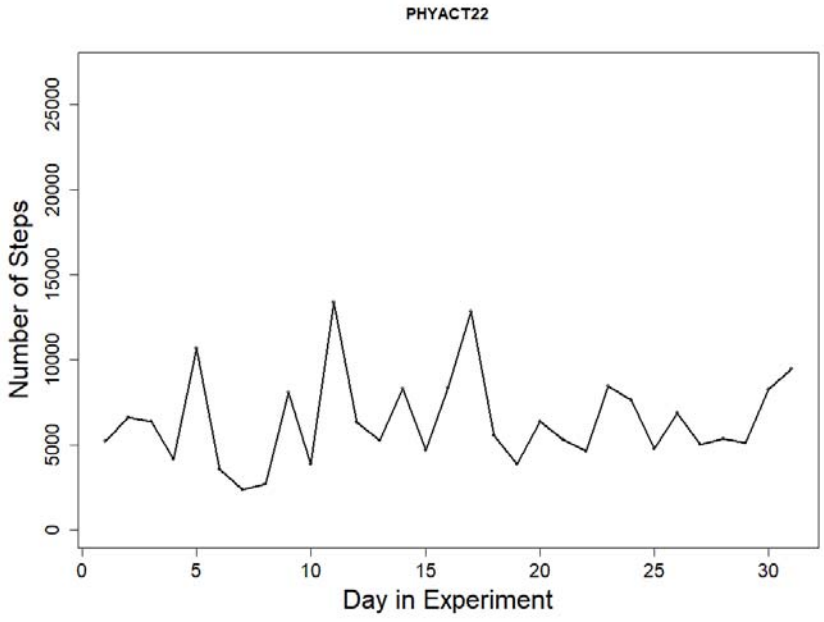

Fig 3. Individual subjects steps measured with the Fitbit Flex 2

Examining figure 4, the subjects have been arranged by median steps so that the most active subjects are on the L side of the graph and the least active are on the R side of the graph. With 0 steps is no activity and 25,000 is an extreme amount of activity. The larger box and wiskers indicates a larger variation in daily steps. This graph shows the increased variability with increasing number of steps per day.

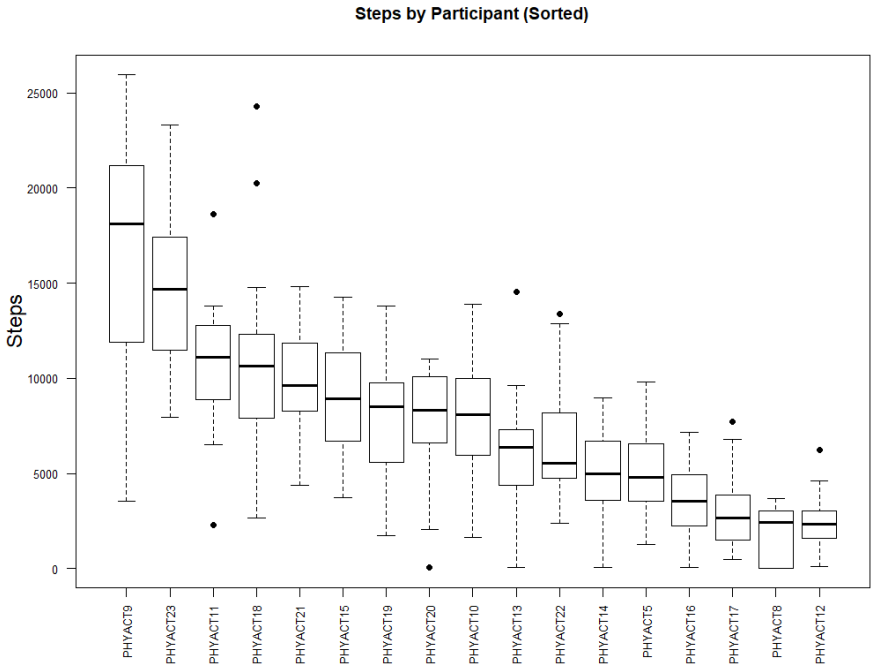

Fig 4. This is a box plot summarizing steps by each participant over the course of the experiment. Every participant is arrayed on the X axis. The amount of steps is on the Y axis. Each individual box is a summary of daily steps for each subject which includes a black line that shows median number of steps. The remainder of each box captures the degree of variability. The dots show outliers.

