Translating Science into Tools for Return of Facial Function
IRB Protocol Number: 25.0178
Primary Investigator: Kathleen Kerr, MS, CCC-SLP
Co-Investigators: Lori Arguello, MS; Hisham Marwan, DDS
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1. Introduction and Purpose:

This IRB application is planned in conjunction with a TCR4 grant application (pending review).

The intraoral splints presented here are a set of three novel splints designed to deliver a passive stretch to scarred or contracted orofacial musculature. The oral splints presented in this project were created with detail to shape, size, ease of use and the ability to be used in a unilateral or bilateral fashion **inside** the mouth (Arguello et al., 2023; Arguello et al., 2024). The presented research can offer data for the use of a new treatment tool which has the potential to reduce or limit the need for surgical interventions aimed at increasing movement of facial structures such as oral commissuroplasty. A pilot study was previously completed (UTMB IRB #18-0005) and the IRB determined that there was minimal risk associated with correct use of the splints. This study involved outpatients with history of facial burn injury and orofacial contractures. Results demonstrated a change in distance between facial landmarks with application of the intraoral splints. Physical prototypes were created with the assistance of the MakerHealth Space Lab at UTMB, following the designs and initial prototypes of the creators (**US patent # 11,969,387 B2**). See Appendix A. This pilot study resulted in two publications (Arguello et al., 2023; Arguello and Kerr, 2024). Validation of the intraoral splints in a larger cohort to include facial trauma is needed using the formally manufactured oral splints, as well as determination of possible prescriptive protocols. We hypothesize that there will be an expected gain of improved mobility of the orofacial musculature, as well as improved range of facial expressions in outpatients with facial trauma including burn injuries and gunshot wounds.

The oral splints designed for use in this study were designed to target specific points of contracture across the mid- and lower face with placement within the mouth in targeted locations. These novel oral splints allow the physician or burn care therapist to address multiple points of contracture across the mid- and lower face, including underneath the upper and lower lips, deep in the sulci near the nasal alae, along the gumlines and across both cheeks. These intraoral splints have been created in three shapes and in small, medium, large and extra-large sizes. The selected shape/size is then used to provide stretching based on location and extent of contracture. Stress/stretch can be applied to re-arrange collagen fibers, lengthen skin and muscle tissue (Dewey et al., 2011). This change in facial skin, tissue and muscle is currently captured subjectively in the visual appearance of asymmetries and presence of scar tissue, as well as measurements of vertical and horizontal mouth opening (vertical range of motion, or **VROM**, and horizontal range of motion, or **HROM**). The proposed facial measurement software will allow for objective measurement of dynamic facial movement through selected measurements between defined facial landmarks.

Intraoral splints are proposed for use with adults and children over the age of seven in this study. It is important that children are included in this study as children are particularly vulnerable to facial burns and other facial trauma due to several factors. Therefore, children with facial trauma may make up a significant share of those who may benefit from this research.

Use of the splint(s) is intended to be prescribed by a trained Speech Pathologist. The exact splint to be used will be selected by the Speech Pathologist based on the participant's specific deficit areas and needs. Risks include discomfort from stretching, bleeding if facial burn sites are not fully healed, possible allergic reaction to intraoral contact with food-grade silicone, remote choking risk, asymmetrical range of motion and remote tearing of the mucous membrane.

The expected benefits are that the splints will increase mobility of the orofacial skin and musculature, as well as reduce and possibly prevent burn-induced scar formation. This product represents an advance in the care of

these patients. Without this new treatment, patients will continue to struggle with contractures of the facial skin and musculature and contractures may worsen over time.

2. Background:

Advancements in burn care have significantly improved survival rates for individuals with extensive total body surface area burns. However, the focus of rehabilitation has primarily been on medical interventions to preserve life and restore mobility in the upper and lower extremities, often leaving the face as a secondary concern. This delay in addressing facial scarring and orofacial contractures can result in severe and disfiguring outcomes. Traditional treatments, such as horizontal and circumferential oral splints, surgical interventions, laser therapy, silicone masks, and injections, have shown only partial success in preventing or treating microstomia and orofacial contractures, even when applied promptly. Unfortunately, when these interventions fail, there are few alternative treatments available. Therefore, there is an urgent need for a more systematic, progressive, and early approach to managing the functional and aesthetic challenges associated with dermal and full-thickness facial burns. Microstomia post-burn, defined as reduction in oral aperture due to facial scarring and contracted facial skin and muscles, can lead to impaired oral motor function, inadequate oral hygiene, and negative effects on swallowing and speech/articulation, as well as limited degrees of facial expression (Yeroshalmi et al., 2011; Clayton et al., 2015 & 2017; Arguello & Kerr, 2022). Each of these difficulties has the potential to negatively impact the patient's psyche.

