Easy Stretch Toolkit: A Pilot Study
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1. Introduction and Purpose:

The Easy Stretch Toolkit (patent pending) is a set of three novel intraoral tools designed to deliver a passive stretch to scarred or contracted orofacial musculature, with the goals of: 1) increasing measurable range of motion for multiple facial muscles and tissues , and 2) reducing the impact and appearance of scar tissue. We designed the Easy Stretch Toolkit for patients negatively impacted by facial burns. We propose a pilot study to test if the tools can directly 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. We hypothesize that there will be an expected gain of improved ability to increase use of orofacial musculature, as well as improved range of facial expressions and related motor functions in patients with facial burn injury. The Easy Stretch Toolkit is proposed for use with adults and children over the age of 7 in this pilot study. Use of the device(s) is intended to be utilized by a trained Speech Pathologist. The exact tool to be used will be selected by the Speech Pathologist based on the patient's specific deficit areas and needs. In this pilot study, investigation into the efficacy of the Toolkit will be limited to subjects with chronic facial burns, with future plans to expand the project to subjects of all ages in the acute healing phase if preliminary results prove the tools are effective. Physical prototypes were created with the assistance of the MakerHealth Space Lab at UTMB, following the designs and initial prototypes of the creators (patent pending). See Appendix A. The current treatment options for patients with scars secondary to orofacial burns are discussed in the Background and pictures of tools are shown in Appendix B-F. Because our tools are similar, and in some ways potentially safer than the current tools available in the market, we believe that the Easy Stretch Tools are a minimal risk device. This product represents an advance in the care of these patients. There is minimal risk associated with correct use of the product (discomfort from stretching, bleeding if facial burn sites are not fully healed, possible allergy from intraoral contact with food-grade silicone, remote choking risk, asymmetrical range of motion, remote tearing of the mucous membrane); the expected benefits are that the tools will increase mobility of the orofacial skin and musculature, as well as reduce and possibly prevent burn-induced scar formation. This protocol and enrollment procedures are revised due to the Covid -19 Pandemic to allow for increased ability to enroll participants due to the University's restrictions on travel.

2. Background:

To date, there is not a definitive prescriptive regime for rehabilitative management of facial burns. Facial burns can impact oral motor function, swallowing, speech/articulation, oral hygiene and facial expression [1]. Some of the techniques currently utilized in management of orofacial contractures following burn injuries include but are not limited to: external stretching interventions, massage, compression garments, range of movement exercises (poorly defined in many studies), oral splints/mouth spreaders, lip commissuroplasties and other multiple invasive surgical procedures such as placement of tissue expanders, among others. Although the literature shows some success in functional outcomes with the currently available treatment methodologies, there is limited data available to determine the specifics of a treatment plan, especially as it relates to techniques used and timing and frequency of the chosen techniques [2]. In their articles on burn rehabilitation,

Clayton and colleagues [1,2] described at least two potential orofacial and dysphagia rehabilitation protocols, which consisted of a combination of techniques including range of movement exercises, mouth splinting, use of the Orastretch and two dysphagia exercises. They reported functional gains in both the patients' dysphagia and range of motion of oral musculature as measured by vertical range of motion and horizontal range of motion. This data provides the beginnings of a prescriptive approach for management of facial burns.

Another widely used therapeutic tool is the pressure garment [3,4]. Compression garments are used to decrease blood flow, nutrients and oxygen that reach the scar tissue, thereby reducing collagen synthesis. It is well documented that pressure garments must be worn for at least 23 hours per day and for greater than 6 months to obtain the maximum benefits. Macintyre and Baird [3] discussed the challenges of pressure garment use, including non-compliance with treatment and discomfort as a result of weather or poor fit, among other issues. They also discussed the lack of evidence specifying the exact amount of pressure needed to obtain the desired result. Similar challenges were documented by Atiyeh et. al., with particular attention to the difficulty in identifying and maintaining optimum pressure [4].

