A Sensor-enhanced Mouth Guard to Quantitatively Measure Bite Compression Forces.

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SPECIFIC AIMS

Challenge. Sleep bruxism is one of the most common sleep-related movement disorders, affecting 1 in 3 US adults[1] due to various mental health conditions, and results in excessive teeth grinding and jaw clenching[2]. Current strategies to address bruxism (such as Botox injections to the jaw, opioids, nonsteroidal anti-inflammatory drugs[3–5]) are expensive, invasive, cumbersome, and ineffective, as they can only provide temporary bruxism relief[6–8]. The most common method to protect patients against bruxism-related teeth damage is a night guard. Yet, night guards also bring other significant drawbacks, as these products are designed to be "one-size-fits-all," making them uncomfortable, cumbersome, and inconvenient for patients to wear throughout the night. A custom-made nightguard is available by a licensed dental provider, but the excessive mark-ups and rare coverage by dental insurances make this an unachievable alternative for most. Moreover, bruxism is significantly underreported, as most people are either unaware of their condition[9–13], are not properly diagnosed by their dentist or do not have access to proper dental care. Yet, awareness of the condition is critical for proper diagnosis and to develop an effective treatment plan. Currently, there is nothing in the market that can effectively measure and diagnose bruxism activity using quantitative means. For these reasons, there is a dire need for a solution that can (1) measure and quantify bruxism severity levels to give providers the proper insights/assessments; and (2) offer patients a reliable, effective, and comfortable solution that prevents dental damage and alleviates bruxism-related pain.

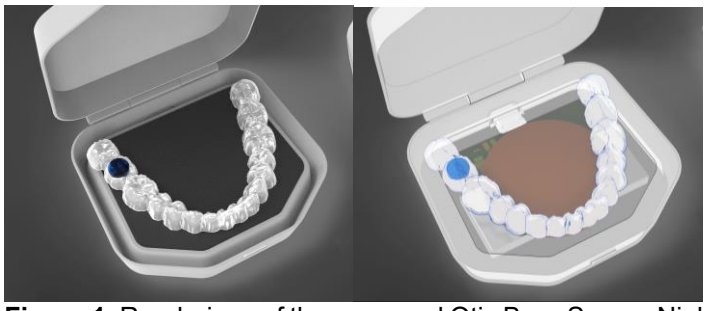

Figure 1. Renderings of the proposed Otis Brux-Sensor Night Guard innovation (OBSNG).

Proposed Solution. Otis Dental, Inc. (Otis) proposes to develop the Otis Brux-Sensor Night Guard, which is a novel, patented, wireless dental appliance system with pressure sensors that can quantitatively measure bite compression forces during sleep **Figure 1**). The technology is comprised of the Otis Custom Night Guard with an embedded electronics system that is coupled to a portion of the guard covering an axial plane of a tooth. The electronics system will be comprised of an antenna, capacitive sensor, microcontroller, and power supply. The sensor will produce and measure signals corresponding to bite compression forces generated by a patient throughout sleep time. Finally, the data will be transmitted to an external computing device for display and analysis by both patient and dental provider. The Otis Brux-Sensor Night Guard is a truly innovative technology as there are no dental products or tools that can provide effective protection against bruxism for patients while simultaneously collecting real-time data to gain better insights for treatment by dentists. If successful, patients will have improved protection against bruxism-related teeth pain and damage via a more comfortable and durable night guard. Dental providers will have the ability to record, analyze and monitor bruxism compression forces and trends over time to optimize patient treatment plans more effectively. This technology builds off of the company's success from its first product, the Otis Custom Night Guard, which is currently available on the Otis Dental website, Target.com, and in over 4,300 Walgreens locations, nationwide.

Project Aims. Otis is on a mission to disrupt the dental health space by developing high-quality oral care products that help Bruxism sufferers understand the root cause of the condition, thereby improving their quality of life in a more significant way. Herein this NIH STTR Phase I proposal, the goal is to develop a working prototype of the Otis Brux-Sensor Night Guard that can measure, analyze, and identify forces/trends between patients with no/mild to moderate/severe bruxism. Phase I will be pursued in collaboration between Otis Dental, Inc. and Brash Inc. in a multi-PI arrangement between Mr. Lee and Dr. Beranek, respectively. Together, the following technical aims will be pursued: **Aim 1: Develop and optimize the Otis Brux-Sensor hardware and software architectures to capture bite compression forces; Aim 2: Miniaturize the electrical circuit sensor hardware component from Aim 1 to be integrated into the molar region of the Otis custom night guard.;** and, **Aim 3: Conduct a usability pilot study with 28 patients to capture bite compression force profiles and optimize data collection.**

Development Plan. Otis's goal is to be the first to offer a reliable tool for both dentists and patients to improve their awareness of bruxism, which is critical to developing effective treatment plans and better oral care practices, respectively. In Phase II, the Otis team will further optimize the Otis Brux-Sensor Night Guard prototype in preparation for a clinical study to distinguish levels of Bruxism severity across a wide range of the US patient population, and pursue FDA clearance and prepare for market entry. By doing so, Otis will be the first ever to

deliver an affordable and noninvasive technology that allows patients, dentists, and mental health providers to work in sync towards a better diagnosis and treatment plan.