Multidisciplinary burn care teams prioritize early intervention, often implementing positioning and splinting protocols for affected body parts immediately upon admission to maximize functional recovery. However, the timing and methodology of oral splinting for orofacial contractures and microstomia remains debated, with a lack of consensus regarding the appropriate types of splints, timing of initiation, and duration of treatment (Yeroshalmi et al., 2011; Clayton et al., 2017). Oral splinting is frequently delayed until scar maturation or until orofacial contractures are readily apparent, thus resulting in significant facial disfigurement that has no specific nor developed treatment approach. Furthermore, currently available oral splints are two-dimensional in nature, providing a stretch in limited planes of movement and failing to affect the complex network of overlapping muscles in the face (Arguello & Kerr, 2024).

This concept of directionality of the contracture and stretch is particularly pertinent for the facial burn survivor. In contrast to microstomia cases, patients with facial burns can also experience retraction of the skin and muscles around the mouth, which exposes the teeth and negatively impacts lip closure for functions such as intelligible speech, straw drinking and retaining food while chewing (Clayton et al., 2015, 2017; Arguello & Kerr, 2024). The same need for stretching of contracted skin and muscles applies here, but the oral splint must be adaptable for directionality of the stretch and one which can contour to facial skin tension lines (Orengo, 2015; Arguello & Kerr, 2024). Stretching along the direction of tension lines (Langer's lines) helps to orient collagen fibers in the same direction within the dermis. It is also important to note that the muscles of facial expression originate from or insert into the skin (Orengo, 2015). This is important to consider when looking at dynamic movement of the face as overlying contracted skin could be a limiting factor for muscle movement.

The presented research can offer data for the use of a new treatment tool which has the potential to reduce or limit the need for surgical interventions aimed at increasing movement of facial structures such as oral commissuroplasty. Surgical interventions are costly and use multiple resources including an operating room, anesthesiologist, surgeon, staff and other monetary resources. An oral commissuroplasty often must be repeated due to re-occurrence of contractures, which incur additional costs and increase risks for further scarring. There is a need for a low-cost, research-backed regimen which can serve as a treatment adjunct or frontline treatment prior to surgical intervention. Additionally, the concept of a low load and prolonged stretch is not uncommon when splinting the upper and lower extremities (Dewey et al., 2011). This stretching methodology was used to develop the presented intraoral splints in designs intended for targeted areas within the mouth, allowing the user to address multiple problematic areas across the mid and lower face. The design

includes multiple sizes for inclusion of a graded stretch. Change over time in a small cohort was determined to be of significant clinical interest in terms of the lengthening or shortening of the distance between two facial landmarks. Change was seen in patients with recent facial burns, as well as chronic facial burns (Arguello et al., 2023; Arguello et al., 2024). Validation of the intraoral splints in a larger cohort is needed, as well as determination of possible prescriptive protocols.

Part of the gap in current practice patterns such as determining success of a treatment is lack of access to a reliable and cost-effective objective facial measurement tool that allows for assessment of facial range of motion and facial asymmetries. Protocols for goniometric measurements of the face are weak at best and there is no widely accepted tool that allows calibration of each individual patient based on a known individual constant such as pupil distance. Assessment tools that allow physicians, burn care therapists, and burn survivors to objectively assess restricted facial movement patterns, as well as response to both surgical and non-surgical interventions are lacking (Richard et al., 2009). Physicians and burn care therapists often rely primarily on visual appearance (symmetry, presence and appearance of scar tissue) and measurement of mouth opening (VROM, HROM) to document need for intervention or change in response to intervention. 3D imaging tools are costly and may not be available in all burn centers or outpatient clinics treating facial burn patients (Coulson et al., 2000; Koller et al., 2000; Hadlock & Urban, 2012; Jorge et al., 2012). There is not currently a measurement tool that allows individual users to compile and store pictorial or numerical data on their own. Development of an easy-to-use objective facial measurement software application is needed to demonstrate response to intervention and to ensure that comparisons being made are accurate both within and across participants. The proposed facial measurement software can be translated into daily use by physicians and burn care therapists to identify restricted facial movement and assess response to intervention, whether it is a surgical or therapeutic intervention. Future directions of research can begin to develop a database of facial measurements based on treatment or surgical methodologies applied to the face.

In summary, this research seeks to improve the treatment of orofacial contractures and microstomia by introducing a novel intraoral splinting technique and enhance the current objective facial measurement tool. These innovations have the potential to significantly improve functional and aesthetic outcomes for facial trauma and facial burn survivors, reduce the need for surgical interventions, and enhance the overall quality of care in burn rehabilitation. This study will be conducted as a single-subject design. Each patient will serve as his/her own control based on the purpose of the study and the large heterogeneity among patients. Conditions which would result in participant exiting the study might include non-compliance, subject withdrawal of consent, unexpected need for additional surgeries or concomitant treatments during the study period.