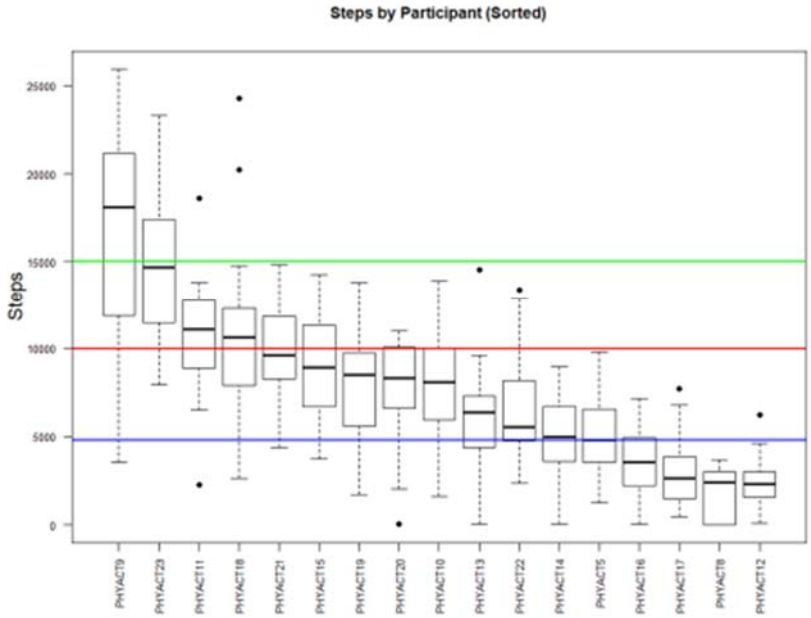

Fig 5. Compares median steps to various measures.

Figure 5 shows the same data of mean steps but compares this to different markers. This red line marks the universally recognized goal is 10,000 steps per day which correlates to 5 miles of walking. The majority of the subjects do not meet this goal on a daily basis and fall below this recommendation. The blue line indicates average steps in the US as assessed from smartphones [79]. A study used smartphone data from over 700,000 individuals in 111 countries found the average steps taken per day world-wide is 4,960. The US ranked 30th out of 110 countries with 4,774 average steps. From this, the majority of the subjects had a higher daily step count than the US population, although well below the 10,000 recommended steps.

The green line in Figure 5 is the US Army's recommended goal of 15,000 daily steps. With 56% of the subjects being on active duty, only 2 achieved this goal.

Comparing the self-report activity levels (Figures 5, 6, 7) to the actual measured activity levels (Figures 3, 4, 5), there was no correlation. This indicates a significant difference between how active the subjects think they are, and how active they actually are.