RESEARCH STRATEGY

1. SIGNIFICANCE

Bruxism is a medical condition characterized as a stereotyped oromandibular activity, resulting in excessive teeth grinding and jaw clenching[1]. It is one of the main causes of tooth and gingival/gum destruction, dental prosthesis/implant failure, tooth pain, jaw and/or masticatory muscle soreness, and headaches[2,14,15]. Sleep bruxism is one of the most common sleep-related movement disorders, affecting 1 in 3 US adults[1] and is mainly due to stress, anxiety, and other mental health conditions. Current strategies to address bruxism (such as Botox injections to the jaw[16], opioids[6–8], nonsteroidal anti-inflammatory drugs (NSAIDs[3–5]), and heat pads) are expensive, invasive, cumbersome, and/or can only temporarily alleviate bruxism symptoms. The most common and affordable method to protect against bruxism is a night guard. Yet, this also brings other significant drawbacks[17,18]. Over-the-counter (OTC) night guards available in most drug stores are typically produced in a "one-size-fits-all" design, making them uncomfortable, cumbersome, and inconvenient to wear throughout an entire duration of sleep. To make them affordable and accessible, OTC night guards are made out of soft, poor-quality plastics that are weak, wear away quickly, and provide little to no protection. As an alternative, patients can have a custom-fitted night guard made with higher-quality materials that are more durable, effective, and comfortable to wear during sleep. However custom night guards are expensive (ranging between $500-$1000) and must be prescribed by a licensed dental provider. This limits their accessibility to many, as those with dental insurance have little-to-no coverage, and the remaining population has no dental insurance. The custom night guard process by a dentist is also time-consuming, requiring multiple dental office visits that include a messy, throat-gagging experience with the dental clinician, a long waiting period while a third-party dental lab fabricates the product, and multiple follow-up dentist visits for adjustments due to patient comfort and/or bite issues.

Since stress, anxiety, and other mental health conditions are the primary causes of sleep bruxism, these current options only protect patients against dental damage without providing any means of monitoring and/or truly alleviating the condition, itself. In fact, due to the COVID-19 pandemic, the dental industry is seeing a significant increase in stress-induced bruxism cases, calling it the "Pandemic Bruxism" given how the COVID pandemic has severely affected the general population's mental health[23,24]. *Yet, bruxism is significantly underreported*[19–21], *as most people are either unaware of their condition*[9–13], *are not properly diagnosed by their dentist or do not have access to proper dental care.* Bruxism awareness is critical for proper diagnosis and to develop an effective treatment plan. However, *there is currently nothing in the market that can effectively measure and diagnose bruxism activity using quantitative means*. Typically, patients become aware of bruxism during annual visits when a dental professional identifies symptoms, such as tooth damage and/or jaw pain, clicking, or popping. These outdated, manual processes are highly ineffective and introduce significant variability between dental professionals within their assessment and diagnosis protocols, leading to frequent misdiagnosis or ineffective treatments. For these reasons, there is a critical need to use data that can objectively address and treat bruxism effectively by (1) measuring and quantifying bruxism severity levels that give dental providers proper insights/assessments; and, (2) offering patients a reliable, effective, and comfortable solution that prevents dental damage and reduces sleep bruxism symptoms.

Herein, this STTR Phase I proposal, in collaboration with Brash, Inc., Otis Dental proposes to develop the Otis Brux-Sensor Night Guard (OBSNG), which is a novel wireless custom night guard system with pressure sensors that can quantitatively measure bite compression forces during sleep (patent granted in June 2021). If successful, anyone suffering from Bruxism will have improved protection against the painful and damaging symptoms via a sensor-enhanced custom night guard. Dental providers can analyze and monitor bruxism compression force trends over time, thereby streamlining quality patient care through optimized treatment plans. This technology builds off of the company's success from its first product, the Otis Custom Night Guard. The Otis Custom Night Guard is a more effective, durable, affordable, and comfortable night guard that has been approved by licensed dental professionals and large-chain retailers. It is currently available on the Otis Dental website, Target.com, and in over 4,300 Walgreens locations, nationwide. In collaboration with oral surgeons at UCSF and SF VA Medical Center, a year-long validation study was conducted on the night guard with ~100 patients. Results were positive, as 93% of patients preferred the ease, quality, comfort, and fit of the much more affordable Otis Custom Night Guard compared to competitive OTC brands and/or traditional custom night guards by dentists. The company plans to enter the digital health market by introducing the OBSNG as an affordable subscription-based business model.