3. Concise Summary of Project:

The design of the proposed study is intended to examine two central aims:

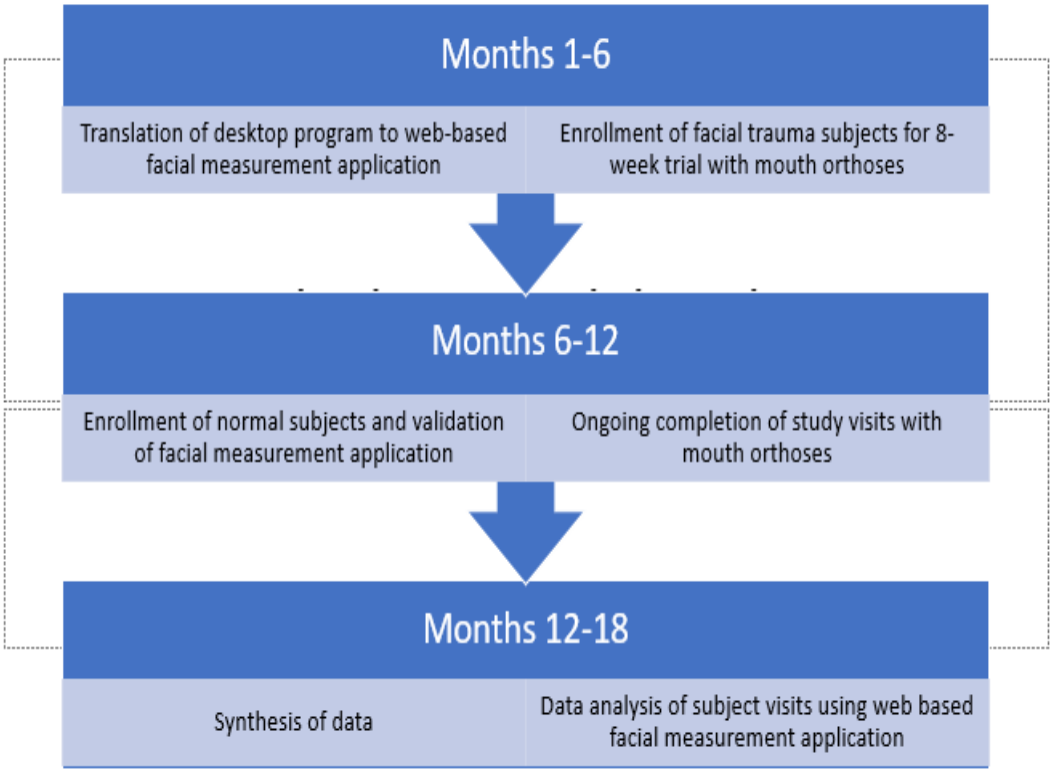
Aim 1: to validate the use of the intraoral stretching methodology and use of the presented oral splints in the outpatient facial burn and facial trauma populations. As each participant completes his/her treatment plans, data will be collected and analyzed to determine if any patterns of change are seen and for further formal analysis of the larger dataset.

Aim 2: to further develop an easily accessible, cost-efficient facial assessment tool that provides objective measurements to determine change over time in response to the applied intervention. The goal is to produce a functional facial assessment tool that can be used by patients and professionals alike. The preliminary web-based tool allows for assessment of distances between facial landmarks as a burn survivor produces targeted facial expressions (examples: at rest, open mouth wide, broad smile showing teeth). Change in distances between selected facial landmarks can then be evaluated post-treatment. A web-based application version would enhance usability and data collection for both patients and practitioners, contributing to facial trauma

research. For the proposed research study, a preliminary version of the software may be used (same used in previously completed IRB #18-0005).

Timeline:

During the first 3 months, site identification and education regarding participant referrals will be completed. Subject recruitment and enrollment for use of the mouth orthoses will begin immediately upon completion of outreach for participant referrals and is anticipated to span a 12-month timeframe. Validation of the web-based software application will be pursued concurrently with an anticipated completion within 6-12 months. Analysis and synthesis of all results will be completed within the 20-month grant timeframe, followed by submission for publication.



Experimental Device:

The intraoral splints for use in this study are now formally manufactured and will be purchased for use in this study using awarded grant funds. All tools are hand washable and will belong to the patient (will not be used between patients). Tools include the ball tool, bar tool and boomerang tool. See Appendix A for photo of the manufactured splints and Appendix B for picture of proposed placements.

Technology:

Proposed data points (see below) were adapted from the study completed by Hadlock and Urban (2012) and used in the previously completed pilot study (Arguello et al., 2023 & Arguello & Kerr, 2024). The investigators will use a UTMB customized facial measurement software designed for this study to measure pre- and post-use change. The software does not yet have a name as it is a software created in-house and it is not yet a

commercialized product. The specific measurements to be taken during selected facial movements are discussed below.