Intraoral tools that are currently available on the market for use for jaw strengthening/opening and tongue exercises in other patient populations were reviewed for their potential application with the burn population. The Nuk brush (see Appendix B) is a cylindrical tool with a nubby textured surface at the end, which is used for oral sensory exploration and biting exercises. The Beckman professional oral probe (see Appendix C) is another tool that is used for tongue exercises and for sensory input. The Chewy Tubes P's and Q's (Appendix D) are other tools available for biting exercises to address jaw strength. The Orastretch (Appendix E) and Therabite (Appendix F) devices are applicable to the burn population and are designed to improve mouth and jaw opening by applying pressure to open the mouth in a vertical direction. The aforementioned tools are valuable tools for tongue movement, jaw strength and jaw opening but do not address stretching of the facial skin and muscles or range of motion of the oral musculature. The Orastretch and Therabite tools (Appendix E and F) provide alternatives for jaw opening but, as with the other tools mentioned above, do not directly address other common problem areas including restricted range of motion and scarring to the lips, cheeks, nasolabial folds, mentolabial junction, modiolus and forehead. In addition to challenges with use of specific tools, no consistent protocol exists for active or passive ROM or stretching [5]. To reiterate, all of the above are considered acceptable care with varying results, but there is no single standard of care.

In the course of our own clinical treatment for facial burn victims, many of them in both the chronic and acute care stages of burn rehabilitation, we have encountered significant challenges in the range of motion and elasticity of the facial skin and muscles in the aforementioned problem areas (vertical range of motion [VROM] and horizontal ROM [HROM], lips, cheeks, nasolabial folds, mentolabial junction, modiolus and forehead); we attempted to treat these deficits using a combination of the most widely known techniques, as detailed above. Although it is was not specifically created for the treatment of burn patients, we used the Beckman Oral Motor Protocol but did not achieve the desired results, largely due to the brief nature of the stretches, the location of the stretches and poor carryover by caregivers in completing the required repetitions. The patients' managing medical team also utilized pressure garments, with improvement in scar appearance; however, the patients experienced continued oral motor deficits and severely restricted range of motion. Based on our

clinical experience, we have encountered significant challenges in the treatment of these facial burn victims. We have tried several unconventional methods for orofacial stretching with minimal success and thus we developed a customized set of intraoral devices (called the Easy Stretch Toolkit) which we are ready to test in this pilot clinical trial. The Toolkit would deliver a passive stretch to multiple sites, thereby increasing range of motion and elasticity and directly impacting both oral-facial skin and musculature. The design and purpose of the Easy Stretch tools differ greatly from other intraoral tools currently on the market (reviewed above). The Easy Stretch tools would address multiple deficit areas in a new way. Without this new treatment, patients will continue to struggle with contractures of the facial skin and musculature and that contractures may worsen over time.

The Toolkit is not currently available to the general population and the current project will be the first time this product has been studied. We, the investigators and the creators posit that the Easy Stretch Toolkit will be applicable for neonate, pediatric and adult burn victims. This trial will include the adult and pediatric burn population. If this clinical trial is successful, our goal would be to expand to children under the age of 7, including the neonate population and ultimately to market, mass produce and sell the product to all patient populations, including patients with acute burn injuries. We would plan to conduct a larger trial (with a power analysis after we determine effect sizes) to further investigate efficacy of the Easy Stretch Toolkit. The need for early intervention in facial scar management was documented by Parry et. al. and Clayton et. al. [1,6]. In the future, another focus would be on the early use of these devices as a method for both preserving and increasing range of motion and elasticity in patients immediately following a burn injury. Additional target populations include patients with lip contractures following cleft lip surgery, as well as research into use of the Toolkit as an oral stimulation device for use in the NICU population. Use of the Easy Stretch Toolkit with each of these populations will need to be researched and studied by the creators; we plan to submit amendments to this parent protocol to include additional patient populations and indications in the future.

3. Concise Summary of Project:

Our proposed study and design is intended to study two Aims:
1) To determine whether use of the devices results in measurable change in range of motion and quality of life via pre- and post-use data and measurements for orofacial movements and function.
2) To develop an effective prescriptive rehabilitative plan for orofacial scar management for the patient to follow including an 8 week active treatment period.

Experimental Device:

The Easy Stretch Toolkit is manufactured at UTMB in the MakerHealth Space Lab. Three dimensional images of both the handles and heads were created in the computer 3D CAD application, *Fusion 360.* Two types of tool handles were created, the L shape and the T shape with the program *Adobe Illustrator* using the dimensions from the *Fusion 360* designs. The designs for each handle were then loaded into the program for a Universal Laser Cutter, which replicated the design and engraved the handles.

Sheets of Delrin, a high-tension impervious plastic, were used to cut out the handles. Delrin was selected due its known FDA approval for use in the food industry and for its ability to withstand autoclaving. After the handle is cut using the laser cutter machine, each handle is inspected for rough edges and sanded with a fine grit sandpaper as needed.

