PATIENT SATISFACTION AND QUALITY OF LIFE: ASSESSING THE EFFECTIVENESS OF A NEW NOVEL DEVICE AND FINANCIAL IMPLICATIONS

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ABSTRACT

This study aimed to evaluate the effectiveness, potential savings, and patient satisfaction for the Urbanek Splint (US) in treating temporomandibular joint disorders (TMDs) for the selected sample who had been treated with the device, which was developed using patient-centered methods. We used bootstrapped t-tests to test the severity of symptoms and quality of life (QOL) ratings before treatment and after treatment with the Urbanek Splint, and we also tested differences between the previously treated (PT) and the not previously treated (NT) groups. We evaluated additional aggregated cost and usage information based on the FAIR Health, Inc. claims databases. Given the participant-reported previous cost of TMD treatment and the national cost of treating TMDs, initially using the Urbanek Splint could save $2,724 to $6,615 (discounted $2,215 to $5,379) for the average individual in our sample. The Urbanek Splint users in this study, both previously treated (PT) and not previously treated (NT) groups, show decreases in symptom severity, some complete elimination of symptoms, and increases in quality-of-life measures. Additionally, both previously treated (PT) and not previously treated (NT) groups show high satisfaction levels with the Urbanek Splint.

Keywords: Temporomandibular joint disorder, Urbanek Splint, Quality of life, Cost-effectiveness, Patient-centered care

INTRODUCTION

Temporomandibular joint disorders (TMDs) are painful disorders of the temporomandibular jaw joint (TMJ) that can most often lead to jaw pain and headaches. An estimated 4.8% of adults in the United States (11.2 to 12.4 million people) reported pain around the TMJ in 2018 (NASEM, 2020). A large majority (81%) of people seeking treatment for orofacial pain were women (Durham, et al., 2016).

The causes of TMDs vary, and treatments range from bruxism guards to jaw replacement surgery to physical therapy (NASEM, 2020). TMDs are often treated by dentists or maxillofacial surgeons, but TMD symptoms can also be treated by non-dental medical providers (NASEM, 2020). Searching and paying for various TMD treatments can lead to high costs for the individual, and TMDs often lead to ripple effects throughout a patient's life, affecting activities like talking, eating, or focusing at work (NASEM, 2020).

This study looks at patient responses to determine the effectiveness of the US on the dimensions of quality of daily activities and reduction of the severity of TMD-related symptoms.

The study explores patients' past TMD treatments and the costs associated with ineffective treatments. This study looks at the effectiveness of a novel treatment for TMDs, the costs of previous treatments, and patient satisfaction for those who have been treated for a TMD (PT) and those who have not (NT). Previous treatments are important in highlighting the average cost of ineffective treatment paid by TMD patients over their lifetime.

Much of the recent clinical research on TMDs focuses on the effects of occlusal guards or surgical options for treating TMDs, and some research has proven that surgery is not better than other conservative treatments (such as medication) at relieving the severity of TMD symptoms (Schiffman, E.L., et al., 2014).

There is no singular best method for TMD treatments, as shown by the wide variety of treatments available and recent clinical trials (Dalewski et al., 2019; Kutuk et al., 2019; Nagata et al., 2019; Ramakrishnan et al., 2019; da Fonseca Rodrigues et al., 2019; Yilmaz et al., 2019; Tatli et al., 2017; Nagata et al., 2015; Wahlund et al., 2015; Mora et al., 2013; Guarda-Nardini et al., 2012). This study adds to that literature by introducing a new medical device for treating TMDs and tests its effectiveness for reducing symptom severity and increasing quality of life (QOL).

Due to the non-localized nature of TMD symptoms, individuals may seek care from medical and dental health practitioners (NASEM, 2020) who may not be aware of all available treatments (Gadotti et al., 2018). Each practitioner without specialized knowledge of TMDs faces a challenge in providing effective treatments to relieve TMD symptoms and some resort to the irreversible correction of mechanical aspects of the bite (Peters et al., 2015).

Individuals with TMDs face a lengthy search for effective treatments and use 10 to 20% more dental services than those without TMDs, with an average of one additional dental procedure a year (Hobson, K. A., et al., 2008). The clinical research confirms the number of treatments for TMDs, while also revealing a continuance of symptoms after surgeries (Dalewski et al., 2019; Kutuk et al., 2019; Nagata et al. 2019; Ramakrishnan et al., 2019; da Fonseca Rodrigues et al., 2019; Yilmaz et al., 2019; Tatli et al., 2017; Nagata et al., 2015; Wahlund et al., 2015; Mora et al., 2013; Guarda-Nardini et al., 2012; NASEM, 2020). Therefore, research points to a need to focus on a holistic, patient-centered view of TMD treatment, where increasing a patient's quality of life (QOL) is at the center of a provider's health strategy (Edvall et al., 2019; Song, Y. L. and Yap, A. U. J., 2017).

As individuals with TMDs seek various treatments, they incur more costs through the cost of the search and costs of ineffective treatments. The greatest costs come from visiting many practitioners, implying that misdiagnosis and less-than-optimal treatments lead to increased costs for TMD patients while symptoms continue (Seo et al., 2020). One estimate for the per-person cost of treatment of any orofacial pain is $2,280 (£1,751), where the high cost is driven by several consultations (Wahlund et al., 2015). As pain is a common symptom for those with TMDs, indirect costs may not be entirely borne by the individual. Literature also points to the importance of including indirect societal costs in calculations of the total cost of chronic pain conditions (Olafsson et al., 2017). These indirect costs take the form of reduced productivity and are usually calculated using the human capital approach (Wieser et al., 2005).

While pain and jaw mechanics are common outcome variables in clinical TMD treatment research, this study measures patient-reported changes in symptom severity for a list of painful and non-painful TMD symptoms (Dalewski et al., 2019; Nagata et al., 2019; NASEM, 2020). As with other chronic pain conditions, TMDs are associated with lower quality of life (QOL)

measures (Bitiniene et al., 2018; Dahlström and Carlsson, 2010; de Magalhães et al., 2009; Von Korff et al., 1993). When examining other chronic conditions, those with TMDs experience impacts in their QOL similar to diabetes, arthritis, depression, and myocardial infarction (NASEM, 2020).