Market Demand. Based on the prevalence of bruxism and revenue generated by distributors of night guard materials and dental labs, the global sleep bruxism treatment market is projected to be worth $400B (market is

rapidly growing). Otis' dental materials supplier, Glidewell, is one of the largest and most reputable dental supply companies in the US. As a leader in the night guard and dental lab space, they are the exclusive distributor of Erkodent's Erokoloc-Pro night guard discs (used by most dental labs in the world to make custom night guards), reporting an annual revenue of approximately $30M in custom night guard discs sales, alone. There are over 9,000 dental labs in the US that purchase Glidewell's Erkoloc-Pro disc at the retail price of $4/disc and then charge dentists a fabrication fee of $60-$100. These custom night guards are then sold by dentists at a mark-up, between $500-$1,000. Based on these calculations alone, there is a total available market of $3.75B in custom night guard sales. And with over 100 global distributors of the Erkoloc-Pro discs, this leads to a ~$375B market. Over the course of just two years and nominal marketing spend, Otis has generated year-over-year growth and projects $2.5M in revenue for 2022 – demonstrating the market and clinical demand for improved night guard products. Based on the company's experience and past success, it expects to achieve exponential growth upon introducing the Otis Brux-Sensor Night Guard to the oral and mental health markets.

Commercialization Potential and Developmental Plan. The STTR goal is to develop a working prototype of the OBSNG that can measure, analyze, and identify forces/trends between patients with no/mild to moderate/severe bruxism. These efforts will be done with Brash, Inc., a product design firm that fuses form and function to design products that consider the connection between the user, product, and environment. These critical milestones would enable for FDA filing and eventually market introduction in the US.

2. INNOVATION

Overview. The OBSNG is a wireless custom night guard system with pressure sensors that can measure bite compression forces generated during sleep (**Figure 1**). The technology will be comprised of the Otis Custom Night Guard with an embedded electronics system that is coupled to a portion of the guard covering an axial plane of a tooth. The electronics system will be comprised of an antenna, capacitive sensor, microcontroller, and power supply. The sensor will produce and measure signals corresponding to bite compression forces generated by a wearer, over a period of time of sleep. Finally, the data will be transmitted to an external computing device for display and analysis by both wearer and dental provider. The OBSNG is affordable with an estimated cost of $100 for customers, which is critical to ensure it is accessible to all patients. Holding steadfast to the brand's mission in providing accessible and affordable oral care products, Otis will offer the Brux-Sensor as a free add-on option to their custom night guards, with wearers provided add-on app feature options at a nominal monthly subscription rate. In doing so, wearers can fully customize the function and effectiveness of both the product and technology, based on their unique stress-reducing needs. There are four key components to the innovation:

1. **The Otis Custom Night Guard.** The Otis Custom Night Guard offers more comfort and protection from Bruxism compared to current products in the market (OTC and custom-made). After years of research and multiple rounds of pilot testing, Otis determined that their Custom Night Guard would be made with an equal ratio of hard co-polyester and soft polyurethane materials. In doing so, the soft inner liner would provide a level shock absorbance from jaw clenching, while the hard outer layer would provide protection against teeth grinding. It was also determined that making their custom night guards in a 2-3mm thickness, rather than the traditional 4-5mm thickness, would provide optimal comfort and user compliance.
2. **The Brux-Sensor.** To generate the Brux-Sensor, force-sensing resistors (FSRs) will be placed on either side of the posterior region of the Otis Custom Night Guard to collect optimal compression forces generated by jaw muscles around the Temporomandibular Joint. This sensor will allow for accurate measurements of the clenching forces applied by the patients over time. The force data can be measured at high frequencies in excess of once per second and stored in an onboard memory, allowing for a complete time-force profile for one night of usage. In the long term, an accelerometer will be integrated into the sensor to track sleep quality and jaw motion. Eventually, Otis will correlate this data to assess the patients' stress/anxiety level and establish relevant correlations with jaw forces and bruxism treatment plans.
3. **The Storage/Travel Case.** Each OBSNG will come with a storage/travel case designed to store/protect the Otis custom night guard when not in use. The case will also act as a recharge station when not being used – enabling wireless charging and seamless data transferring to the Otis App for biofeedback.
4. **The Otis App.** Otis will develop an app that allows patients to access personalized and regimented dental care tips and exercises that alleviate bruxism rates, dental wear and pain, headaches, shoulder tension, etc. (e.g., DIY jaw/head/ neck/shoulder massage videos). The app will also provide educational wellness information, instructional exercises to reduce stress levels and improve sleep quality (e.g., 4-7-8 breathing, meditation reminder, etc.), and discounts to partnering stress therapy apps (e.g., Noom, Headspace, Calm, etc.). Once fully integrated and accepted into the market, the Otis app will also include a GPS-powered referral feature that helps patients find reputably reviewed mental health therapists/services and/or dentists, and work with major dental and mental health insurances to partially or fully cover Otis Dental products.