4. Study Procedures:

Protocol

Software Validation

The web-based application for objective facial measurements will be validated using 100 typical, uninjured faces and data taken from 10 independent raters completing the target facial measurements. Once this process is complete, the software will be used to evaluate response to intervention for the 50 facial trauma and facial burn subjects enrolled to use the mouth orthoses. This information will then be used to determine which facial measurement points are most statistically relevant and can inform future work in facial measurement software programs. Procedures for taking photographs and storing the photographs are the same as for the study visits using the mouth orthoses.

Study Visit for Software Validation (Uninjured) Subjects:

After the subject consents to participate in the study, they will be assigned a Subject Study ID number to which the subject will be referred throughout the study and after, to maintain privacy and data confidentiality. The subject will then complete a single study visit, either in person or virtually, as depending upon their preference. During this visit, the Speech Pathologist will take measurements, including pupil distance, and take photographs of the subject's face while the subject is completing specific facial movements (detailed below).

Pictures will be taken with patients in a seated position and with their head in a neutral and mid-line position. Subjects will be asked to take photos with their eyes open and their face fully within the frame. The therapist will give a visual model of the requested facial expression, and the participant will practice the expression one time. The therapist will then give the prompt for the expression requesting maximal excursion and take the photograph on the second trial.

Measurements to be taken:

- Pupil distance
- Inter-alar distance (Horizontal distance between outside of the nares)
- Pupil to the outside of the nares (right and left)
- Pupil to the outside corner of the mouth (right and left)
- Nares to the outside corner of the mouth (left and right)
- Length of philtrum
- Superior border of upper lip to inferior border of lower lip
- Horizontal distance between outside corners of lips
- Inferior border of lower lip to inferior tip of chin
- Distance between inferior border of upper lip to superior border of lower lip

Measurements will be taken during each of the following targeted facial expressions:

- At rest
- Wrinkle the nose
- Broad smile with teeth together

- Lip pucker as if drinking from a straw
- Open mouth wide

Data will then be used to assess reliability of the facial measurement software, to include inter-observer reliability to determine the consistency of marker placement between different users and intra-observer reliability, to determine consistency of marker placement by the same user. Additionally, we will measure time-efficiency and user satisfaction (ease of use and overall perceived tool value) for the observer.

Study Visit Using the Mouth Orthoses (Subjects with Facial Burns or Facial Injury):

We will recruit a target of 50 adult or pediatric participants who have sustained facial burns or a facial injury. A facial injury can be any disorder that results in scarring, tightness, limited range of motion of facial skin or musculature, or fibrosis. For this study, facial burn injury or facial injury will be defined as an injury to the midface or lower half of the face and may be unilateral or bilateral. Participants must be in the chronic phase of recovery to complete the 8-week treatment. Chronic burns are defined as those burns that are not in the acute healing phase, i.e., there are no concerns for injury to new or healing skin or wound dehiscence. A 50-subject sample size can generate meaningful estimates for the change and its variation, with a 95% confidence level goal and less than a 2.2 mm margin of error.

To ensure sufficient enrollment of eligible participants, we propose partnering with up to four additional institutions to expand the recruitment catchment area. Partner institutions will primarily function as referral sources, identifying appropriate patients and making referrals to the investigators for completion of in-person or virtual study visits. Virtual visits are proposed as an alternate approach to allow for greater catchment of participants and have been proven an effective method for assessing change over time using a customized objective facial measurement system (Arguello et al., 2023 & Arguello & Kerr, 2024). Potential participating organizations include the Brooke Army Medical Center/US Army Institute of Surgical Research, John S Dunn Burn Center, Southwestern Regional Burn Center, Parkland Hospital and the University Medical Center in Lubbock, Texas due to their physical proximity to the University of Texas Medical Branch. These institutions will be approached if TCR4 grant funding is awarded. In addition, social media posts outlining the opportunity to participate in the research will be posted on social media platforms including the UTMB webpage, Instagram, Facebook burn survivor groups, outreach to national burn centers and the Phoenix Burn Society site.

All participants will need to be able to attend weekly visits in person or virtually for a total of 8 weeks of treatment. Participants must be able to complete the entire 8-week prescriptive program. Pediatric participants must be accompanied by a caregiver who will commit to attending all study visits. Subjects will be offered the option to participate in the study in-person, or electronically, via telehealth. Those subjects opting to participate via telehealth will use their own technological equipment (computer or other device capable of connecting to telehealth sessions and taking screenshots). The telehealth option is available to all participants aged 7 years and over. Those who opt to be seen in person may be seen at a UTMB clinic or, if they live locally, at their place of residence. The in-home visits will be made available as an option for those subjects whose injuries may be too severe for them to travel to a UTMB clinic easily and comfortably, and who may not have the necessary technology available to them to enable them to participate in the study visits virtually.

