

# **Looking into the improvement of the therapy of TMJ issues by the implementation of an in-house SLS-printed device**

A design project in collaboration with QUT Design, an industrial design student with a passion for health design, and the Herston Biofabrication Institute.

# DISCLAIMERS

## **AUTHENTICITY STATEMENT.**

This is to certify that to the best of my knowledge, the content of this report is my own work. This report has not been submitted for any subject or for other purposes. I certify that the intellectual content of this report is the product of my own work and that all the assistance received in preparing this report and sources have been acknowledged.

## **AI USE STATEMENT.**

I have utilised Generative AI in this report (ChapGPT to assist in various ways. The way I have used Generative AI includes solely the summation of keywords into topics, and topics into categories.

*Alexander Mougnot*  
*N10615571*  
*10.09.2023*

# ABSTRACT

## **OBJECTIVE.**

To inform future development of a product that can improve the quality of treatment patients of trismus and TMDs receive in rural and urban hospital settings.

## **DESIGN.**

This report is a qualitative study involving Maxillo-Facial Surgeons and Speech Therapists with experience in the therapy of Trismus and other TMJ issues to provide informed insights into the daily reality facing patients and their clinicians and identify opportunity areas for improvement.

## **SETTINGS + PARTICIPANTS.**

A literature review, two in-depth semi-structured interviews with three maxillofacial surgeons from the RBWH, one in-depth semi-structured interview with a RBWH speech therapist, and two online surveys – one provided to rural and urban speech therapists and the other to previous and current patients of TMDs and trismus. Collaboration with Herston Biofabrication Institute research fellows.

## **RESULTS.**

Current methods of measuring mandibular and masticatory motion are lacking by consensus of qualitative participants, and research and development in this space is narrow despite the general consensus. Current scanning and imaging technologies exist but are specialised for orthodontics and dentists, require long setup times, and as such offer little practical benefit to maxillofacial surgeons and speech therapists involved with treating and assessing jaw conditions.

The most common trismus device is stacked tongue depressors, which have multiple identified issues that affect patient safety and compliance but is largely the norm due to high cost of other devices. Current trismus devices do not cater for patients with atypical oral anatomies or for patients with minimal maximum interincisal opening (MIO), and so the patients at most risk of trismus cannot receive the therapy they require. Furthermore, patients without the ability to enact manual force to engage therapy devices or open their jaw manually are left without options for active stretching physical therapy. Both these issues are negatively impacted by relatively low demand that discourages commercial interest.

## **CONCLUSION.**

This research emphasised how when it comes to the accessibility of therapy devices, patients are at the mercy of laws of supply and demand. Furthermore, it highlights how the improvement of non-critical assessment practices can be easily overlooked, in favour of tackling more pressing problems at hand, yet that these remain to be daily issue that impact the well-being of patients and clinicians. This research report delves into these domains to provide a strong foundation for a research-based yet design-led project.

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# INTRODUCTION.

## **BACKGROUND.**

Trismus – commonly known as lockjaw – is a common condition among head and neck cancer patients affecting roughly 42% (Santiago-Rosado & Lewison, 2023), but can also present as complications from maxillofacial surgery, severe head trauma, infection, dental procedures, among a myriad of other circumstances (Santiago-Rosado & Lewison, 2023). It is commonly defined as a reduction in mouth opening of less than 35 mm between the teeth, and in severe cases less than 15 mm. Understandably, this greatly reduces the patient's ability to perform fundamental life functions, such as eating, swallowing, and speaking (Santiago-Rosado & Lewison, 2023), which often leads to further complications such as weight loss and depression (Faravel et al., 2023).

The prevalent therapies involve with mobilising the jaw, passively stretching it to increase MIO, though there are multiple issues with these devices, including their high cost, unsuitability for patients with oral anatomical variants, unsuitability for various jaw movement arcs, the requirement for manual force when some patients do not have the ability, and the lack of ability to quantify the force applied to the jaw. All of these factors result in many patients not receiving the quality of therapy they require, prolonging their symptoms, and reducing their quality of life.

As the research progressed, it was discovered that there is a need for improvement in the measurement methods of the jaw and its movements in 3 dimensions. Current methods for measuring lateral excursions via rulers are inaccurate across observers and there is also no accessible means to tracking jaw movement, without using large unspecialised jaw trackers with significant preparation time.

## **REPORT OVERVIEW.**

This report delves into the trismus therapy and jaw movement assessment space to discover which major pain points lie between clinicians, patients, and their proper therapeutical care. It does this through a research process entailing a literature review and primary research methods that are run in parallel, each informing the other.

The literature review analyses in-depth the current research on trismus and its therapies, as well as the assessment methods involved in the patient's recovery pathway. Being tied to disorders of the temporomandibular joint (TMJ), TMDs are explored insofar as their diagnostic and assessment requirements and current practices. Current devices and technologies for both domains (trismus therapy and jaw movement measurement) are analysed to provide an overview of the current state of the market.