Given the literature, this study considers the US a conservative treatment method for TMDs. If proven effective, it could prevent unnecessary surgery and replace other conservative treatment methods, saving TMD patients from the expense of ineffective treatments and preventing increasing costs of the chronic illness to society. The paper is organized as follows: Section 2 outlines the paper's methodology, Section 3 presents the study's results, and Section 4 discusses implications and limitations.

METHODS

Study Design and Participants

This study received IRB approval (request ID 21-10122q, approved 8/31/2020) and is funded by TMD Services, LLC. The study's participants are patients treated by TMD Services, LLC, who provided a list of 844 potential participants. Once cleaned, there were 257 usable responses, with a usable response rate of 30.5%.

The requirements to participate in this survey were that the participants had to be over 18 years of age, and they had to have been treated with the US, a medical device invented and patented by Dr. Tony Urbanek (patent ID: US9314320B2). This device has received FDA approval. Unlike common occlusal splints or grinding guards, the purpose of the Urbanek Splint (US) is not to change how the teeth fit together. Instead, it relieves the load off the temporomandibular joint, thus reducing painful inflammation.

The survey contains six blocks of questions in part taken from previously published research (Lindofors et al., 2019; Krause and Prodoehl, 2017; Jagur et al., 2012; Bharmal et al., 2009).

Analysis

To measure the Urbanek Splint's (US) impact on relieving TMD symptoms and improving quality of life (QOL), this study splits patients into two groups: those previously treated for a TMD (PT) and those using the US as their first treatment (NT).

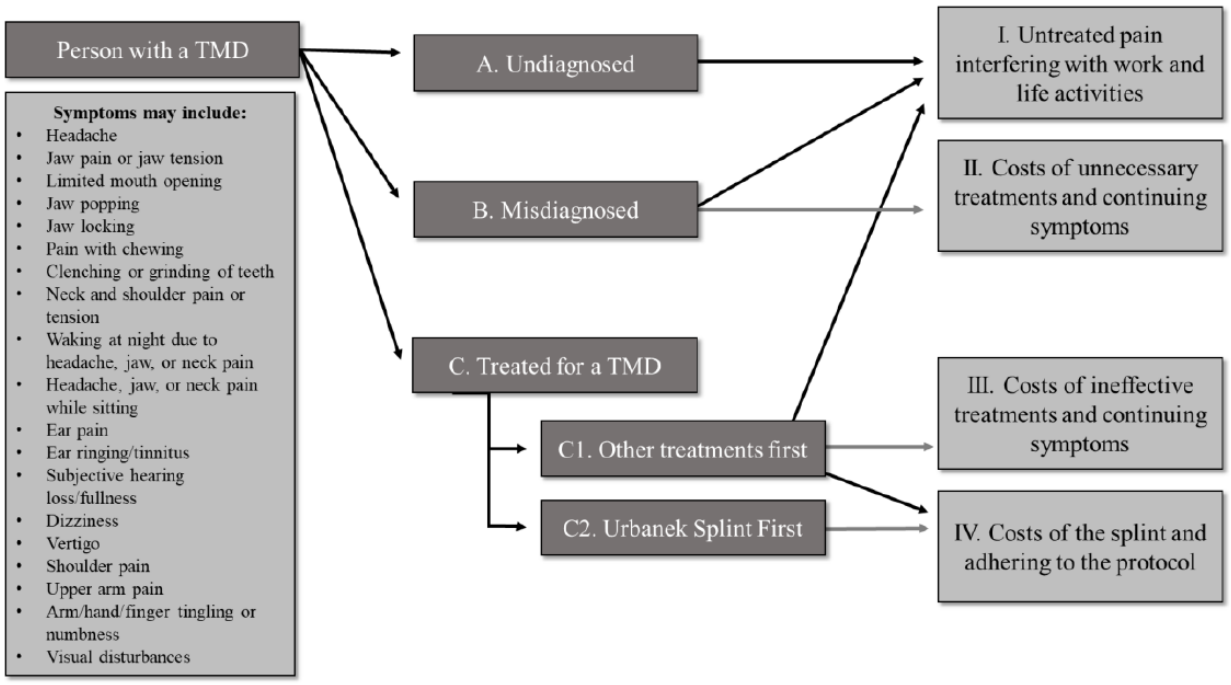
Those in the previously treated (PT) groups are associated with three types of costs: costs of untreated pain interfering with work and life activities (I), costs of ineffective treatments (II), and costs of the Urbanek Splint (US) and adhering to the Urbanek Splint (US) treatment protocol (III). Those in the previously treated (PT) group have paid for ineffective treatments while bearing the burden of TMD symptoms and pain, and then they paid for the Urbanek Splint (US) and bore the cost of adhering to the treatment protocol. Those in the not previously treated (NT) group have the cost of the Urbanek Splint (US) and its treatment (III). It should be noted that those with TMDs often go undiagnosed or misdiagnosed, and some of the costs reported in this

paper for the previously treated (PT) group are costs of treatments for the *symptoms of TMDs prior to diagnosis*; this falls into the first cost category of ineffective treatments (I) (Figure 1).

Patients previously treated for a TMD likely have higher costs in the form of seeing more practitioners and living with painful symptoms, and they may have more severe symptoms that motivated them to seek different TMD treatments. Someone with less severe symptoms may accept a smaller reduction in TMD symptoms (e.g., someone who cannot sleep due to TMD pain would be more willing to pay the costs of searching than someone who occasionally gets headaches because of her TMD).

This study aims to understand how the Urbanek Splint (US) helps in relieving the symptoms of TMDs for those who have been through many types of treatments (PT) and those who have not (NT). Previously treated patients represent an experienced group. Those not treated for a TMD are taking the Urbanek Splint (US) as it is *without* comparison to other TMD treatments. By analyzing the two groups separately, the study can determine if the Urbanek Splint (US) is effective at relieving TMD symptoms and if it is effective compared to other treatments.