The head shapes from *Fusion 360* were then used to create one and two piece 3D molds. These molds were then exported to a program called *Curio*, which sends the images to the *Ultimaker* 3D printer. Once printed, the molds are removed from the machine and filled. A handle is seated in the mold and Sorta Clear 40 Smooth On food grade silicone is mixed per instructions in a 10:1 ratio and poured into the molds. Sorta Clear 40 Smooth On was selected, as it is a known food grade silicone and has the ability to withstand high temperatures in autoclaving. Once filled, the molds sit for 16 hours to fully cure/set. The tools are removed from the molds and any redundant silicone is trimmed off with scissors. A small dot of medical grade silicone glue is then placed where the stick and head attach to increase security of the head on the stick. As previously noted above, the material used to assist in securing the head of the tool to the stick is a medical grade epoxy that is FDA approved for Grade IV medical devices. Once cured, the device in its entirety had stood up to high level disinfecting and autoclaving. Sterilization has been confirmed with the Resi-Test along with the Sterigage Steam indicator.

Each tool is then wiped with an enzymatic wipe and autoclaved at 260 degrees using a pass/fail indicator. Each "passed" tool will be available for use in the study. Any tool failed will be removed from the package, re-cleaned and re-autoclaved.

Tools available for the study are then labeled on the outside of the autoclave package using a Dymo Label maker stating "Investigational Tool for research purposes only".

All tools are hand washable and will belong to the patient (will not be used between patients). Tools include the circle tool (yellow), bar tool (blue), L tool (green). See Appendix G for proposed placements.

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 during the treatment period.

Proposed data points (see below) were adapted from the study completed by Hadlock and Urban [7]. In their 2012 study, they assessed resting facial distance relationships and changes in these relationships during movements to form different facial expressions using a novel device called Facial Assessment by Computer Evaluation (FACE). The creators of the Easy Stretch Toolkit will use UTMB customized facial measurement software designed for this study to measure pre- and post-use change. See Appendix K. The specific measurements to be taken during selected facial movements are discussed below.

4. Study Procedures:

Protocol

In this initial pilot study, we will recruit 20 adult or pediatric patients who have sustained facial burns or who have sustained 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 the purpose of 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, ie., there are no concerns for injury to new or healing skin or wound dehiscence. A 20 subject sample size can generate meaningful estimates for the change and its variation, and within the range that sample size is recommended for feasibility study based the consideration in gain of precision for each increase of 1 in sample size [13]. Participants will need to be able to complete the entire 2 month prescriptive program. All participants will need to be able to attend weekly visits via in person or electronic means (telehealth) such as Skype, Zoom or other electronic platform for an enrollment screening, followed by a total of 8 weeks of treatment. Pediatric participants will need consent from a caregiver who will commit to being present for all in person or electronic visits as well. Participants who are referred to the study will be contacted via phone to determine eligibility criteria. If the participant meets eligibility requirements and selects telehealth option, a copy of the written consent form will be emailed to the participant. Verbal consent will then be obtained for enrollment in the study and background information will be obtained for the case history form. A package will be mailed to the participant including a full set of tools, a pupil distance eye ruler, copy of the consent form, written subject handouts including pages for weekly documentation of use of the tools, and return envelopes for homework and tools. If the subject lives locally and wishes to be seen at a UTMB clinic or their place of residence, visits may be done in person as well. Telehealth option is available for all study participants, ages 7 and up.

In cases of verbal consent, the investigators will request verbal confirmation by the subject/parent that they signed and dated the written consent form. If unable to print the consent/assent/permission, the subject/parent will sign and date a blank piece of paper with a written statement that they voluntarily agree to participate in the protocol. This statement will include the protocol number and name (Easy Stretch Toolkit, #18-0005). After signing and dating the newly created document, the study participant or legally authorized representative will send a photograph of the signed and dated statement or consent form by fax, text message or email to the investigator/designee or may return the document by mail at a later date. In all cases, informed consent will be obtained prior to participation in the trial.

After informed consent by the subject and parent/caregiver (if applicable), each subject will complete an initial assessment during which the Speech Pathologist will select the appropriate tool(s) from the Easy Stretch Toolkit and provide training to the subject and/or caregivers in use of the device(s). During each visit, the Speech Pathologists will select the desired tools from the Toolkit and their accompanying oral placement. The recommended photographs of the 9 facial expressions will be taken via screen shots. Education will be provided regarding tool selection and placement location during each weekly visit. Participants will need to return their homework sheets and self-made photographs of each facial expression via email to the Speech Pathologists each week or by mail at the end of the study period.