Subjects preferring to be seen in person will participate in the written Informed Consent process with a consenting investigator. To participate in the study, the subject will provide written consent, signed and dated by the subject or, in the case of a pediatric subject, by the parent or legal guardian. The subject will receive a copy of the signed document. The Informed Consent process is described fully in Section 9 of this document. Subjects selecting the telehealth option will participate in the Informed Consent process virtually and ***verbal consent*** will be obtained. The full process for obtaining verbal consent is detailed in Section 9. p

Initial Study Visit & Assessment for Trauma Patients

After the subject (parent or legal guardian, if applicable) consents to participate in the study they will be assigned a Subject Study ID number to which they will be referred throughout the study and after, to maintain privacy and data confidentiality. The subject will then complete an initial assessment as part of the initial study visit. During this preliminary visit, the Speech Pathologist will obtain background information for the case history form and take baseline measurements of pupil distance, VROM, HROM, facial measurements at rest and while the subject is completing specific facial movements. The baseline measures will be used to compare with subsequent measures. Initial and subsequent splint selection will take place in person, or via telehealth, depending on the participant's preference. The Speech Pathologist will determine appropriate splint shape, size and location within the mouth using information obtained from the case history, including participant-identified areas of facial asymmetry, tightness or scar bands; visual information, including photographs; real-time assessment via trials with the tool shapes and sizes during the visit; and participant feedback regarding the fit, comfort and degree of stretch.

Data to be gathered throughout the study will include pupil distance, VROM, HROM, facial measurements at rest and while the subject is completing specific facial movements, with the goal of demonstrating increased range of motion of the oral musculature and improved facial and scar appearance over time (Appendix E).

Using the initial set of measurements, the Speech Pathologists will select the appropriate splint(s) from the set of intraoral splints. The splints are available in sizes small, medium and large for each specific splint shape. Speech Pathologists will also determine proper initial placement of the splint(s).

During this first study visit, subjects and caregivers (may be parent or legal guardian, in the case of the pediatric population) will be trained in the procedures they are to follow during their participation in the study, the use of the splint(s), proper placement and documentation instructions for the Home Practice Record. Training will continue until they can demonstrate independent carryover of the placement and verbal confirmation of the prescribed protocol.

Upon completion of the initial visit, subjects will be issued a numbered tool kit corresponding to the subject's study ID number. The tool kit will contain all materials needed to complete study tasks, including a complete set of orofacial splints, a pupil distance eye ruler, a copy of the fully executed consent form, written subject handouts including pages for weekly documentation of use of the tools, and postage-paid return envelopes for their Home Practice Records and splints. Subjects selecting the telehealth option will be mailed the complete tool kit, as described above.

Daily Study Activities

Following the initial study visit, regular study activity will begin. Subjects will proceed according to the training and instructions they were given during the initial study visit. The appropriate device head shape determined during the initial visit will be placed and worn by the subject for 60 minutes (+/- 10 minutes) twice per day for each day of the study. The subject (parent or legal guardian) will document the use of the device, including shape and size, placement, frequency of use, date and length of use on the provided Home Practice Record forms (Appendix D).

Weekly Study Visits

For monitoring purposes, data will be gathered at the initial assessment and 1 time per week thereafter (+/- 2 days) for the duration of the 8-week trial. This includes weekly photographs, and their associated measurements once uploaded to the facial measurement software. Photographs will be taken via a departmental iPad during in-person visits and via screenshots and saved to a secure departmental server for telehealth visits. Data will be evaluated as to the prescriptive plan for deficits for specific facial landmarks and their associated muscle groups (cheeks, nasolabial folds, upper lip, mentolabial junction and modiolus).

Participants will need to return their Home Practice Record sheets and via email to the Speech Pathologists each week or by mail at the end of the study period if participant does not have access to email.

Because use of the devices will be prescriptive, the applicable head shape(s) and placement(s) will vary by individual and by week. Specifically, placement(s) is (are) expected to vary each week based on the clinical needs of the subject and outcomes seen from the prior week's intervention. Therefore, during each weekly visit, the Speech Pathologists will select the desired splint(s) from the set and the appropriate oral placement. Photographs of the 5 facial expressions will be taken via screenshots. Education will be provided regarding tool selection and placement location during each weekly visit.

Subject safety will be met via an initial training session and weekly one-on-one follow-up visits via WhatsApp, another secure video calling app, UTMB's Teams, or in-person visit with the monitoring Speech Pathologist to assure appropriate use of the devices.

The participants will not be responsible for any research-related costs; insurance companies will not be billed. Validated parking will be offered if they attend visits in person. Telehealth and in-home visits can also be completed as per participant preference.

Assessment of the patient after completion of informed consent

- Photograph of the patient's face from the front, with measurements taken from the photograph at specific points.
- Oral-motor facial examination will be conducted.