Fig 1 TMD Patient Groups and Associated Costs



Source: Authors

For the effectiveness and quality of life (QOL) analysis, the survey asked respondents about symptoms and QOL in the six months before treatment with the Urbanek Splint (US) and after treatment with the Urbanek Splint (US). These questions allow for bootstrapped t-tests (Durham, J., et al., 2016) on each group's reported symptom, and QOL means. Tests are also

conducted to see if previously treated (PT) and not previously treated (NT) groups' *Before Urbanek Splint* means significantly differ. Suppose the previously treated (PT) group has more severe symptoms or worse quality of life than the not previously treated (NT) group. In that case, the stronger effect of their TMDs may have led the previously treated (PT) group respondents to continue to seek treatment.

This study first presents expenses associated with previous treatments reported by previously treated (PT) group respondents. Respondents were asked about the previous TMD treatments received and about the total costs of treatment before and after diagnosis, but not about the timing of costs or the cost associated with the type of treatment. To provide estimates of annual treatment costs in the survey, the study utilizes cost estimates for patients in selected U.S. cities based on aggregated, claims-based data provided by FAIR Health, Inc. for 2019 (FAIR Health, Inc., 2021). Second, the study presents the average costs of the previously treated (PT) groups by costs incurred before and after TMD diagnosis.

Satisfaction measures are presented as reported in the data, and the study analyzes if the reported measures differ between the previously treated (PT) and not previously treated (NT) groups. Satisfaction with the Urbanek Splint (US) confirms the success of the treatment method (Gouveia et al., 2015).

RESULTS

Data

Table 1 presents the descriptive statistics for survey participants, separated by prior treatment for TMDs. Most of those surveyed are women (a total of 226). The two groups do not differ with respect to average age or number of years treated with Urbanek Splint (US). The groups report a similar prevalence of TMD symptoms. The difference between the groups (besides previous TMD treatment) is in the number of years since a TMD diagnosis. The previously treated (PT) group is more likely to have seven to 20 years since being diagnosed.

Table 1: Descriptive Statistics

		Treated Previously (PT)†	Not Treated Previously (NT)
		158	99
Gender	Women	92.4%	80.8%
	Men	7.6%	19.2%
Age		48.4	47.8
Employment			
	Employed Full time	57.6%	54.5%
	Employed Part time	6.3%	6.1%
	Retired	19.0%	22.2%
	Not employed	15.2%	17.2%
Number of years experiencing TMD symptoms before being diagnosed with a TMD			
	Less than 1 year	15.2%	16.3%
	1 to 3 years	22.8%	24.5%
	4 to 6 years	16.5%	15.3%
	7 to 10 years	17.8%	15.3%
	11 to 15 years	6.3%	12.2%
	16 to 20 years	8.2%	3.1%
	More than 20 years	12.7%	12.2%
Number of years since being diagnosed with a TMD			
	Less than 1 year	7.0%	10.1%
	1 to 3 years	21.5%	48.5%
	4 to 6 years	19.0%	22.2%
	7 to 10 years	17.7%	7.1%
	11 to 15 years	6.3%	2.0%
	16 to 20 years	5.7%	2.0%
	More than 20 years	21.5%	8.1%
Number of years treated with Urbanek Splint			
		2.41	2.20
TMD Symptoms			
	Headache	87.3%	84.8%
	Jaw pain or jaw tension	91.8%	93.9%
	Limited mouth opening	83.5%	80.8%
	Jaw popping	88.6%	85.9%
	Jaw locking	70.3%	69.7%
	Pain with chewing	82.9%	82.8%
	Clenching or grinding of teeth	89.9%	92.9%
	Neck and shoulder pain or tension	89.2%	82.8%
	Waking at night due to headache, jaw, or neck pain	76.6%	75.8%
	Headache, jaw, or neck pain while sitting	82.9%	82.8%
	Ear pain	79.1%	79.8%
	Ear ringing/tinnitus	71.5%	72.7%
	Subjective hearing loss/fullness	60.1%	55.6%
	Dizziness	64.6%	66.7%
	Vertigo	57.0%	56.6%
	Shoulder pain	74.7%	69.7%
	Upper arm pain	60.1%	58.6%
	Arm/hand/finger tingling or numbness	61.4%	59.6%
	Visual disturbances	51.9%	47.5%
	Other (please specify)	6.3%	10.1%

†In order to determine the similarity of our two groups, we conducted a t-test on our continuous variable measures age and time treated with the Urbanek Splint. The results showed that the two groups do not significantly differ with respect to age (p.val = 0.3954) or time treated with US (p.val = 0.1921).

EFFECTIVENESS AND QUALITY OF LIFE

The effectiveness of symptom severity reduction by the Urbanek Splint (US) is presented in Table 2 by each TMD symptom and by group (previously treated (PT) or not previously treated (NT)). Severity reduction is shown by the *Difference* columns, with the percentage

change shown in the second row for each symptom. The average symptom severity reduction for the three most severe symptoms for the previously treated (PT) group is 2.45 (or 63%), and the average symptom severity reduction for the other symptoms is 1.66 (or 66%). Calculated with a bootstrapped t-test method, the differences in the *Before Urbanek Splint (US)* and the *After Urbanek Splint (US)* average symptom severity for the previously treated PT group are all significant ($p < 0.01$), except the symptom category "Other." The study concludes that the Urbanek Splint (US) significantly reduced symptom severity for the previously treated (PT) group.

The average symptom severity reduction for the three most severe symptoms in the not previously treated (NT) group is 2.52 (or 70%), and the average symptom severity reduction for the other symptoms is 1.61 (or 72%). The differences for the not previously treated (NT) group in the *Before Urbanek Splint (US)* and *After Urbanek Splint (US*) average symptom severity are all significant at the 0.01 level. The study concludes that the Urbanek Splint (US) significantly reduced symptom severity for the not previously treated (NT) group.