The OBSNG is a truly innovative technology as there are no dental products or tools that can provide effective protection against bruxism for patients while simultaneously collecting real-time data to gain better insights for dentists. Notably, the data collected from the OBSNG will offer distinctive advantages/benefits to stakeholders within the dental healthcare ecosystem including patients, dentists, and payers. Patients will benefit from the Otis Brux-Sensor Night Guard as they can cloud bruxism data to their dentist and monitor potential tooth/jaw damage and/or existing restorations at risk of breakdown (e.g., filling, crowns, implants, etc.), together. By doing so, patients will have access to a transparent platform that provides a deeper understanding of their dental health (e.g., history, progress, restorations, costs, coverage, etc.), while dental professionals benefit from a liable tool that can provide objective data that measures bruxism severity level using quantitative means, properly diagnoses bruxism, and develop optimal treatment plans based on their patients' unique Bruxism severity and needs. As a result, the dental industry can rebuild trust with their patients and produce better oral health outcomes. For payers and health insurance companies, the data can also provide incentive programs that reward discounts to members who show improved oral and/or mental health (e.g., less dental treatments, fewer mental health office visits). The innovative materials, creative solutions, properties, and advantages of the OBSNG are: (1) a technology-based by several clinical and commercial applications in the pipeline; (2) ability to record and monitor bruxism force data, and cloud this data to dentist EHR software and/or smart device app; (3) offering a truly customer-service oriented experience by digitally scanning and storing teeth impressions for faster, discounted recurring orders; and, (4) planned partnerships with over 1 M dentists across the US.

3. APPROACH

3.1 Interdisciplinary team and expertise. Otis is a subscription-based oral care company on a mission to provide a better solution to patients' oral and mental health concerns. The company was founded in 2017 in San Francisco, CA by Andrew Lee, RDH, MBA (PI), a licensed dental professional who also struggles with dental pain and loss of sleep from stress-induced bruxism. The team brings over 50 years of combined experience in general dentistry, dental hygiene, Temporomandibular Joint Disorders (TMD), sleep medicine, start-ups, finance, marketing/branding, engineering, and business strategy. These collaborative efforts will provide us with the knowledge, technical capability, and commercial experience crucial to advance the innovation towards a final design in preparation for a clinical trial, commercialization, and market adoption. **Andrew Lee, RDH, MBA (CEO, Founder, lead PI)** has +13 years of dental experience in private practice and UCSF, with an advanced MBA education concentrated in healthcare management and biotechnology, and +8 years of experience in start-ups. He is the sole inventor of the patented OBSNG technology. **Richard Beranek, Ph.D. (Technical Advisor; Brash Inc.; co-PI)** has led the development of over 15 new projects in medical devices, consumer electronics, robotics, software, and IoT products. With a B.Eng. in Aerospace Engineering and Ph.D. in Mechanical Engineering, Dr. Beranek previously founded GaitTronics to commercialize SoloWalk, a robotic walker used in early mobilization rehabilitation. As CEO, he led the company's business development activities including financing, marketing, and sales activities. **Paul Williams, DDS (Dental Advisor)** is a general dentist that emphasizes a preventive approach for optimal oral health. He currently serves as Otis' dental advisor. His clinical interests are in Dental Sleep Medicine and TMD treatment.

3.2 Proposed Studies.

Summary. The OBSNG will be prototyped to measure, analyze, and identify forces/trends between patients with no/mild to moderate/severe bruxism. This will lead to a working prototype that will be further optimized in Phase II, to measure and distinguish different bruxism levels using statistical means in a larger trial. Phase I will be pursued in collaboration between Otis and Brash Inc. in a multi-PI arrangement between Mr. Lee and Dr. Beranek. Lee will be responsible for supplying the custom night guards, overseeing all aspects of the milestones, and leading the small pilot study in Aim 3. Beranek will lead the prototype developments, testing, and miniaturization of the Brux-sensor in Aims 1 and 2, as well as collecting and analyzing the data in Aim 3.

Aim 1: Develop and optimize the Otis Brux-Sensor hardware and software architectures to capture bite compression forces. Brash will lead the developments to build out the electronic circuit architecture of the Otis Brux-sensor and complementary firmware to measure and analyze bite compression forces reproducibility and accuracy, as well as implement functionality. Using off-the-shelf parts, Brash will construct a design around the force sensor that can be integrated within a module for the data to be measured and analyzed. The prototype will undergo testing with an in-house testing jig to confirm functionality before miniaturization.