The tools are available in small, medium and large sizes. The small to medium sizes for each shape should be the correct size for children's mouths. Subjects and caregivers (may be parent or guardian, in the case of pediatric population) will be trained until they can demonstrate independent carryover of the placement and verbal confirmation of the prescribed protocol. See attachment for patient/caregiver education materials to be used, which will include written instructions for the patient (Appendix I). Data to be gathered includes pupil distance, VROM, HROM and facial measurements at rest and while the subject is completing specific facial movements, with goal of demonstrating increased range of motion of the oral musculature and improved facial and scar appearance over time (Appendix H). Initially it will be proposed that the chosen head shape be used

for 60 minutes (+/- 10 minutes) 2 times per day for each day of the study. Frequency of use of the device will be closely documented by the Speech Pathologists and the patient or caregiver using the provided charting system (Appendix I). 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. 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. As a result, 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). Subject safety will be met via an initial training session and weekly one-on-one follow-up visits via FaceTime, Skype or in person visit with the monitoring Speech Pathologist to assure appropriate use of the devices. Patient (or parent) handouts (Appendix I) will be provided to assist with recording of time spent using the devices and with which tool and placement location.

Assessment of the patient after completion of informed consent

- Photograph of the patient's face from the front, as well as their side profile (weekly), with measurements taken from the photograph at specific points. At this time, profile photographs will not be used for measurements or analysis but will be kept to show visual changes over time.
- Oral-motor facial examination will be conducted.

Targeted muscle groups [8]

The facial muscles to be targeted include:

- Levator labii superioris – elevates the upper lip and deepens nasolabial furrow
- Buccinator – controls movement of the cheeks and assists in sucking in neonates and mastication in pediatrics and adults
- Depressor anguli oris – assists with frowning, pulls corner of mouth inferiorly
- Mentalis – protrudes lower lip, inward and upward movement of the soft tissue of the chin
- Zygomaticus major – pulls angle of mouth upward and laterally
- Zygomaticus minor – raises upper lip
- Nasalis – compresses bridge, depresses tip of nose, elevates corners of nostrils
- Levator anguli oris – assists with smiling, elevates angle of the mouth
- Depressor septi – depression of the nasal septum
- Risorius – draws back the angle of the mouth laterally
- Depressor labii inferioris – depression of the lower lip
- Obicularis oris – sphincter around the mouth, brings lips together, retracts lower lip

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 Easy Stretch devices, departmental iPad with iPad stand or access to personal computer or smartphone, UTMB customized facial measurement software, computer, CEN-TECH 6" digital caliper.

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. A single blinded observer will be used to complete the measurements taken in the facial measurement system.

Measurements to be taken:

- Pupil distance
- Horizontal distance between outside of nares
- Pupil to outside of nares (right and left)
- Pupil to outside corner of lip (right and left)
- Superior edge of philtrum to outside corner of lip (right and left)
- Nares to outside corner of 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

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

- At rest
- Wrinkle the nose
- Gentle smile
- Broad smile with lips closed
- Broad smile with teeth together
- Vocalizing prolonged “eee” sound
- Vocalizing prolonged “ooo” sound
- Lip pucker
- Mouth opening as measured by distance between inferior upper lip and superior lower lip

The customized UTMB facial software is a two dimensional measurement system. Jorge Jr., et al, provided a summary of several past and present measurement systems, considered as subjective vs objective and simple vs complex, in their article exploring measurement of peripheral facial paralysis [9]. Although a three dimensional measurement system such as the Vicon system [9] is beneficial for quantifying measurements across multiple axes especially the anteroposterior axis, the creators chose to pursue a two dimensional measurement system for its cost effectiveness and ease of use. The UTMB customized facial software is based upon use of pupil distance, as this is a static landmark and subsequent measurements can be graded based on this measurement. Fields and Peckitt performed a similar measurement in their study, called the Facial Nerve Functional Index, measuring percentage change from the corner of the lip with a mouth closed position to the external corner of the ipsilateral eye vs smiling broadly [9]. In their 2015 article on use of their 3D dynamic quantitative analysis system of facial motion (3D ASFM) and assessment of mimic muscles during facial contraction, Feng et al proposed that the mouth-eye association and their related movements have the greatest influence on quality of life [10].

Endpoints include 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 that 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 [9,11]. 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 [9]. 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.

The primary outcome will be change in degree of facial movement during different facial expressions as described above pre- and post-study. The secondary outcome will be any improvements in quality of life pre- and post-study as captured by the Facial Disability Index. The Facial Disability Index will be used as a validated quality of life instrument [12]. See Appendix M. Although it is somewhat dated (1996) and it was intended for use with facial neuromuscular disorders and facial palsy, its questions were deemed the most relevant for this study after thorough review of available burn, facial palsy and general quality of life measures.