Table 2 also shows results for the test of means of symptom severity before treatment with the Urbanek Splint (US) between the previously treated (PT) and the not previously treated (NT) groups. For all but "Jaw popping" and "Jaw locking," the previously treated (PT) group had higher symptom severity before treatment with the Urbanek Splint (US) than the not previously treated (NT) group (at least $p < 0.10$). The average severity difference for the significant symptoms is 0.66, and the average prevalence for the significant symptoms is 62% (97/158) for the previously treated (PT) group and 56% (55/99) for the not previously treated (NT) group. The previously treated (PT) group showed significantly higher severity pre-Urbanek Splint (US) for common TMD symptoms.

Table 2: Effectiveness: Symptom Severity Reduction

	Previously Treated for TMD (PT)						Not Previously Treated for TMD (NT)						PT - NT	
Severity of Symptoms[†]	Before US	n[‡]	After US	n	Difference	t-test	Before US	n	After US	n	Difference	t-test	Before US	t-test[§]
Headache	**3.3701**	127	**1.252**	127	**2.1181**	0.0000	**3.1268**	71	**1.1549**	71	**1.9718**	0.0000	**0.2433**	0.277
	1.3262		*1.2908*		-63%		*1.6469*		*1.3591*		-63%			
Jaw pain or jaw tension	**4**	136	**1.3162**	136	**2.6838**	0.0000	**3.675**	80	**1.1125**	80	**2.5625**	0.0000	**0.325**	0.0246**
	1.0256		*1.2214*		-67%		*1.0998*		*1.312*		-70%			
Limited mouth opening	**3.0588**	119	**0.9664**	119	**2.0924**	0.0000	**2.9545**	66	**0.7576**	66	**2.197**	0.0000	**0.1043**	0.6709
	1.5639		*1.2346*		-68%		*1.6495*		*1.1905*		-74%			
Jaw popping	**3.2385**	130	**1.1769**	130	**2.0615**	0.0000	**3.44**	75	**0.96**	75	**2.48**	0.0000	**-0.2015**	0.3596
	1.5392		*1.2787*		-64%		*1.4165*		*1.2241*		-72%			
Jaw locking	**2.4227**	97	**0.6598**	97	**1.7629**	0.0000	**2.4423**	52	**0.5**	52	**1.9423**	0.0000	**-0.0196**	0.9548
	1.8362		*1.1627*		-73%		*1.7197*		*1.0937*		-80%			
Pain with chewing	**3.0957**	115	**0.8348**	115	**2.2609**	0.0000	**3.0299**	67	**0.7612**	67	**2.2687**	0.0000	**0.0658**	0.7678
	1.4866		*1.0673*		-73%		*1.5272*		*1.0884*		-75%			
Clenching or grinding of teeth	**4.0821**	134	**1.6269**	134	**2.4552**	0.0000	**3.6795**	78	**1.1538**	78	**2.5256**	0.0000	**0.4026**	0.0176**
	1.0623		*1.3302*		-60%		*1.3531*		*1.3491*		-69%			
Neck and shoulder pain or tension	**3.624**	125	**1.4**	125	**2.224**	0.0000	**3.1029**	68	**0.9559**	68	**2.1471**	0.0000	**0.5211**	0.0112**
	1.2291		*1.4424*		-61%		*1.4776*		*1.2629*		-69%			
Waking at night due to headache, jaw, or	**3.0755**	106	**0.8019**	106	**2.2736**	0.0000	**2.4138**	58	**0.6034**	58	**1.8103**	0.0000	**0.6617**	0.016**
	1.5036		*1.2756*		-74%		*1.6758*		*1.0077*		-75%			
Headache, jaw, or neck pain while sitting	**3.3333**	117	**1.094**	117	**2.2393**	0.0000	**2.8182**	66	**0.8182**	66	**2**	0.0000	**0.5152**	0.0336**
	1.4324		*1.326*		-67%		*1.6353*		*1.2392*		-71%			
Ear pain	**3.0882**	102	**1.0098**	102	**2.0784**	0.0000	**2.2787**	61	**0.5902**	61	**1.6885**	0.0000	**0.8095**	0.0038***
	1.5739		*1.3895*		-67%		*1.6138*		*1.0389*		-74%			
Ear ringing/tinnitus	**2.9612**	103	**1.6019**	103	**1.3592**	0.0000	**2.7018**	57	**1.3509**	57	**1.3509**	0.0000	**0.2594**	0.3406
	1.7259		*1.7283*		-46%		*1.6471*		*1.4576*		-50%			
Subjective hearing loss/fullness	**2.0833**	84	**0.9881**	84	**1.0952**	0.0002	**1.9048**	42	**0.6905**	42	**1.2143**	0.0002	**0.1786**	0.575
	1.8446		*1.3753*		-53%		*1.605*		*1.2195*		-64%			
Dizziness	**2.0706**	85	**0.6941**	85	**1.3765**	0.0000	**1.7885**	52	**0.5192**	52	**1.2692**	0.0000	**0.2821**	0.3282
	1.6168		*0.9883*		-66%		*1.6007*		*1.1962*		-71%			
Vertigo	**1.8472**	72	**0.6111**	72	**1.2361**	0.0000	**1.5435**	46	**0.3913**	46	**1.1522**	0.0004	**0.3037**	0.3394
	1.6068		*0.9576*		-67%		*1.6827*		*0.9995*		-75%			
Shoulder pain	**2.5769**	104	**1.1442**	104	**1.4327**	0.0000	**2.2239**	67	**0.6119**	67	**1.6119**	0.0000	**0.353**	0.1482
	1.5623		*1.3468*		-56%		*1.5746*		*1.1276*		-72%			
Upper arm pain	**1.9634**	82	**0.7195**	82	**1.2439**	0.0000	**1.2667**	45	**0.2667**	45	**1**	0.0000	**0.6967**	0.0306**
	1.7101		*1.2792*		-63%		*1.558*		*0.58*		-79%			
Arm/hand/finger tingling or numbness	**2.0595**	84	**0.631**	84	**1.4286**	0.0000	**1.7391**	46	**0.3913**	46	**1.3478**	0.0000	**0.3204**	0.3406
	1.6672		*0.9791*		-69%		*1.8907*		*0.9304*		-78%			
Visual disturbances	**1.4394**	66	**0.5606**	66	**0.8788**	0.0002	**0.8919**	37	**0.1622**	37	**0.7297**	0.0002	**0.5475**	0.0562*
	1.5		*1.0096*		-61%		*1.2424*		*0.3737*		-82%			
Other (please specify)	**1.4286**	7	**0.1429**	7	**1.2857**	0.1746	**0**	5	**0**	5	**0**	N/A	**1.4286**	0.0466**
	2.4398		*0.378*		-90%		*0*		*0*		N/A			