Procedure: *Electrical*. To build out the electrical architecture, Brash will develop a circuit on a breadboard that consists of 4 off-the-shelf components: Bluetooth module, force sensor, signal conditioning circuit, battery, charging circuit, accelerometer. **Figure 2** depicts a flowchart of the expected electronic design. It is important to identify module components that already have software support from the manufacturer so that the firmware can be developed. First, Brash will use a microcontroller compute module and integrate a low-power Bluetooth

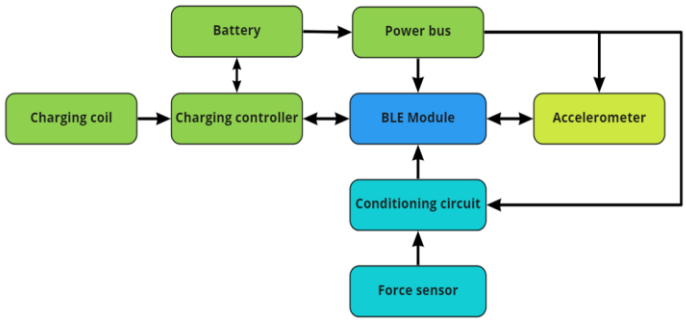

Figure 2. Flowchart of the expected electronic circuit design.

module to enable communication between the data captured from the sensor to the software. To identify the most appropriate off-the-shelf Bluetooth module, available modules (e.g., nRF52833) will be considered and then optimized for size, power efficiency, and FCC CE certification for the device to be a medical certified product. Next, a thin film force resistive sensor will be integrated into the circuit to measure bite compression forces and collect high-quality data. Finally, a battery, likely a lithium-ion cell, will be integrated to develop a rechargeable system when the night guard is stored in the travel case. In the long-term, an accelerometer will also be integrated to measure the gyration and jaw motion. ***Firmware***. A software program will be developed to capture pure analog data captured by the sensor, analyze the data, correlate them to a force level, and provide reliable outputs. The software will also include a data transfer method using Bluetooth Low Energy (BLE), power management for battery charging and management, as well as accelerometer data collection and processing. It most likely will be developed in C or C++ depending on the microcontroller being used. ***Validation & Data Analysis***. A test jig will be developed to replicate bite compression motions under a wide range of compression forces by simulating patients with no/mild and moderate/severe bruxism (average maximum bite compression forces is around 500 N[22]). The test jig design would consist of a force testing machine coupled with a mechanical model of the patient's mouth. The completed bruxism sensor would be placed on the model to calibrate the FSR to the applied force. Otis/Brash anticipates the end-product will require patients to perform a pre-calibration step to measure the absolute forces at the beginning of each session before data is collected during sleep. To replicate this step, Brash will calibrate the sensor by using known test mass standards comparable (e.g.,0, 0.1, 0.5, 1, 2, 10 kg) typical loading forces in the jaw. After calibration, the test jig will be programmed to capture force linear loading and unloading force profiles with a range of loading rates (e.g., 1 min to maximum force down to 1s to maximum force). A root mean squared error will be calculated to compare the reference force and measured force by the test jig. The result will provide an initial validation that the measurements are accurate within the force and inform Brash how the accuracy might be affected by the loading rates. Brash will also compare loading and unloading errors since FSR sensors have known hysteresis, likely resulting in a larger error in unloading force profiles. Repeatability will also be examined by programming a repeated force profile over a full measurement cycle of 8 hours. This step is critical as repeatability will be the principal metric of interest as it allows for comparative analysis to determine if a user's bruxism is improving or worsening over time. To verify the repeatability and hysteresis of the Brux-senor, the calibration will first be validated by applying a gradually increasing linear force ramp up at varying rates (e.g., 10, 50, 100N/s). A full 8-hour test will also be pursued to simulate the sleep time period.

Milestone: Accuracy to be established when the Brux-sensor can measure clenching forces after calibration within a 10%-15% margin of varying loading rates; Repeatability to be established when a full sleep cycle of measurements allows for relative comparison between measurement sessions.

***Problems and Solutions*:** It might be challenging to capture the full extend and jaw forces with a single point sensor. If so, Brash will experiment with different sensor profiles (shapes) and placement. Brash might consider using multiple sensors. Another potential challenge might be due to the difficulty of establishing a calibration procedure that ensures that the accuracy is within an acceptable range. Although FSR linearity is reported to be within +/- 3% variable effects (e.g., loading rates, electronic noise, hysteresis) may lead to additional errors. Additionally, since the sensor is only measuring a part of the load path which may interfere with the clenching forces from this partial load path, this may introduce non-linearities that may require a more complex calibration process to improve accuracy and reproducible. If we encounter this problem, Brash will optimize the test jig and evaluate a more complete calibration matrix using additional variables such as the loading rate and direction.

Aim 2: Miniaturize the electrical circuit sensor hardware component from Aim 1 to be integrated into the molar region of the Otis night guard. Core off-the-shelf components will be used to develop modules to design a custom printed circuit board. This will be integrated into the Otis Brux-Sensor Night Guard to prepare prototypes that can be used by patients in the pilot study in Aim 3. The Brux-sensor will be placed in the molar region of the nine carbs since that is the location (habeas adjacent) where the jaw generates the greatest compression forces. The PCB will also be developed and optimized for all components to work together.