Measuring Outcomes

The investigators will use photographs of the patient to measure multiple facial features and excursions during movement. Required materials include: a set of the manufactured intraoral devices, departmental iPad with iPad stand or access to personal computer or smartphone, UTMB customized facial measurement software, computer, CEN-TECH 6" digital caliper.

Outcome measure #1:

Endpoints include the degree of excursion during different facial movements. Description of change will be documented in degree of difference in millimeters of movement when producing each expression with subsequent statistical analysis to determine the mean changes and variation of changes, and if change was not the result of chance. Multiple studies have attempted to define a "normal" range of motion. Specifically, although facial landmarks are consistent, it must be considered that there are differences in facial expressions and excursions within the same individual for both sides of the face, as well as between individuals of different races, ages and gender. For this reason, the creators are unable to predict a percent change as there are currently no consistent norms for range of motion and excursions of facial landmarks. Therefore, change will be evaluated within a single subject over completion of the course of treatment.

Pictures will be taken with the patients in a seated position and head in neutral and midline position. Subjects will be asked to take photos with their eyes open and their face fully within the frame. The therapist will give a visual model of the requested facial expression and the participant will practice the expression one time. The therapist will then give the prompt for the expression requesting maximal excursion and take the photograph on the second trial.

Measurements to be taken:

- Pupil distance
- Inter-alar distance (Horizontal distance between outside of the nares)

- Pupil to the outside of the nares (right and left)
- Pupil to the outside corner of the mouth (right and left)
- Nares to the outside corner of the mouth (left and right)
- Length of philtrum
- Superior border of upper lip to inferior border of lower lip
- Horizontal distance between outside corners of lips
- Inferior border of lower lip to inferior tip of chin
- Distance between inferior border of upper lip to superior border of lower lip

Measurements will be taken during each of the following targeted facial expressions:

- At rest
- Wrinkle the nose
- Broad smile with teeth together
- Lip pucker as if drinking from a straw
- Open mouth wide

Outcome measure #2:

The Mouth Impairment and Disability Assessment (MIDA) has a 28-item self-report portion, divided into four subscales, completed by the patient, and an impairment-based section completed by the burn therapist. There was a strong and statistically significant ($p < 0.0001$) correlation of the symptoms subscale as well as vertical opening with the functional activities subscale of the MIDA. This instrument will be administered to the subject during the first study visit and the final visit.

Outcome measure #3:

The primary outcome will be a change in the degree of facial movement during different facial expressions as described above, pre- and post-study. A secondary outcome will be any improvements in quality of life pre- and post-study as captured by the CARe. The CARe Burn Scales is a set of age-appropriate burn-specific quality of life PROMs (Child Form for children < 8 years (parent-proxy), Young Person Form for young people aged 8–17, Adult Form for adults aged 18 and over, and a Parent Form for parents of children and young people aged 0–17 with a burn). The scales measure a wide range of physical, psychological and social aspects of living with a burn injury or supporting a child with a burn. This instrument will also be administered during the first and final visit.

5. Sub-Study Procedures:

Not applicable.

6. Inclusion Criteria

Validation Subjects:

- Age 18-100
- Male or female sex
- Individual with an atraumatic face

- Does not have impaired oral opening, or has maximal interincisal distance >30 mm
- Can give informed consent
- Agrees to have facial photographs taken

Trauma Subjects:

- Age 7-100
- Male or Female Sex
- Patients who have sustained facial trauma, facial injury or a facial burn and are now in the chronic phase
- Chief complaint(s) of limited mouth opening, difficulty chewing or speaking, decreased range of motion for oral structures, and/or limited facial expressions
- Subject or caregiver (parent or guardian, in case of pediatric population) must be able to give informed consent
- Subject or caregiver (parent or guardian, in case of pediatric population) must be able to perform exercises at home and must be able to record time spent using the splints
- Participants who are undergoing other treatment methods such as facial surgeries, use of compression garments, skin grafting, etc., must suspend all these treatments for the duration of the 8-week trial
- Access to internet and smartphone or computer capable of taking screenshots and with adequate audio and video capabilities (for those opting to participate via telehealth sessions)

7. Exclusion Criteria

Validation Subjects:

- Under the age of 18
- History of facial trauma or facial injury
- Unable to give informed consent
- History of neurological deficit
- Incarceration or pregnancy

Trauma Subjects:

- Planned or unplanned surgeries for facial skin grafting around lips or nose, or oral commissure release during the 8-week trial
- Completion of any massaging or other stretching exercises or programs not specified by the investigators
- Use of new creams or topical treatments for the duration of enrollment in the study
- Acutely burn-injured patients
- Incarceration or pregnancy
- History of neurological deficit

8. **Sources of Research Material:**

We are collecting clinical and demographic data from UTMB electronic medical charts (EPIC), a detailed medical history to be provided by the subject or, if a pediatric subject, by the parent or legal guardian, and

data to be collected according to Appendices C, D, E. These will be obtained via photographs of the subject during different facial expressions which are uploaded into a software program for measurements to be taken.