[†]Respondents reported their symptom severity on a scale from 0 to 5, where 0 indicates the symptom is not at all severe and 5 indicates the symptom is so severe as to be debilitating. Respondents were instructed to choose "N/A" if they had not experienced a symptom.

[‡]Reponses were cleaned so that every response used in analysis had both a Before US and an After US symptom severity rating.

[§]'***' is significance at the 0.01 level, '**' is significance at the 0.05 level, '*' is significance at the 0.01 level

The results for the effectiveness of the Urbanek Splint (US) in reducing the quality of life (QOL) interference are presented in Table 3 by each QOL dimension and by group (PT or NT).

The average QOL interference reduction for the three most affected QOL dimensions is 1.82 (64%), and the average QOL interference reduction for the other QOL dimensions is 1.51 (70%). The differences in the *Before Urbanek Splint (US)* and the *After Urbanek Splint (US*) average QOL interference for the previously treated (PT) group are all significant ($p < 0.01$). We conclude that the Urbanek Splint (US) significantly reduced the QOL interference of TMDs for the previously treated (PT) group.

The average QOL interference reduction for the three most affected QOL dimensions is 1.86 (70%), and the average QOL interference reduction for the other QOL dimensions is 1.17 (76%). The differences in the *Before Urbanek Splint (US*) and the *After Urbanek Splint (US*) average QOL interference for the not previously treated (NT) group are all significant at the 0.01 level. The study finds that the Urbanek Splint (US) significantly reduced QOL interference of TMDs for the not previously treated (NT) group.

Table 3 shows the results for the test of means of QOL interference before treatment with the Urbanek Splint (US) between the previously treated (PT) and the not previously treated (NT) groups. For all but the dimension "Yawn or open your mouth," the previously treated (PT) group has higher QOL interference before treatment with the Urbanek Splint (US) than the not previously treated (NT) group. The average interference difference for the significant QOL dimensions is 0.59, and the average prevalence for the significant QOL dimensions is 78% for the previously treated (PT) group and 72% for the not previously treated (NT) group. The study concludes that the previously treated (PT) group showed significantly higher QOL interference pre-Urbanek Splint (US) for commonly affected QOL dimensions.

Table 3: Effectiveness: Quality of Life Interference Reduction

	Previously Treated for TMD (PT)						Not Previously Treated for TMD (NT)						PT - NT	
Life activities[†]	Before US	n[‡]	After US	n	Difference	t-test	Before US	n	After US	n	Difference	t-test	Before US	t-test[§]
Socialize with family and close friends	**2.1667** *1.6518*	120	**0.6333** *1.0995*	120	**1.5333** -71%	0.0000	**1.3803** *1.4279*	71	**0.4225** *0.9511*	71	**0.9577** -69%	0.0000	**0.7864**	0.0014***
Perform daily work	**2.2645** *1.5746*	121	**0.6116** *1.1133*	121	**1.6529** -73%	0.0000	**1.6806** *1.4025*	72	**0.4306** *1.0185*	72	**1.25** -74%	0.0000	**0.5839**	0.0100**
Perform daily household chores	**2.0806** *1.5906*	124	**0.5565** *1.0461*	124	**1.5242** -73%	0.0000	**1.4444** *1.3624*	72	**0.3194** *0.8693*	72	**1.125** -78%	0.0000	**0.6362**	0.0056***
Sit in the company of other or participate in other social settings	**1.9835** *1.6481*	121	**0.5455** *1.0247*	121	**1.438** -73%	0.0000	**1.4118** *1.5184*	68	**0.3088** *0.7582*	68	**1.1029** -78%	0.0000	**0.5717**	0.0224**
Exercise (such as walking, jogging, or cycling)	**1.8908** *1.6814*	119	**0.563** *1.1019*	119	**1.3277** -70%	0.0000	**1.25** *1.3754*	68	**0.25** *0.7799*	68	**1** -80%	0.0000	**0.6408**	0.0064***
Performing hobbies (such as reading, knitting, or fishing)	**1.7778** *1.6974*	117	**0.5641** *1.1625*	117	**1.2137** -68%	0.0000	**1.1094** *1.2739*	64	**0.1563** *0.5696*	64	**0.9531** -86%	0.0000	**0.6684**	0.0046***
Sleep at night	**2.7077** *1.5574*	130	**0.9769** *1.2848*	130	**1.7308** -64%	0.0000	**2.1974** *1.5579*	76	**0.7895** *1.2787*	76	**1.4079** -64%	0.0000	**0.5103**	0.0296**
Concentrate	**2.5159** *1.6086*	126	**0.7937** *1.1954*	126	**1.7222** -68%	0.0000	**2.0714** *1.5163*	70	**0.4857** *1.032*	70	**1.5857** -77%	0.0000	**0.4444**	0.0568*
Eat	**2.7405** *1.5372*	131	**1.0076** *1.292*	131	**1.7328** -63%	0.0000	**2.5844** *1.6088*	77	**0.8831** *1.1807*	77	**1.7013** -66%	0.0000	**0.156**	0.4958
Talk, laugh, or sing	**2.5238** *1.6381*	126	**0.8492** *1.2779*	126	**1.6746** -66%	0.0000	**2.2917** *1.6224*	72	**0.5417** *1.02*	72	**1.75** -76%	0.0000	**0.2321**	0.3442
Yawn or open your mouth	**3.0373** *1.6379*	134	**1.0448** *1.2795*	134	**1.9925** -66%	0.0000	**3.141** *1.5351*	78	**1.0128** *1.3722*	78	**2.1282** -68%	0.0000	**-0.1037**	0.6377
Overall, how much did the pain/discomfort from your TMD	**3.0889** *1.363*	135	**0.9704** *1.2091*	135	**2.1185** -69%	0.0000	**2.5904** *1.4486*	83	**0.7952** *1.1236*	83	**1.7952** -69%	0.0000	**0.4985**	0.0120**