Procedure: The mechanical structure and design, circuit board footprint placement, costs, dimensions thermal design, and material of the mouthguard will be evaluated. ***Component selection and testing***. The components at

this stage will primarily be driven by the size and power requirements. Small form factor components, such as BGA (ball grid array) components, will be selected to miniaturize the electrical circuit sensor. The component efficiency will also be optimized and measured to be within the uA range. Initial mock-ups of all components using the breadboard will be completed. Development kit testing will also be performed to confirm the expected performance in operation components. The targeted sleep current is expected to be on the order of 10-20 uA with active measurement 100 to 200 uA depending on measurement frequency. *Schematic capture*. Brash will design the PCB circuits for the selected components. With an optimization focus towards size and power efficiency, Brash will avoid leakage through resistors and capacitors and design the FSR signal conditioning circuit to maximize signal quality in the expected force range. *Placement and layout*. The placement of each component on the PCB will be optimized to ensure the form factor will work when integrated into the night guard. This will require iteration of developing initial placement and PCB for factors, creating CAD mockups, evaluating if the design is manufacturable, and determining comfort for patients. The layout of the electrical routing of the signals will be designed to minimize EMC noise while maximizing EMI robustness as per IEC-60601 standards. *Testing and iterations*. Initial prototypes of the PCB will be tested to ensure core functionality, as well as to validate that the current consumption will meet expected targets. Components and PCB design will be adjusted depending on the results. A final version will then be integrated into a night guard for ex-vivo calibration and force testing followed by the pilot study in Aim 3. *Electronic design validation*. To validate the circuit design, the electronics must perform active measurements for 8 hrs within a 48-hr stand-by time. Brash will also investigate whether the circuit can store this compression force data locally, using the test jig, during this timeframe to be transferred via Bluetooth protocol. Brash will also ensure that the mechanical integration of the electronics and battery within the Otis custom night guard will not impede the night guard's functionality or the user's comfort.

Milestone: Miniaturized electric circuit board to meet the following metrics: 8 hours operations; 48 hours sleep time (standby time) of the device; standby currents 15-20 microamps current; operating current average ~100-200 microamps range (function of how often we are taking measurements)

Problems and Solutions: Optimizing the current consumption may be technically challenging as it requires a tight interplay between hardware and device firmware. If so, Brash will consider using microcontrollers for low-power applications to minimize the risk of hardware design errors that may result in higher current consumption. As an alternative, Brash might leverage existing firmware that can match the targeted current consumption rates. Secondly, Brash might find that after establishing a working form factor for integration with the night guard, the night guard may not properly fit over the patients' teeth nor fit their mouth geometry. To mitigate this risk, instead of integrating typically rigid and square-shaped PCB circuits, Brash will explore flexible PCBs or rigid-flex PCBs with multiple pieces. It is also unclear if an off-the-shelf FSR will have the ideal workable dimensions for integration, in which case a custom design may be required from the manufacturer (Tekscan).

Aim 3: Conduct a usability pilot study with 28 patients to capture bite compression force profiles and optimize data collection. Otis will determine whether the OBSNG prototype can reliably capture bite compression force data with participants. In summary, Otis will screen and recruit 28 participants (50/50 Male/Female; 14 with no/mild bruxism and 14 with moderate/severe bruxism) to wear the Otis Brux-Sensor Night Guard prototype for 21 days over a 6+ hour sleep period each night. Mr. Lee (lead PI) is a licensed dental hygienist with over 13 years of performing oral health screenings and will train each patient on how to use the device and perform the calibration step before each participant begins the study. Otis/Brash will confirm that the prototype can store the data, transmit it to the software, and analyze the data. Brash will analyze the data collected to determine whether the patient's jaw forces can be analyzed and replicate similar compression forces from the jig. Using this data, Brash/Otis will evaluate whether a trend difference can be identified between patients with no/mild bruxism compared to participants with moderate/severe bruxism. Brash/Otis will also evaluate whether the core functionality of the technology can measure forces while using the device to ensure measurements are repeatable within reasonable deviance. The study protocol will be reviewed and approved by an internal review board (IRB) (TBD).