The subjects will not be responsible for any research-related costs; insurance companies will not be billed. Validated parking will be offered if attending visits in person.

5. Sub-Study Procedures:
Not applicable.

6. Criteria for Inclusion of Subjects:
We plan to recruit 20 adult or pediatric patients who have sustained facial burns or who have sustained a facial injury resulting in scarring, tightness, limited range of motion of facial skin or musculature or fibrosis and are in the chronic phase of recovery to complete the 8 week treatment.

1. Age 7-80
2. Male or Female Sex
3. Patients who have sustained a facial burn and are now in the chronic phase, or any patient experiencing facial tightness or limited range of motion due to other problems, including patients s/p radiation to the head and neck, trauma, scarring and scleroderma
4. Chief complaint(s) of limited mouth opening, difficulty chewing or speaking, decreased range of motion for oral structures, and/or limited facial expressions
5. Subject or caregiver (parent or guardian, in case of pediatric population) must be able to give informed consent
6. 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 devices.
7. Participants who are undergoing other treatment methods such as use of compression garments, skin grafting, radiation or other facial surgery, etc must suspend all of these treatments for the duration of the 2 month trial.
8. Internet access including access to FaceTime, Skype or Zoom and email access if electing telehealth option for enrollment

7. Criteria for Exclusion of Subjects:
The following will exclude patients from participation in the study:

1. planned or unplanned surgeries for facial skin grafting around lips or nose or oral commissure release during the upcoming 8 weeks
2. completion of any massaging or other stretching exercises or programs not specified by the creators
3. use of new creams or topical treatments for the duration of enrollment in the study.
4. acutely burn-injured patients
5. incarceration, or pregnancy

9. Sources of Research Material:

We are collecting clinical and demographic data from the electronic charts. We are also collecting data as shown in Appendix H, I, J, K, L. 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 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 / referred by any clinician or physician and their patient(s) will be sent a recruitment letter or informational pamphlet with the approval of the referring clinician/physician (see Appendix L, as well as recruitment brochure).

To further clarify, 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. The physicians will be asked to refer eligible patients; the physicians would not be engaged in the research. Subjects will be seen at their place of residence or UTMB outpatient clinics or via telehealth. Subjects may self-refer from marketing materials. Outreach will include social media, such as postings to burn support group websites or Facebook pages, Speech Pathology special interest group pages, Facebook, UTMB Department of Otolaryngology Facebook page. In all recruitment scenarios, the investigators will notify the subject's managing physician of their participation in the study. If the subject cannot be reached by phone, a letter will mailed to the potential subject with study information.

The investigators would like to request a waiver of written consent to verbally screen potential subjects via phone, electronic media or in person using the eligibility checklist and inclusion/exclusion criteria, prior to their first visit when they will sign the consent document. Because the investigators are pursuing multiple recruitment avenues apart from chart review, a flexible screening process is necessary.

At the time of the initial contact with the patient, a full description of the study will be provided. Consent will be obtained prior to or at the beginning of the first treatment session. In the case of a pediatric subject, verbal assent will be obtained for children ages 7-12 and written assent will be obtained for children ages 13-17. Parental permission will be obtained via the consent form as parent/guardian is now included as part of that consent form.

At the time of consent a detailed medical history form and written consent for participation will be obtained by the investigators. A copy of the consent form will be mailed to the subject. Ongoing participation in the study will be reviewed during the weekly visits. Subjects will be scheduled for an immediate start date.

10. Potential Risks:
Adverse effects are not expected. However, potential risks include possibilities for: discomfort from stretching, bleeding if facial burn sites are not fully healed, allergy from 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 Dr. Harold Pine, Faculty Sponsor, at 6 month intervals. Significant problems related to 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.

12. Procedures to Maintain Confidentiality:
Pictures will be taken using a departmental iPad and patient data will be stored on secure UTMB computers. Patient's written or verbal consent will be obtained prior to photographing the patient.

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.

14. Biostatistics:

Sample size calculation shows that a sample size of 20 (accounting for 10% missing rate) will be able to detect an effect size of 0.7 by using a two-sided paired t-test, if the real study has statistical power of 0.8 and the significance level (alpha) is 0.050.