[†]Respondents reported their quality-of-life interference on a scale from 0 to 5, where 0 indicates the activity is not affected by TMD pain or discomfort and 5 indicates the activity is impossible due to TMD pain or discomfort. Respondents were instructed to choose "N/A" if they had not experienced TMD interference in a life activity.

[‡]As with symptom severity, responses were cleaned so that every response used in analysis had both a Before US and an After US QOL interference rating.

[§]'***' is significance at the 0.01 level, '**' is significance at the 0.05 level, '*' is significance at the 0.01 level

Comparison of Costs

The Urbanek Splint (US) was created to relieve symptoms of TMD so that patients will not have to continue to search for alternative TMD treatments. We use two methods to measure the cost-effectiveness of the Urbanek Splint (US) compared to other TMD treatments. First, we analyzed aggregated cost and utilization data provided by FAIR Health, Inc., based on claims data from its FH NPIC® repository of privately insured medical claims. We received aggregated data reflecting the utilization of certain services and benchmark data reflecting the imputed allowed amounts typically paid by insurers for those certain services. We used these data to calculate an estimated weighted average annual cost of selected TMD treatments based on location. Due to survey limitations, patients' treatment length is not known. Given the previously treated (PT) group's average length of time with TMD symptoms (14 years), it is assumed that treatments spanned multiple years. Based on the data, it is also not possible to determine if respondents' treatments overlapped.

Table 4 shows the average costs for various TMD treatments. These costs are the weighted average per person for 2019 for the city of Nashville, TN, and are reported as *average point estimates* to show how the costs of other treatments compare with the Urbanek Splint (US). The "Years to Breakeven with Urbanek Splint (US)" estimates show the price of the Urbanek Splint (US) divided by the annual price of the other TMD treatments. The most prevalent and

least costly TMD treatment is occlusal guards (night guards, grinding guards), with 60% of the previously treated (PT) group reporting use. Surgery is the least prevalent and most expensive TMD treatment; only four percent of the previously treated (PT) group report having undergone surgery for their TMD.

As shown in Table 4, many other TMD treatments are less expensive than the Urbanek Splint (US) (the device costs around $1500). The "Years to Breakeven" estimates in the fourth row of Table 5 show that only surgical treatments are more expensive yearly. Respondents would have had to replace their occlusal guards every year for more than seven years to make switching to the US worth it. However, survey data shows that many respondents reported more than one TMD treatment method. Row five of Table 5 notes the average number of previous TMD treatments associated with the treatment category. For example, occlusal guards are associated with respondents having three treatment methods (including the initial category), with an average cost of $425 (excluding the initial category). Given the total cost of the category and the associated treatments, row seven of Table 4 shows how the annual costs compare with the Urbanek Splint (US).

The second panel of Table 4 details the average annual costs for the TMD treatment categories for selected cities in the United States. Most cities report costs at about 83% of the costs to those in Nashville for the selected TMD treatments. For all costs in Table 4, consultations, x-rays, etc., are not included, making the actual cost of treatments higher than what is presented.

Table 4: TMD Treatment Costs

	Chiropractic	Occlusal guards	Massage therapy	Acupuncture	Botox injections	Surgery[§]	Physical therapy
Weighted Average Cost (2019)[†]	$269.08	$202.00	$402.33	$425.69	$766.07	$2,897.24	$316.58
n of PT Group Reporting Treatment	47	95	51	17	11	6	28
Percent of PT Group Reporting Treatment	30%	60%	32%	11%	7%	4%	18%
Years to Breakeven with US Cost	5.57	7.43	3.73	3.52	1.96	0.52	4.74
Average Number of Treatments[‡]	3	3	4	4	5	3	3
Average Costs of Associated Treatments	$683.15	$425.13	$657.55	$839.26	$1,013.26	$359.67	$681.42
Years to Breakeven with US Cost	1.58	2.39	1.42	1.19	0.84	0.46	1.50

Average Weighted Costs (2019)	Chiropractic	Occlusal guards	Massage therapy	Acupuncture	Botox injections	Surgery	Physical therapy	Cost Ratio
Atlanta, GA	$241.25	$195.16	$292.71	$336.77	$670.65	$2,435.61	$264.05	0.8403
Augusta, ME	$243.47	$206.70	$395.60	$393.72	$579.36	$2,400.52	$320.48	0.8600
Austin, TX	$285.98	$370.79	$353.52	$265.95	$484.92	$3,249.55	$294.65	1.0050
Columbus, OH	$279.84	$209.90	$349.78	$480.63	$802.26	$2,587.15	$281.76	0.9455
New York, NY	$661.22	$364.71	$582.08	$695.25	$1,635.44	$5,553.19	$552.74	1.9028
Pheonix, AZ	$333.26	$198.36	$365.88	$356.41	$459.45	$2,389.85	$299.54	0.8340
Seattle, WA	$302.63	$224.28	$335.68	$342.84	$559.60	$2,376.66	$280.54	0.8377
Topeka, KS	$265.21	$176.14	$383.50	$443.06	$636.66	$2,157.95	$285.63	0.8237

[†]Costs are calculated from averages based on FairHealth, Inc. medical and dental claims for Nashville, TN. Costs are calculated using CPT codes associated with the treatment category, multiplied by the average number of times a cost code appears for a single patient, weighted by the prevalence of that cost code for a TMD patient, and then summed together.
[‡]This includes prescription medications, occlusal correction/braces, and other treatment categories for which we do not have cost estimates.
[§]This category includes an oral surgical splint, arthrocentesis, other injections, arthroscopy, arthroplasty, condylectomy, and meniscectomy.