Procedure: *Screening/recruitment*: Otis will recruit 28 participants to meet our recruitment criteria from the Otis Dental customer database. For recruitment, Mr. Lee will reach out via email to all Otis Dental customers who are currently wearing the Otis Custom Night Guard, and advertise an opportunity to be part of the study. All interested participants will reply to Mr. Lee, who will then send them more information providing an overview and scope of the pilot study. Participants will fill out a screening survey to ensure they are willing to wear a custom night guard for 3 weeks (21 days), undergo an initial tele-dental health screening by Mr. Lee (licensed dental hygienist) before participating in the study, and have data collected from the sensor-enhanced custom night guard. Demographic background information (e.g., age, gender, race, health history, etc.) will also be collected at this time. To meet the eligibility criteria, participants must have access to a smartphone, be fluent English-speaking,

be 18 years of age or older, are healthy with no major underlying health challenges, and have a sleep regime of at least 6 hours. To ensure confidentiality, all participants will be assigned a random 3-digit number as an ID which they will be referred to throughout the study. All demographic data and data collected throughout the study will be securely stored in a Cloud and only accessible by Otis/Brash. All participants will be informed that their participation is voluntary and they can drop out any time. ***Onboarding***: Once the 28 participants have been identified (50/50 Male/Female), Mr. Lee will perform a virtual (e.g., Zoom) oral health screening on each of the participants to identify any physical symptoms of bruxism and ensure they qualify to participate in the study. This includes an examination of the upper/lower dentition, gingival tissue, tongue, surrounding oral mucosa, jaw joints, and masticatory muscles. Here, Mr. Lee will evaluate the participant's physical wear on teeth, and have participants palpate the jaw and muscles to see if there is any clicking/popping for the misalignment of the joint. Since all participants are customers and have used the Otis custom night guard, Mr. Lee will also review each participant's digital records within the Otis database to ensure his health examination aligns with what is on file. Afterward, Mr. Lee will assess the Otis custom night guard to determine the level of wear based on current use. Using assessment from the oral health screening outcomes and Otis custom night guard wear, Mr. Lee will assign each participant to the no/mild bruxism or moderate/severe bruxism group according to **Table 1**.

Table 1. Parameters/Metrics to distinguish participants with no/mild Bruxism or moderate/severe Bruxism

	Oral health screening assessment *(Anticipated physical symptoms of bruxism performed by Mr. Lee)*	Qualitative bruxism assessment *(Baseline assessment before study – after 1 week of using the Otis custom night guard)*	Anticipated quantitative assessment *(data collection after study completion – performed by Brash)*
Participants with No/Mild Bruxism	Minimal-to-no physical wear on anterior teeth and/or posterior molars; Minimal-to-no clicking/popping and/or misalignment of the jaw joint; Minimal-to-no gum recession; Reported stress levels to be low/mild	Night guard shows mild wear after 1 week of use	Compression forces between 25-100N
Participants with Moderate/Severe Bruxism	Moderate-to-severe physical wear on anterior teeth and/or posterior molars; moderate-to-severe clicking/popping and/or misalignment of the jaw joint; moderate-to-severe gum recession; Reported stress levels to be moderate/high	The night guard shows significant wear after 1 week of use.	Compression forces between 100-200N

Procedure: Each participant that meets the screening criteria and is eligible to participate in the study will meet with Mr. Lee to receive a prototype of the OBSNG. Mr. Lee will provide both written and verbal instructions on how to use the OBSNG. Dr. Beranek and Mr. Lee will also calibrate the device before first use by candidates, followed by another calibration, after the last use by the candidate. This will allow the team to determine any potential data discrepancies due to gradual wear throughout the utilization of the device. All participants will be asked to wear the Otis Brux-Sensor Night Guard before going to bed for 21 consecutive days. Here, participants will be instructed to (1) take the Otis Brux-Sensor Night Guard out of the storage case; (2) seat the device on their upper dentition; (3) sleep with the device on for a minimum of 6 hours; (4) clean the night guard with a tepid water rinse, after each use; (5) place the night guard back into the storage case and allow to air dry for next use). All who complete the study will be compensated with a $100 Visa Gift card and they can keep the custom night guard (retail value of up to $500). ***Data analysis:*** The team will begin averaging all compression force episodes throughout each of the 6+ hours of sleep per night and graph all 21 nights of averaged scores to show every candidate's Bruxism pattern during the study. The team will determine the bruxism severity (no/mild or mod/severe), based on the range of compression forces and validate each candidate's bruxism severity.

Milestone: > 90% of the prototypes can store data for the 21-day trial throughout the 6+ hour sleep period and transmit the data to the software; moderate/high bruxism participants having averaged compression forces 100 - 200 N) greater than the average compression bite force profiles to that of the no/mild bruxism participants (or 25-50% greater); agreement between oral assessment, physical nightguard wear, and compression forces according to **Table 1**; confirm reproducibility and accuracy of data collection by checking daily variability of bruxism patterns from both groups to determine if severe bruxer values (100 – 200 N compression force) are consistently higher than mild bruxers values (25 - 100 N of compression force), from night-to-night.

Problems and Solutions: If the sensor becomes damaged due to saliva and/or water cleaning, various dental adhesive materials will be tested to protect the sensor from damage, without jeopardizing nocturnal function.