9. Recruitment Methods and Consenting Process:

The investigators will request a HIPPA Waiver to identify potential subjects. Potential trauma subjects may be patients or former patients of the investigators. Additionally, they may be identified via clinic lists or outside referral sources. The potential subjects will be identified and referred by any clinician or physician. The identified and referred patient(s) will be sent a recruitment letter or informational pamphlet with the approval of the referring clinician/physician (see Appendix F).

The investigators will pursue various methods for recruiting subjects, including UTMB or outside physician referrals, outside speech pathologist referrals, referrals from other professionals and community engagement activities. We do not plan a multisite study but seek the option to widen the scope of patient referrals by contacting other burn centers and burn support groups and through participation in community outreach activities. Physicians will be asked to refer eligible patients; however, the referring physicians or professionals would not be involved in the research. Participants will be seen at UTMB outpatient clinics, via telehealth or at their residence, depending upon their preference and circumstance. Participants may self-refer from marketing materials. Outreach will include social media (Appendix J), such as postings to burn support group websites or Facebook pages, Speech Pathology special interest group pages, Facebook, UTMB Department of Otolaryngology Facebook page, UTMB Oral and Maxillofacial Surgery social media pages. In all recruitment scenarios, the investigators will notify the participant's managing physician of their participation in the study. If the participant cannot be reached by phone, a letter will be mailed to the potential participant with study information. Because the investigators are pursuing multiple recruitment avenues apart from chart review, approval for a flexible screening process is necessary and requested.

The investigators will screen potential participants verbally, via phone, electronic media or in person according to the eligibility checklist and inclusion/exclusion criteria (Appendix I) to determine patient eligibility for participation in the study. Eligible patients will be invited to take part in the study, assigned a Subject Study ID number according to the order of their invitation to take part and the first study visit will be scheduled, either as an in-person or telehealth visit, depending upon the subject's preference. Before, or at the beginning of the first study visit, and before any study activity takes place, the subject and consenting investigator will go through the Informed Consent process.

Informed Consent Process

In-Person

During the In-Person Informed Consent process, the consenting investigator will first provide the subject with a copy of the Informed Consent document to review and to follow along as the investigator reads the Informed Consent Document aloud. The Informed Consent document contains a summary of the key information about the study, emphasizing the voluntary nature of their participation, and an outline of subject's rights as a study participant, the length of subject's participation, purpose of the study, procedures subject will be expected to take part in, potential risks of participation, potential benefits, alternatives to participation, cost to subject related to participation, compensation for participation and medical treatment for research-related injuries. Detailed study information follows the summary and will also be read aloud by the investigator. The detailed study information will include information about the IRB and name, affiliation and contact information for the study's principal investigator. Throughout the Informed Consent process, the consenting investigator will verify subject is engaged in the process, will respond to verbal and non-verbal cues that items may need clarification and will provide opportunities for the subject to ask questions about the study. Finally, once the entire Informed Consent document has been reviewed and discussed, the subject has been allowed the opportunity to ask questions or express concerns and is satisfied that they fully understand the study and their

participation, the subject will be asked if they wish to participate in the study. If they do, they will be directed to sign the Informed Consent document in the field designated for subject's signature and record the date signed. Their signature will acknowledge their understanding of the study, the scope of their participation, their rights as a subject and all other items contained in the document, along with their consent to participate in the study. Once the subject has signed and dated the document, the consenting investigator will review the subject's signature and date, verify accuracy, then sign and date in the designated field. A copy of the fully executed Informed Consent document will be provided at that time. This will complete the Informed Consent process, after which the subject will be scheduled for an immediate start date.

Via Telehealth

Eligible patients opting to participate via electronic means (telehealth), will receive a copy of the written Fast Facts Information Sheet via email or mail prior to discussing it with the investigator. The process will be conducted between the subject and consenting investigator as if an in-person encounter, apart from ***verbal consent*** being obtained for enrollment in the study. A written copy of the consent form will then be mailed to the participant with a return envelope for the participant to return a signed copy of the consent form.

In all cases, informed consent or assent, either written or verbal, will be obtained prior to participation in the trial.

Pediatric Patients

In the case of a pediatric subject, once the parent or legal guardian has gone through the Informed Consent process, verbal assent will be obtained from children ages 7 through 12 years and written assent will be obtained from children ages 13 through 17 years. At the age of 18, if the individual is still enrolled in the study, they will be asked to provide re-consent under the Adult Informed Consent form.

As informed consent is an on-going process, the subject will be asked if they wish to re-affirm their consent to participate during each of the weekly in-person or telehealth study visits.