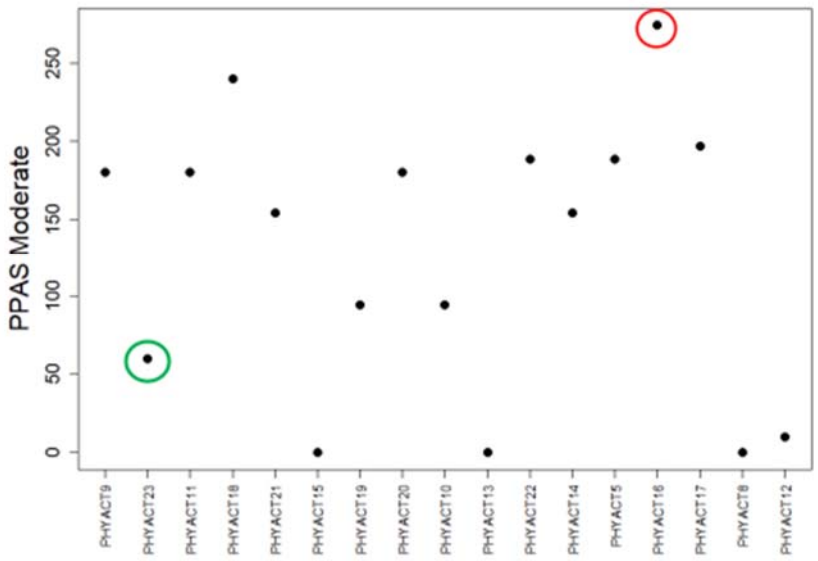

Fig 6. This slide shows the same x axis as in Fig. 4, with the subjects arrayed in order of measured daily activity from highest on the left to lowest on the right. The Y axis shows perceived physical activity as measured by the PPAS self-report

In figure 6, the point circled in green represents the PPAS score for subject PHYACT 23, which is low compared to the other subjects. Comparing this to the actual activity levels in figure 4, this subject is actually the second most active subject in this study. Comparing this finding to subject PHYACT16 circled in red. This subject rated their activity level to be the highest, but in relation to the actual activity levels in fig 4, is one of the least active subjects in this study. These results indicate that self-reports of physical activity are not accurate when compared to the tracking device step count.

An interesting finding in this study was found when comparing self-assessed moderate physical activity (Figure 7) to self-assessed vigorous activity (Figure 8). There is slightly more accuracy when comparing self-reports of vigorous activity with activity measured with the tracking device than when comparing self-report of moderate activity with tracking device data. This is also consistent with a recently published article

assessing validity of physical activity monitors on endometrial cancer survivors [80]. In this study, Self-reported physical activity was also not associated with steps recorded.

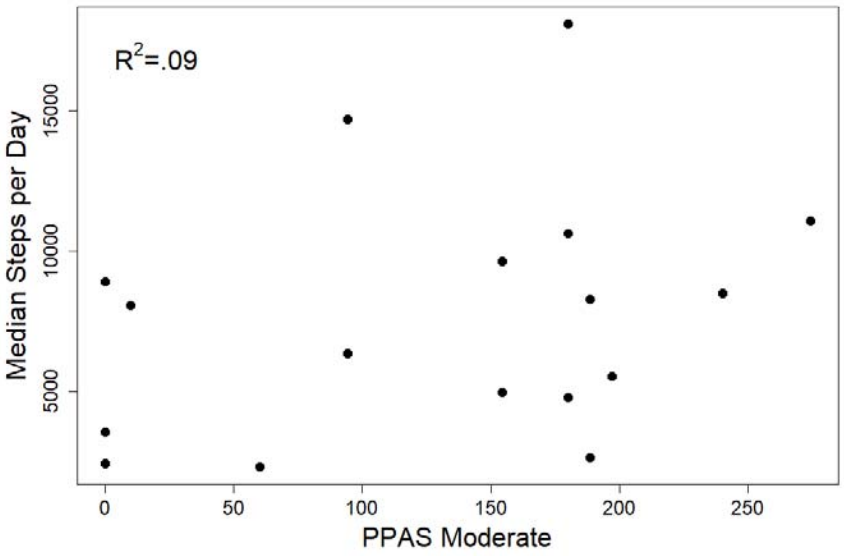

Figure 7. Moderate PPAS compared to actual steps per day.