Statistics. Upon Phase I completion, Otis will pursue a Phase II proposal to further optimize the prototype via a larger clinical study by analyzing varying severity levels of bruxism using statistical means and AI/ML techniques.

References

1. Teeth Grinding: Causes, Treatments, and Consequences. *Cedars Sinai* https://www.cedars-sinai.org/blog/teeth-grinding.html.
2. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual. (ICSD-2)*. *Diagnostic Coding Manual* (2005).
3. Singh, N. N. & Sahota, P. Sleep-Related Headache and its Management. *Current Treatment Options in Neurology* **15**, (2013).
4. Myung, Y., Seo, J.-I., Kim, B. E., Kim, Y. G. & Kim, S. T. Clinical characteristics of sleep bruxism patients with idiopathic facial pain. *Journal of Dental Rehabilitation and Applied Science* **37**, (2021).
5. Almoznino, G., Benoliel, R., Sharav, Y. & Haviv, Y. Sleep disorders and chronic craniofacial pain: Characteristics and management possibilities. *Sleep medicine reviews* vol. 33 (2017).
6. de Baat, C. *et al.* Medications and addictive substances potentially inducing or attenuating sleep bruxism and/or awake bruxism. *Journal of Oral Rehabilitation* **48**, (2021).
7. Trotti, L. M. Restless Legs Syndrome and Sleep-Related Movement Disorders. *CONTINUUM Lifelong Learning in Neurology* vol. 23 (2017).
8. Winocur, E., Gavish, A., Voikovitch, M., Emodi-Perlman, A. & Eli, I. Drugs and bruxism: A critical review. in *Journal of Orofacial Pain* vol. 17 (2003).
9. Manfredini, D., Winocur, E., Guarda-Nardini, L., Paesani, D. & Lobbezoo, F. Epidemiology of Bruxism in Adults: A Systematic Review of the Literature. *Journal of Orofacial Pain* **27**, (2013).
10. Cheifetz, A. T., Osganian, S. K., Allred, E. N. & Needleman, H. L. Prevalence of bruxism and associated correlates in children as reported by parents. *Journal of Dentistry for Children* **72**, (2005).
11. Wetselaar, P., Vermaire, E. J. H., Lobbezoo, F. & Schuller, A. A. The prevalence of awake bruxism and sleep bruxism in the Dutch adult population. *Journal of oral rehabilitation* **46**, (2019).
12. State Government of Victoria. Teeth grinding (bruxism). *Better Health Channel* (2015).
13. Yap, A. U. J. & Chua, A. P. Sleep bruxism: Current knowledge and contemporary management. *Journal of Conservative Dentistry* vol. 19 (2016).
14. Wigdorowicz-Makowerowa, N. *et al.* Epidemiologic studies on prevalence and etiology of functional disturbances of the masticatory system. *The Journal of Prosthetic Dentistry* **41**, (1979).
15. Carra, M. C., Huynh, N. & Lavigne, G. Sleep Bruxism: A Comprehensive Overview for the Dental Clinician Interested in Sleep Medicine. *Dental Clinics of North America* vol. 56 (2012).
16. de la Torre Canales, G., Câmara-Souza, M. B., do Amaral, C. F., Garcia, R. C. M. R. & Manfredini, D. Is there enough evidence to use botulinum toxin injections for bruxism management? A systematic literature review. *Clinical Oral Investigations* vol. 21 (2017).
17. Luis Gabriel, L., Melissa, V., Johana, R. & Efrain, L. Bruxism Management: A Comprehensive Review. *Clinical Medical Reviews and Case Reports* **7**, (2020).
18. Dalewski, B. *et al.* Pressure algometry evaluation of two occlusal splint designs in bruxism management-randomized, controlled clinical trial. *Journal of Clinical Medicine* **10**, (2021).
19. Kim, S. H. A case of bruxism-induced otalgia. *Journal of Audiology and Otology* **20**, (2016).
20. Singh, A., Tandon, R., Singh, A. & Gupta, B. Bruxism: An Ignored Malady. *Orthodontic Journal of Nepal* **4**, (2014).
21. Miettinen, T. *et al.* Screen-printed ambulatory electrode set enables accurate diagnostics of sleep bruxism. *Journal of Sleep Research* **27**, (2018).
22. Claude, A., Robin, O., Gehin, C. & Massot, B. Design and evaluation of a novel technology for ambulatory monitoring of bruxism events. *Sensors and Actuators, A: Physical* **295**, (2019).
23. Colonna, A., Guarda-Nardini, L., Ferrari, M. & Manfredini, D. COVID-19 pandemic and the psyche, bruxism, temporomandibular disorders triangle. Cranio - Journal of Craniomandibular Practice (2021) doi:10.1080/08869634.2021.1989768.
24. Dadnam, D., Dadnam, C. & Al-Saffar, H. Pandemic bruxism. British Dental Journal vol. 230 (2021).