Panel A of Table 5 presents the treatment costs for previously treated (PT) group respondents for two periods: the years with a TMD diagnosis prior to treatment with the Urbanek Splint (US) and the years with TMD symptoms before TMD diagnosis. These costs correspond to categories III and II in Figure 1, respectively. Costs are averaged over the length of time category. Cost outliers over $10,000 were removed (n = 11). Those without costs for both diagnosis and pre-diagnosis questions were removed, resulting in 78 of the previously treated (PT) group represented in Table 5.

Most previously treated (PT) respondents are within the one to ten years categories for time with TMD diagnosis (63%), with about 18% of respondents in the 20-plus year category. Most respondents are within the zero to ten years categories for time with TMD symptoms pre-diagnosis (73%), with only nine percent of respondents in the 20-plus year category.

The average total cost for all respondents for the years before TMD diagnosis is $2,082, and the average total cost for the years after TMD diagnosis is $2,142. For the average patient in

this sample, the Urbanek Splint (US) could have saved $2,724 in ineffective, unnecessary treatments for TMD symptoms (total costs minus the cost of the Urbanek Splint (US)). If we use a discount rate of 3% (Attema et al, 2018) and the average of Years with a TMD Diagnosis of about 7 years, then the discounted cost savings rate is $2,215.

Most respondents in the previously treated (PT) group sample (87%) report having insurance (medical or dental). Assuming the costs presented in Table 4 and Table 5 are in some way paid by insurance, while the Urbanek Splint (US) device is not covered by insurance, the cost savings would be primarily borne by insurance companies, not the individuals.

Panel B of Table 5 presents the range of total costs in the previously treated (PT) sample, with total lifetime costs ranging from zero to $125,000. The average years of TMD treatment, the average number of TMD symptom treatments, and the average number of comorbidities all increase as the costs of treatments increase. The large range of total lifetime costs implies that for those in the sample who have spent more than the cost of the Urbanek Splint (US) (about 50%), the cost savings of the Urbanek Splint (US) is much higher than our $2,724 average estimate. Using a weighted average of the midpoints of the lifetime costs in Table 6, the estimated cost savings is $6,615 ($8,115 minus the cost of the Urbanek Splint (US)). The discounted rate of these cost savings (using the same assumptions as above) is $5,379.

Table 5: Costs for PT Group by Number of Treatment Years and Cost Ranges

Panel A: Costs by Years Before and After TMD Diagnosis for PT Group

Years with TMD Diagnosis†	n	Average Cost of TMD Treatment	Years with TMD Symptoms Pre-Diagnosis‡	n	Average Cost of Symptom Treatment
Less than 1 year	6	$1,450	Less than 1 year	11	$1,525
1 to 3 years	19	$1,553	1 to 3 years	16	$2,000
4 to 6 years	11	$1,645	4 to 6 years	16	$2,478
7 to 10 years	19	$2,460	7 to 10 years	14	$2,262
11 to 15 years	5	$1,800	11 to 15 years	7	$2,086
16 to 20 years	4	$888	16 to 20 years	7	$2,686
More than 20 years	14	$3,636	More than 20 years	7	$1,300

Panel B: Range of Total Costs for TMD Symptom Treatment for Previously Treated (PT) Group

Range of Total Costs§	n	Average Years of TMD Treatment¶	Average Number of Treatments	Average Number of Comorbidities
$125,000 to 50,001	5	7.00	3.40	5.80
$50,000 to 15,001	5	7.03	3.20	3.00
$15,000 to 10,001	8	12.93	4.00	2.50
$10,000 to 5,001	15	6.43	2.93	4.53
$5,000 to 2,001	25	6.16	2.64	4.08
$2,000 to 1,001	17	5.06	2.41	3.82
$1000 to 501	11	4.91	1.91	1.73
$500 to 201	18	1.33	1.28	2.50
$200 to 0	12	1.83	1.17	2.58

†For category 1, categories and costs are determined by the questions: "How long have you been diagnosed with a TMD?" and "Please estimate the cost of treatment for your TMD symptoms after you found out that your symptoms were a result of your TMD and before you started using the Urbanek Splint. This includes costs to you and/or your insurance company for diagnostic services, x-rays, MRIs, CT scans, and failed treatments." ‡For category 2, categories and costs are determined by the questions: "How long had you experienced your TMD symptoms before you were diagnosed with a TMD?" and "Please estimate the cost of treatment for your TMD symptoms before you found out that your symptoms were a result of your TMD. This includes costs to you and/or your insurance company for diagnostic services, x-rays, MRIs, CT scans, and failed treatments.

§Total costs represent the sum of costs prior to and after TMD diagnosis

¶This represents the question: "How long had you been treated for your TMD symptoms, both before and after you found out that your symptoms were a result of your TMD? This does not include the time you have been treated with the Urbanek Splint."

Satisfaction with US

To complement the effectiveness and cost sections, this study also details measures of respondents' reported satisfaction with Urbanek Splint (US). Results are presented separately for the previously treated (PT) and the not previously treated (NT) groups. The change in symptom severity and QOL interference used in the correlations are *Before Urbanek Splint (US)* minus *After Urbanek Splint (US)*.

The response rate for both groups is high (previously treated (PT): 87%; not previously treated (NT): 86%), and the two groups do not have significantly different average ratings for any satisfaction question. Questions I through V are on a 0 to 100 scale, and question VI is an open-answer question.

The average satisfaction levels for all dimensions (I-V) are not lower than 80/100 for either group, implying high levels of satisfaction with symptom relief (I), the timing of symptom relief (II), ease of use (III), confidence in right treatment (IV), and overall satisfaction (V).