Descriptive statistics for continuous and categorical variables will be presented as mean ± SD and quartiles, and frequencies and proportions, respectively. For the weekly measurements, we will use the descriptive statistics and individual trend plots to present the data. The primary outcome is the change in millimeters after the completion of treatment (post – pre measures) for each facial expression. We will use paired t-tests (if data is normally distributed) or non-parametric alternatives (e.g., Wilcoxon signed-rank test) to test if the changes are statistically significant. The change score of facial disability index (FDI) will be analyzed using the same method. The pre-post outcome of the cranial nerve assessment will be classified by categories (Pass-

Pass, Fail-Pass, Fail-Fail), and the frequencies and proportions will be reported. Two-sided statistical significance will be considered for alpha at the 0.05 level for all tests.

References:

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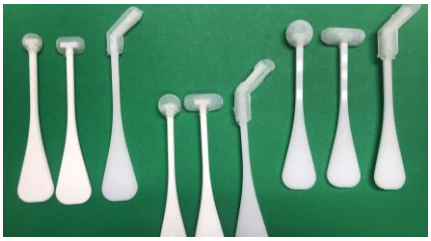
Appendix Legend

A	Current prototype
B	Nuk brush
C	Beckman Oral Probe
D	Chewy Tubes
E	Orastretch
F	Therabite
G	Easy Stretch Tool placements
H	Easy Stretch Weekly Visit Summary
I	Patient documentation handout

J	Cranial Nerve Assessment
K	Example of UTMB customized facial software
L	Recruitment letter for patients and parents/guardians
M	Facial Disability Index

Appendix A

Example Prototypes



Appendix B – Nuk brush

Appendix C – Beckman Oral Probe

Appendix D – Chewy Tubes

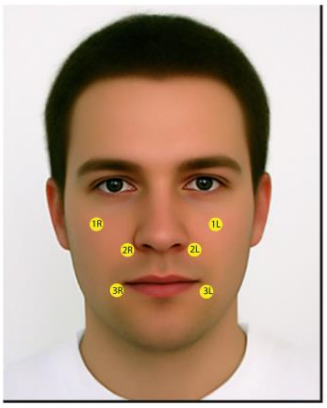
Appendix E – Orastretch

Appendix F - Therabite

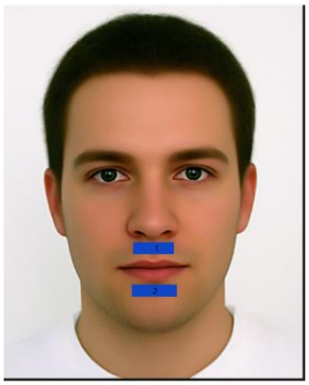
Appendix G

Intended facial placements for the Easy Stretch Tools. Each shape has its own targeted intraoral placement.

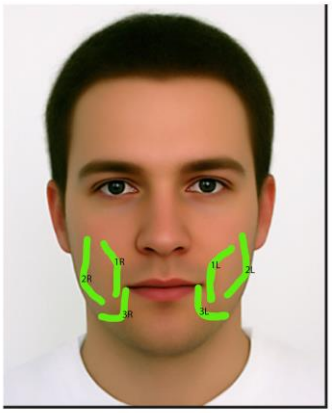
Circle tool



Bar tool



L shape tool



Appendix H – see separate document for complete form with header/footer

Easy Stretch Weekly Visit Summary

Homework completed: yes/no Obtained copy of HW record: yes/no
Current Tool Placement:

Yellow	#1	#2	#3
Blue	#1	#2	
Green	#1	#2	#3

Patient Comments:
_____
_____
_____

Patient verbalizes wish to continue in the study: yes/no

Pictures taken	Check as completed
At rest	
Wrinkle the nose	
Gentle smile	
Broad smile with lips closed	
Broad smile with teeth together	
Vocalize prolonged “eee” sound	
Vocalize prolonged “ooo” sound	
Lip pucker – drink from a straw	
Open mouth wide	
Side profile	

Next Tool Placement:

Yellow	#1	#2	#3
Blue	#1	#2	
Green	#1	#2	#3

Follow up visit date/time: _____

Date/Time this assessment was completed: _____

Signature of principal and/or co-investigator: _____

Appendix I
Example patient documentation handout – see separate document for complete form with header/footer

Easy Stretch Toolkit

Who placed the tools? Circle one: patient/caregiver
Tool (size and color): _____ Placement location*: _____

*See attached picture.