Primary research includes the in-depth interviews with 3 maxillofacial surgeons and 1 speech therapist from the Royal Brisbane & Women's Hospital (RBWH), and 2 online surveys addressing speech therapists from a mixture of rural and urban hospitals, and TMD/trismus patients.

## **AIM OF THE PROJECT.**

This project is undertaken in collaboration with the Herston Biofabrication Institute (HBI) in parallel with their OpenTrismus Project – an open-source, FDM-printed trismus therapy device that primarily focuses on providing patients with a low-cost yet effective therapy alternative. Throughout exploring another device to address the need to cater for anatomical variants and a wider range of jaw movement arcs, it was decided that it is best that the current OpenTrismus is modified to address these issues. Therefore, the scope of this project revolves on the remaining factors and broader factors surrounding trismus and TMDs. The aim of the project is to design and develop a device that can be largely manufactured and assembled by HBI for national distribution, to improve the quality of care towards patients with trismus or other TMJ disorders. This means suitability for SLS printing is desired with the view towards low to mid-volume manufacturing.

It's shown that profitability and market size thwart innovation of medical technology that can improve quality of life (Bergsland et al., 2014). Through this report and design development I hope to contribute my time to helping with the provision and creation of equipment that can improve patient quality of life, and seek to benefit from the added value shown to be provided by physician collaboration in the development process (Shadduck et al., 2023)

# LITERATURE REVIEW

## **AN OVERVIEW.**

A brief description of the anatomy of the jaw and oral cavity precedes a review of the literature surrounding trismus therapies, and the measurement of the jaw and jaw movements for assessing and diagnosing trismus and TMDs. This literature is analysed to identify driving needs within the scope. Within each section, current devices and technologies are reviewed to provide a picture of the current state of the market and identify gaps in the market. A brief review into key qualities of successful medical products is given to guide future design criteria, before identifying gaps in the literature and then a summary.



## **AN BRIEF REVIEW OF THE JAW + ITS MOVEMENTS**

The movement of the jaw is a complex movement that is a two-step process wherein the mandible rotates to depress the mandible, then translates forwards (protracts), the TMJ consists of the head of the mandible articulating with the mandibular fossa when – in the open position – slides forwards onto the articular tubercle (Gilroy, 2022). The articular disk allows these two functions by separating the joint into separate parts: the upper part for the gliding movement, and the lower part for the hinge movement.

The lateral ligament strengthens and stabilises the joint capsule, and other ligaments support the joint during mastication. Mastication is enacted by the masseter, temporalis, lateral pterygoid, and medial pterygoid muscles, which all act at the TMJ to move the mandible (Gilroy, 2022).

Movement patterns have been defined across the sagittal (longitudinal), coronal (frontal) planes, and transversal (horizontal) planes. These “envelopes of motion” are diagrammatic representations of the border movements of the jaw (Chuhuaicura et al., 2021), although the intricacies of most natural functions movements (swallowing, chewing, talking, etc.) lie well within the borders and are complicated (Pinheiro et al., 2011; Posselt, 2001; Salzman, 1953). Anthropometric data on standard arcs of mandibular movement are not readily available, which makes it difficult to design devices to suit the majority or all of patients. Generally, standard mount opening distances lie between 40-60 mm, with the common consensus that less than 35 mm is a case of trismus, although this is dependent on the individual (Dhanrajani & Jonaidel, 2002). This is measured as the linear distance between the functional masticating area for patients, whether between teeth or between gums.

## **JAW-RELATED CONDITIONS + ETIOLOGIES.**

Trismus is a painful condition wherein a patient loses mobility of the jaw, severely affecting their ability to perform basic life functions. It is commonly caused by radiotherapies in head and neck cancer treatment, affecting 38-42% of patients, with 28% experiencing trismus at the one-year mark (1, 3). Trismus can also be caused by complications from oral dental procedures (Dhanrajani & Jonaidel, 2002), local anaesthesia (Garnett et al., 2008), severe trauma (Santiago-Rosado & Lewison, 2023), temporomandibular disorders (TMD) (Beddis et al., 2014), and as a sign of malignancy (Santiago-Rosado & Lewison, 2023).

With restricted mouth openings due to muscle tightness and the associated pain, follow-on effects pose prevalent risks to patients, including depression, anxiety, and weight loss (Pauli et al., 2012). Historically, the literature largely lacks focus on quality-of-life factors when assessing patient success, overly relying on MIO measurements to report patient outcomes. This has been identified in the literature (Cardoso et al., 2021), and since over the past 5 years studies have begun to include quality of life (QOL) assessments in conjunction with quantitative physical measurements (Lee et al., 2018; Santiago-Rosado & Lewison, 2023).