10. Potential Risks:

Adverse effects are not expected; however, potential risks include: discomfort from stretching, bleeding if facial burn sites are not fully healed, allergic reaction to intraoral contact with food-grade silicone, asymmetrical range of motion, and possible tears through the burned skin. The handle is designed to reduce the risk of choking as the subject or caregiver should be holding onto the device when using it. However, there is a remote choking risk if the subject uses the device incorrectly (such as chewing on the device, sucking on the device or removing the head of the device from the handle).

11. Subject Safety and Data Monitoring:

The PI will review the safety of these interventions with all study staff at 6-month intervals. Significant problems related to the insertion of the device such as bleeding, choking will be reported to the IRB immediately. Any related or unrelated adverse events will be reported in a timely manner to the IRB. Additionally, a patient education leaflet will be mailed with the intraoral splints with information regarding correct use of the splints and what to avoid (see Appendix G).

12. Procedures to Maintain Confidentiality:

Subject confidentiality is strictly held in trust by the IRB-approved participating investigators. The following measures will be taken to protect the PHI of study subjects.

- Though it will be necessary to maintain identifiable subject data, subject data will be de-identified immediately following all data collection.

- Patient data will be access-restricted and only accessible to IRB-approved study personnel authorized by the study PI to do so.
- A Subject Identification Key will be created and maintained separately from the data to be analyzed. The Subject ID key will be retained throughout the life of the study then destroyed once there is no longer the need for subject verification.
- The Subject ID key will only be accessible by the study PI and IRB-approved study personnel authorized by the PI to do so.
- Pictures will be taken using a departmental iPad and patient data will be stored on secure UTMB password-protected computers.
- The study file, including all data and regulatory documentation, will be created and stored on UTMB password-protected equipment.
- The study file will be access-restricted to allow only IRB-approved study personnel with authorization of the PI.
- The study file will be encrypted on a secure server behind UTMB's firewall.
- Patient's written or verbal consent will be obtained prior to photographing the patient.
- Paper signed consent document originals will be maintained in a locked office in a locking cabinet. WhatsApp or another secure calling app will be used to protect participant's privacy.
- All communications regarding patients or their data will take place only between IRB-approved study personnel in private settings away from unauthorized individuals.
- No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the principal investigator.
- Individuals authorized to view study records may include federal or local agencies that regulate research including representatives from the Office of Human Research Protections, or the Institutional Review Board. Study records may also be made available for internal compliance reviews and quality assurance representatives. These individuals may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study. The clinical study site will permit access to such records.
- Any published materials related to this study will not contain any identifiable patient information.
- Records will be retained according to IRB and UTMB policies in the prescribed manner, for the required period.

13. Potential Benefits:

Expected benefits include: increasing range of motion for multiple facial muscles and tissues; reducing the impact and appearance of scar tissue; ability to target multiple sites across the face, with particular attention to the cheeks, nasolabial folds, upper lip, mentolabial junction and modiolus; achieving a stretch that currently available tools cannot provide; improved ability to produce different facial expressions; increased speech intelligibility; improved ability to complete oral hygiene. Additionally, the results of this study may inform future development of this and similar tools.

14. Biostatistics:

The investigators plan to engage the help of a biostatistician once funding is received. For the measured outcomes, we plan to perform a paired t-test- Wilcoxon test for each facial movement. The investigators anticipate a target of at least 50 participants to fully evaluate the correlational relationship between the use of the oral splints and gains in orofacial range of motion. This will allow us to achieve a confidence interval of 95% and a margin of error of 2.

- **Sample Size Justification:** The proposed sample size of 50 trauma/burn subjects was selected based on statistical and clinical considerations to support the validity of our within-subject study design and primary outcome analysis. This study utilizes a single-subject, repeated-measures design, in which each participant serves as their control. This design enhances statistical power by minimizing between-subject variability. The primary outcome measure is the change in millimeters between defined facial landmarks during standardized facial expressions. The target is to detect a clinically meaningful change of at least 2.0 mm, based on findings from the previous pilot study (UTMB IRB #18-0005).

A power analysis was conducted to estimate the appropriate sample size. Assuming:

- A two-tailed paired t-test (or Wilcoxon signed-rank test, depending on data distribution),
- An effect size of 2.0 mm,
- Standard deviation of paired differences estimated at 3.0 mm,
- $\alpha = 0.05$, and
- Power $(1-\beta) = 0.80$.

A sample size of 50 participants is sufficient to detect the expected change with a 95% confidence interval and a margin of error of less than 2.2 mm. Additionally, this sample size will enable a preliminary exploration of subgroup effects (e.g., pediatric vs. adult, burn vs. non-burn trauma) while maintaining the study's feasibility and statistical integrity. The methodology used to determine the sample size aligns with the planned statistical analyses, which include paired comparisons of pre- and post-intervention facial range of motion using both parametric and non-parametric approaches, depending on data distribution.

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