Ratings for both groups are highest for question (III), highlighting again the ease of use of the Urbanek Splint (US) (previously treated (PT): 90.94; not previously treated (NT): 89.53).

For all satisfaction questions I through V, the previously treated (PT) group shows significantly positive correlations ($p < 0.10$) with both effectiveness measures, implying that higher reductions in symptom severity and QOL interference are associated with higher levels of satisfaction. For question VI, respondents were asked about their willingness to pay (WTP) for the US, given its effectiveness. The previously treated (PT) group's average willingness to pay (WTP) is greater than the actual amount of the device, and the effectiveness measures are positively correlated with the willingness to pay (WTP) ($p < 0.10$), implying greater reductions in symptom severity and QOL interference are associated with higher WTP.

The not previously treated (NT) group showed only two significant correlations between reduction in symptom severity and level of satisfaction (questions IV and V, $p < 0.10$). In both cases, the correlations are negative, implying that greater reductions in symptom severity are associated with lower satisfaction levels. Question IV's and question V's (confidence in the right treatment) negative correlations may imply that those in the not previously treated (NT) group had not experienced other TMD treatments to know how the Urbanek Splint (US) compares. Thus, the group is more unsure that the Urbanek Splint (US) is the right treatment and is less satisfied with the Urbanek Splint (US) overall.

DISCUSSION

Using the survey of individuals treated with the Urbanek Splint (US), this paper measures the effectiveness, cost savings, and respondent satisfaction of the Urbanek Splint (US) as a treatment for TMD. This paper separated those previously treated for TMD (PT) from those with the Urbanek Splint (US) as their first TMD treatment after diagnosis (NT). We found that the Urbanek Splint (US) reduces symptom severity in the sample by 63% (previously treated (PT)) and 70% (not previously treated (NT)) for the most severe TMD symptoms. The Urbanek Splint (US) reduces the interference of TMD-related pain and discomfort on daily life activities (increased QOL) by 64% (PT) and 70% (NT) for the most affected QOL dimensions. The previously treated (PT) group's symptom severity and QOL interference levels before treatment with the Urbanek Splint (US) are significantly higher ($p < 0.01$) than the not previously treated (NT) group, which is evidence that symptom severity and affected QOL may lead to a continued search for treatments after other treatments prove ineffective. Other treatment methods, such as physical therapy, also report high levels of self-reported reductions in pain (Krause, and Prodeoehl, 2019). Still, this study measures and reports the changes to all TMD-related symptoms, allowing for more specific analysis than simply measures of TMJ pain.

Based on the reported costs of treatments to relieve TMD-related symptoms for the previously treated (PT) group, the Urbanek Splint (US) is associated with an average lifetime cost savings of $2,724 to $6,615 ($2,215 to $5,379 discounted) for ineffective TMD treatments. This is similar to the cost estimates for chronic orofacial pain (Krause, S., and Prodeoehl, 2019).

The previously treated (PT) and not previously treated (NT) groups reported high levels of satisfaction with the Urbanek Splint (US), and though the previously treated (PT) group had

previous TMD treatments and the not previously treated (NT) had not, their ratings of satisfaction do not significantly differ.

A limitation of the study is the non-random participants, as participants were drawn from a group who both had been treated with the Urbanek Splint (US) and had a viable email with which to receive the link to the survey. This study attempted to account for variations in reported costs. However, the reliability of patients' reported treatment costs before and after TMD diagnosis raises concern about under and over-estimating previous costs. Another limiting factor is that not every person in the sample answered every question. To account for this, the effectiveness t-tests (symptoms and QOL) are paired, and responses in the cost calculations that did not have both a pre-and post-diagnosis cost estimate were excluded.

The quality of life (QOL) increase found for patients in this study implies that using the Urbanek Splint (US) can lead to two-thirds higher QOL, even for those with significantly lower initial QOL. The same implication holds for symptom severity reduction, where reductions are large and significant even for those with higher initial symptom severity. These results imply that the patient-centered methods of the Urbanek Splint (US) have led to large and significant results for individuals with TMDs.

Given the length of time a TMD patient spends with TMD symptoms before and after diagnosis, years of treatment costs could be avoided with the use of the Urbanek Splint (US). Even those with "low cost" treatments (e.g., occlusal splints) continue to pay for treatments for multiple years, and many in the previously treated (PT) group used multiple treatments for TMD. The large range of lifetime treatment costs implies a large range of cost savings, and many in the previously treated (PT) sample would have saved from $2,724 to $8,115 ($2,215 to $5,379 discounted) based on lifetime treatment costs. These cost measures do not include the indirect costs of TMD through lost productivity (Olafsson et al., 2017; Wieser et al., 2011). Therefore, the direct cost range is a lower bound of the actual cost of TMD to society through lost days of work as well as the costs of ineffective treatments.

The cost information presented in Table 5 has potential implications for insurance companies. The Urbanek Splint (US) could save the average TMD patient over $2,000 in ineffective and unnecessary treatments. However, as insurance companies bear the costs for insured individuals, they would directly benefit from the Urbanek Splint (US) replacing other treatments. Individuals would directly benefit (in terms of dollar costs) if their TMD treatments were not entirely covered by insurance.

The high satisfaction and reduction of symptom severity associated with using the Urbanek Splint (US) imply that those suffering from a TMD can find relief *and* be satisfied with the treatment method. High satisfaction is associated with higher switching costs, where consumers with high satisfaction are less likely to continue to search for an alternative service (Wong et al., 2014). Since individuals with TMDs are likely to face lengthy searches for effective treatment, the high satisfaction found in this study implies that the use of the Urbanek Splint can help reduce the societal cost of TMD through a reduced search for effective treatment. The lack of significant difference between the previously treated (PT) and not previously treated (NT) ratings for ease of use and satisfaction imply that the Urbanek Splint (US) is a satisfactory TMD treatment method for those with and without experience with other TMD treatments.

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