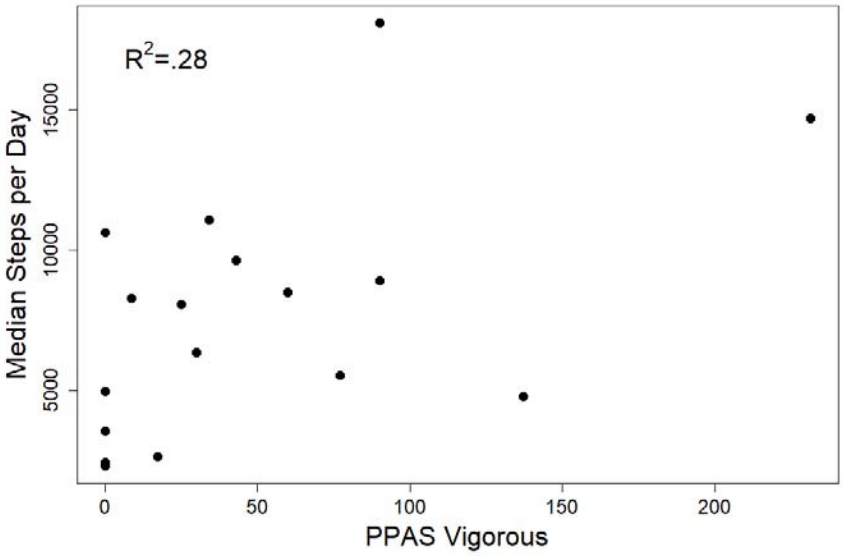

Figure 8. Vigorous PPAS compared to actual steps per day.

When looking at BMI, (Figure 8) 6 out of 25 or 24% of the participants fell into the healthy weight range (BMI 18.5-24.9) while 12 out of 25 or 48% of the participants fell into the overweight range (BMI 25-29.9). Over a third of study participants fell into the obese range (n=7, 28%) with a BMI equal to 30 or above. Thus, 76% of the participants had an unhealthy weight. Looking at CDC statistics[81], the percent of adults aged 20 and over with obesity was 37.9% (2013-2014) and the percent of adults aged 20 and over that were overweight, including obesity was 70.7%. Comparing national trends to this study, the study subjects are less obese than the national average (24% compared to 37.9%) but have a higher percentage of unhealthy weight, 75% compared to the national average of 70.7%.

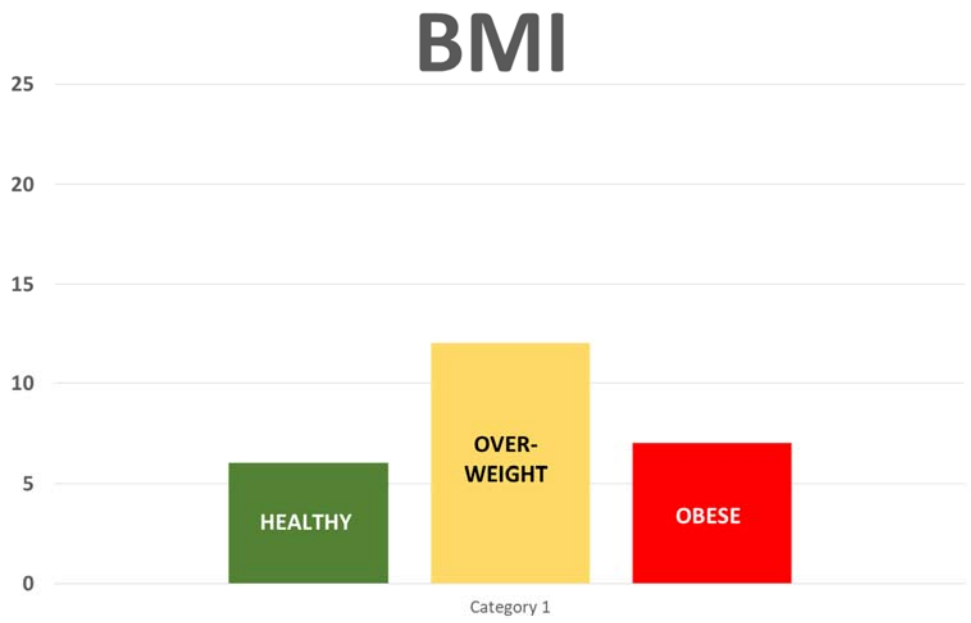

Fig 9 compares healthy, overweight and obese as measured using BMI.

The second goal of this study was to look for associations among physical activity and psychological, behavioral and physiological characteristics associated with COP. We did not find any significant associations with physical activity levels and any of the subjective measure completed by the study participants (Figure 10).