Date	AM – Number of minutes used	PM – Number of minutes used

Appendix J – Cranial Nerve Assessment form - see separate document for complete form with header/footer

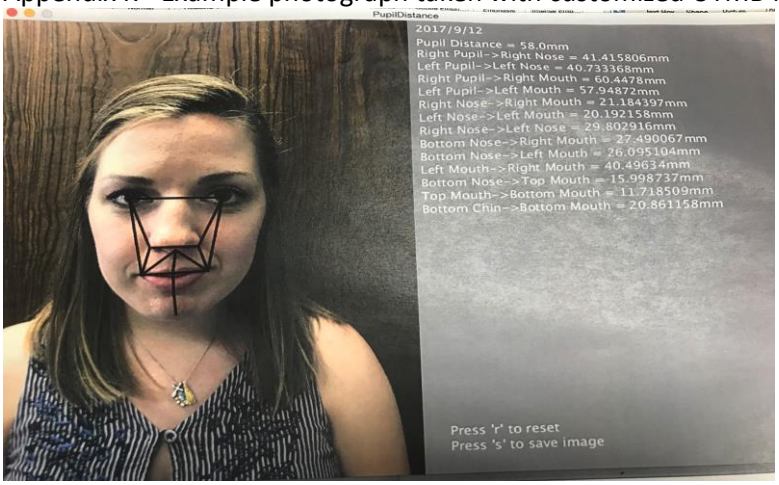
Easy Stretch Toolkit
Cranial Nerve Assessment: Oral Motor / Facial Measurements

Nerve	Task	Comments	Initial Exam Pass/Fail	Final Exam Pass/Fail
CN I Olfactory	Smell orange peel			
CN III Oculomotor CN IV Trochlear	Follow the finger "H"			
CN V Trigeminal	Opthalmic – brush across forehead			
	Maxillary – cheekbone			
	Mandibular- chin			

	Corneal Reflex Test			
	Masseter /Temporalis– clench teeth			
	Jaw Jerk			
CN VII Facial	Crease forehead			
	Close eyes			
	Close eyes against resistance			
	Puff out cheeks			
	Smile and show teeth			
CN IX Glossopharyngeal	Gag reflex			
CN X Vagus	Say “ah”			
CN XI Accessory	Sternocleidomastoid and traps – Head turn against resistance			
	Shoulder shrug - resistance			
CN XII Hypoglossal	Motor to muscles – Stick out tongue			

Week #: 1 Completed on _ _ / _ _ _ / _ _ _ _Time: _____By: _____
Week #: 12 Completed on _ _ / _ _ _ / _ _ _ _Time: _____By: _____

Appendix K - Example photograph taken with customized UTMB facial software



Appendix L – Recruitment letter for patients (version for 18 years and older, as well as version for parents/guardians of patients under 18 years of age)

Dear Patient,
As a care provider, I have a responsibility to serve patients. Part of this responsibility involves promoting research that will help doctors understand the medical conditions that patients face. For this reason, I am writing to tell you about a study being conducted at UTMB by the Speech Pathology department.

My colleagues Lori Jarrett and Kathleen Kerr, Speech Pathologists, are studying a new method of treatment for facial burns that have caused scarring and problems with mouth opening, difficulty chewing or speaking, decreased range of motion, or limited ability to produce different facial expressions. You suffered a facial burn injury and may be eligible to participate in this study since you suffered a facial burn injury. If you participate in this study, you will be asked to: Use an intraoral device under the guidance of the Speech Pathologist to stretch facial skin and muscles; Attend an initial and final in person assessment with the Speech Pathologist; Complete a FaceTime or Skype video call with the Speech Pathologists 1 time per week in between the in person visits; Use the prescribed device 2 times per day for 1 hour at a time; Keep a diary of when and how you use the

device(s) and email these to the Speech Pathologists; Give consent for weekly photographs of your face. The device(s) will be provided to you at no cost.

If you are interested in learning more about the study, please contact Lori Jarrett or Kathleen Kerr at 409-772-2711.

You do not have to respond if you are not interested in this study. If you do not respond, no one will contact you. If you decide not to participate in the study, it will not have any effect on the quality of care you receive from me or any other UTMB provider.

The results from this study may improve your mouth opening for better talking, chewing and oral care, reduce the impact and appearance of scar tissue, or improve your ability to make different facial expressions.

Thank you for considering this research opportunity.

Sincerely,

Dear Parent or Guardian,
As a care provider, I have a responsibility to serve patients. Part of this responsibility involves promoting research that will help doctors understand the medical conditions that patients face. For this reason, I am writing to tell you about a study being conducted by the UTMB Speech Pathology department.