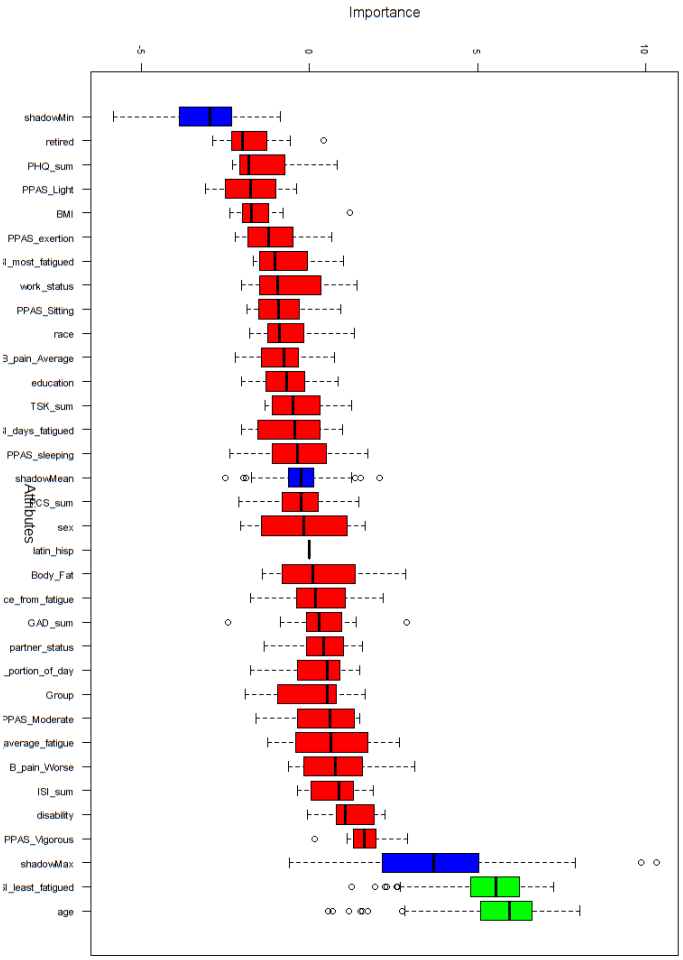

Fig 10. Activity levels compared to self-report measures.

IV. Discussion

This was a pilot study to determine the effectiveness of using activity monitors, in this study the Fitbit Flex 2, in order to assess physical activity levels in COP patients. The ultimate goal was to determine a correlation between physical activity levels and COP patients and to determine if increasing physical activity can be a viable treatment intervention allowing patients to better manage, if not alleviate, their pain states. As was previously discussed, chronic pain is associated with a host of co-morbid conditions [82]. It was also determined that chronic pain, as well as these co-morbid conditions, are associated low levels of physical activity [41, 83, 84]. Previous studies on these various conditions have used physical activity interventions with positive results.[44, 85, 86]. Increasing physical activity alters the factors involved in central sensitization. Altered descending inhibition, or a decrease in endogenous opioids that is found in chronic pain patients, as well as sedentary individuals. Physical activity has also been shown to affect pain signaling, normalizing hypersensitive pain neurotransmitters such as BDNF (brain-derived neurotrophic factor) [43, 51, 87-89].

Current literature supports the concept that increasing physical activity should improve pain conditions. However, this is not always the case. Studies have shown that increasing physical activity can increase pain sensitivity [42, 46]. A study found that pain sensitivity, fear avoidance, and solicitous spousal responses were predictors of physical activity in pain patients [90].

World Health Organization guidelines uses windows of time, 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an

equivalent combination of moderate- and vigorous-intensity activity. Studies suggest that improving health may not be related only to small windows of short burst of physical activity, but in an overall increase in physical activity, or just a decrease in sedentary, or sitting time [35, 84, 91, 92]. It is also of note that chronic pain patients may have a host of factors limiting their ability to engage in moderate to vigorous activity and increasing activity time or walking, may offer more long term improvements, as well as a more attainable goal. For instance, going to the gym may present multiple obstacles, but walking after dinner, parking further away, taking the stairs instead of the elevator, may be a more realistic goal for pain patients.

Walking is also an activity people do throughout the day and is gaining popularity as exercise. 10,000 daily steps, or 5 miles of walking, is a universally recognized goal with origins not in a scientifically based study. Pedometers in Japan were named "manpo-kei" which translates to "10,000 steps meter." This number became popular with Japanese walking groups and thus became the standard [93]. It was with this in mind we used steps as our measure of physical activity.

Overall, the patients found the device easy to use and reported no adverse effects. There was little to no correlation with the subjective data and the objective data (Figure 9). This can be due to the small study sample. However, other findings were of interest. Looking at day to day variability of daily steps among study subjects, there was little variation throughout the course of the study (Figures 1 and 2). As can be seen when looking at an individual graph, there may be some high and lows, but little overall variation. This means that the same assessment of a patient's physical activity can be

seen in 1 week instead of a longer study window of 3-4 weeks, allowing future studies to minimize the study window and allow for a larger study sample.

The average steps per day per subject varied. No clear relation could be made based on variables of age, sex, or duty status. No relation could be made when looking at the various co-morbidities and activity levels. Figure 3 is a box plot summarizing steps by each participant over the course of the experiment. As can be seen in the graph, more steps per day is associated with a larger variation in steps. The red horizontal line marks 10,000 daily steps. Although this was not an interventional study and the subjects were not asked to increase their daily activity, we can see the vast majority of the subjects fall below this goal. The horizontal blue line in fig 3 represents the average daily steps in the US according to an international study of daily steps using smart phones [79]. Interestingly, the US ranked in the mid percentile among 114 nations. The majority of the subjects had higher daily step counts than the average steps according to this study. However, when looking at Fitbit Health and Activity Index, the average steps was 8080 per day. The green line represents US Army's goal of 15,000 daily steps per day. Although the majority of the subjects were active duty, only 2 subjects met this goal.

When looking at BMI levels (Figure 8), it was found that only 24% of the subjects were within a healthy weight limit compared to 37.6% of the US population total according to CDC data. It is well known that the average weight of humans is increasing at alarming rates, causing substantial medical problems, not only in heart disease and diabetes, but with obstructive sleep apnea, which results in poor sleep quality, thereby contributing to central sensitization in chronic pain patients[94, 95].

Perhaps the most interesting finding of this study was in the perceived activity levels of our patients. If a provider is to prescribe a walking regimen to a patient who feels they are already active, then adherence may be an issue. Addressing this with a patient may help to improve future adherence. Comparing figure 5(actual steps per day) to figure 4 (perceived steps per day) it can be determined that patients self-assessment is not accurate. This is seen more clearly when measuring moderate activity (fig 6) then when comparing vigorous activity. With vigorous activity, patients tend to have a more accurate, although still less, assessment of their activity.

This is consistent with research that has shown people have poor reliability recalling physical activity [96], but are better at recalling episodes of vigorous activity such as weightlifting or high intensity workout classes than they are for recalling moderate activities like walking, gardening or cycling [97]. A recently published article assessed the validity of physical activity monitors on endometrial cancer survivors, whose survivors can exhibit a 70% obesity rate. In this study, self-reported physical activity was also not associated with steps recorded [80].

V. Conclusions

This was the first report of activity levels in OFP patients. From the results, it was determined that relatively stable measurement over three study weeks were determined with little day to day variation over the course of the study. Future studies can use 1 week to assess physical activity levels. Few correlates with self-report measures were found. This may be due to the low study sample size. It will be interesting to see if larger study samples will have different results. Concerning the feasibility of using the

device, it was determine that the Fitbit Flex was well tolerated. It was also found that most patients did return the device at the following appointment.

This pilot study is to be the foundation for future interventions to increase physical activity in chronic orofacial pain patients. The results will help develop future studies that aim to reduce decreased physical activity attributed to chronic orofacial pain. By addressing not only the pain complaint, but also the various co-morbidities in accordance with the Biopsychosocial Model, the patient should be able to address their pain, improve their functionality and overall quality of life.

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