My colleagues Lori Jarrett and Kathleen Kerr, Speech Pathologists, are studying a new method of treatment for facial burns that have caused scarring and problems with mouth opening, difficulty chewing or speaking, decreased range of motion, or limited ability to produce different facial expressions. Your child suffered a facial burn injury and may be eligible to participate in this study. If your child participates in this study, he or she will be asked to: Use an intraoral device under the guidance of the Speech Pathologist to stretch facial skin and muscles; Attend weekly in person visits with the Speech Pathologist for 8 weeks; Use the prescribed device 2 times per day for 1 hour at a time; With your help, keep a diary of when and how he or she uses the device(s); Give consent for weekly photographs of your face. The device(s) will be provided to you at no cost.

If you are interested in learning more about the study, please contact Lori Jarrett or Kathleen Kerr at 409-772-2711.

You do not have to respond if you are not interested in this study. If you do not respond, no one will contact you. If you decide not to participate in the study, it will not have any effect on the quality of care you receive from me or any other provider.

The results from this study may improve your child’s mouth opening for better talking, chewing and oral care, reduce the impact and appearance of scar tissue, or improve your child’s ability to make different facial expressions.

Thank you for considering this research opportunity.

Sincerely,

FACIAL DISABILITY INDEX (FDI)

Name: _____ Date: _____

Please choose the most appropriate response to the following questions related to problems associated with the function of your facial muscles.
For each question, consider your function **during the past month**.

Office Use Only
Score / Goal

Physical Function

1. How much difficulty did you have keeping food in your mouth, moving food around your mouth, or getting food stuck in your cheek?
   Usually did with:
   5 = No difficulty
   4 = A little difficulty
   3 = Some difficulty
   2 = Much difficulty
   1 = Usually did not eat because of health
   0 = Usually did not eat because of other reasons

1. _____

2. How much difficulty did you have drinking from a cup?
   Usually did with:
   5 = No difficulty
   4 = A little difficulty
   3 = Some difficulty
   2 = Much difficulty
   1 = Usually did not eat because of health
   0 = Usually did not eat because of other reasons

2. _____

3. How much difficulty did you have saying specific sounds while speaking?
   Usually did with:
   5 = No difficulty
   4 = A little difficulty
   3 = Some difficulty
   2 = Much difficulty, slurring most of speech
   1 = Usually did not eat because of health
   0 = Usually did not eat because of other reasons

3. _____

4. How much difficulty did you have with your eye tearing excessively or becoming dry?
   Usually did with:
   5 = No difficulty
   4 = A little difficulty
   3 = Some difficulty
   2 = Much difficulty
   1 = Usually did not eat because of health
   0 = Usually did not eat because of other reasons

4. _____

5. How much difficulty did you have with brushing your teeth or rinsing your mouth?
   Usually did with:
   5 = No difficulty
   4 = A little difficulty
   3 = Some difficulty
   2 = Much difficulty
   1 = Usually did not eat because of health
   0 = Usually did not eat because of other reasons

5. _____

Total:

_____

(____ - 5) / 5 x 25 = _____ Physical Score

For office use only

(____ - 5) / 5 x 25 = _____ Physical Score Goal

Please Turn Over for Part 2

Facial Disability Index – Part 2

Please choose the most appropriate response to the following questions related to problems associated with the function of your facial muscles.
For each question, consider your function **during the past month**.

Office Use Only
Score / Goal

Social / Well-being Function

6. How much time have you felt calm and peaceful?

6 = All of the time
5 = Most of the time
4 = A good bit of the time
3 = Some of the time
2 = A little bit of the time
1 = None of the time

6. _____

7. How much of the time did you isolate yourself from people around you?

1 = All of the time
2 = Most of the time
3 = A good bit of the time
4 = Some of the time
5 = A little bit of the time
6 = None of the time

7. _____

8. How much of the time did you get irritable toward those around you?

1 = All of the time
2 = Most of the time
3 = A good bit of the time
4 = Some of the time
5 = A little bit of the time
6 = None of the time

8. _____

9. How often did you wake up early or wake up several times during your nighttime sleep?

1 = Every night
2 = Most nights
3 = A good number of nights
4 = Some nights
5 = A few nights
6 = No nights

9. _____

10. How often has your facial function kept you from going out to eat, shop, or participate in family or social activities?

1 = All of the time
2 = Most of the time
3 = A good bit of the time
4 = Some of the time
5 = A little bit of the time
6 = None of the time

10. _____

Total:

_____

For office use only

(____ - 5) / 5 x 20 = _____ Social/Wellbeing Score

(____ - 5) / 5 x 20 = _____ Social/Wellbeing Score Goal

Physical (_____) + Social (_____) = (_____/ 200) total FDI Score

Physical (_____) + Social (_____) = (_____/ 200) total FDI Score Goal