TMDs on the other hand, are far more complex being an umbrella term for over 40 different conditions (Sutter & Radke, 2020), some of which are caused by primary conditions outside of the TMJ elsewhere in the maxillofacial region. Some TMDs can cause trismus when they trigger masticatory muscle spasms (Santiago-Rosado & Lewison, 2023). Affecting 15% of adults (List & Jensen, 2017), diagnosis of TMDs isn't as simple as measuring interincisal opening, as symptoms vary widely – from clicking and other “noises” to nasal stuffiness, muscle tenderness, paraesthesia, or at times no symptoms at all (Beddis et al., 2014). Furthermore, there is academic dispute on the diagnostic ability of not only jaw tracking methods (Costantinides et al., 2020; Manfredini et al., 2012; Sutter & Radke, 2020) but also other imaging methods (Beddis et al., 2014; Santiago-Rosado & Lewison, 2023; Schiffman et al., 2014; Sutter & Radke, 2020). However, it has also been described that imaging shouldn't be relied upon solely, but in addition to jaw tracking which offers insights into the quality of masticatory function and efficacy of therapy methods and verify surgical interventions (Sutter & Radke, 2020; Ueki et al., 2020).

## **CURRENT THERAPY METHODOLOGIES.**

Although acute trismus can resolve itself naturally or with muscle relaxants, chronic trismus requires physiotherapeutic intervention which mobilise the jaw passively or actively (Santiago-Rosado & Lewison, 2023). These therapies focus on restoring the distance of the maximal interincisal opening (MIO) of the mouth - as a proxy for restoring general jaw function.

Regarding physical therapies, jaw-mobilising devices have been shown to be effective, either actively stretching the jaw, or maintaining an opened state for a period (Charters et al., 2022; Pauli et al., 2014). These various devices include plastic corkscrews, the therabite, the orastretch, amongst other, and all work to actively apply a stretching force to the jaw though are quite expensive, the market-leading Therabite costing around the \$500 mark (Charters et al., 2022). Understandably, many patients do not have the means to access these devices. Therefore, tongue depressors are a widely-used device due to their accessibility and low cost (Charters et al., 2022; McSweeney, 2008), although they are shown to be less effective (Şahan & Gökçe, 2023).

In addition to the high cost of available therapy devices, they all require manual force to be applied to open the jaw. Devices have been developed that use motors and hydraulics to assist therapy, though these are not currently available, likely due to cost and low demand (Maloney et al., 2002; Poremba & Moffett, 1989). It is widely noted that various surgeries and cancer treatments result in loss of strength and manual ability (Lee et al., 2007; Oberst et al., 1991), though notably there is no available research on the impacts to patients with loss of strength and ability to do self-conducted therapies.

Furthermore, current commercially available devices lack the ability to apply quantifiable forces to the jaw, which is an important factor in avoiding possible injuries and fractures especially where the oral structure of some patients is weakened post-surgery or post-radiation treatment (Charters et al., 2022; Marunick et al., 2016), instead relying solely on patient perceived resistance and pain (Charters et al., 2022). Also of note is that there is a distinct lack of research on which resistance and forces are best for treating trismus, although Charters et al. have explored creating a device that can apply quantifiable force to the jaw (2022), basing their maximum force of roughly 100N off the research of Koc et al (2010). However, their device still requires the use of manual force to compress the device and install it in the patient's mouth.

These devices are also not largely designed with oral anatomical variants in mind, posing challenges for the therapy of edentulous patients and patients who are missing multiple teeth or other parts of their oral structure (Dijkstra et al., 2006; Martins et al., 2019), with only one device incorporating different bite pieces (Satheeshkumar et al., 2014). A further issue is that all commercial devices require the application of manual force to enact opening force to the jaw.

## **CURRENT MEASUREMENT PRACTICES.**

The most common method for measuring the state of the jaw is simply by using calipers, a ruler, or finger-widths, due to their availability and ease of use for therapists and surgeons (Aliya et al., 2021). Whilst ruler and calipers-made measurements have been shown to be accurate across operators for MIO measurements, the measurements of lateral excursions are less so due to there being no natural reference point (Yoshitake, 2018).

Although MIO is the major indicator for trismus, masticatory motion and jaw pathways are also important factors for clinicians (Posselt, 2001; Tanaka et al., 2016; Yoshitake, 2018), although this isn't easily measured. Mapping out movements across the coronal (frontal) and sagittal (longitudinal) planes offer valuable information on masticatory function for surgeons and therapists. For the therapist, this information advises therapy by quantifies progress or regress (Sutter & Radke, 2020). For the surgeon, it advises them of the current state of jaw movements and post-operatively test the efficacy of their surgical interventions (Sutter & Radke, 2020; Ueki et al., 2020). For both clinicians, pre-operative measurements taken prior to any symptoms would form a baseline to aim for.

Current methods of jaw tracking are large devices that have prohibitive preparation times, specialised mostly for dentistry and orthodontics (Baglio et al., 2004; Yoshitake, 2018). These incorporate a variety of technology, including stereoscopic artificial vision (Baglio et al., 2004), kinesiographs (George, 1983), magnetometry (Revilla-León et al., 2023), ultrasonic systems (Revilla-León et al., 2023), and optical scanners (Kwon et al., 2019). These are mostly however tailored towards the market of optimising occlusion of prosthetics and for orthodontic/dental procedures (Revilla-León et al., 2023), and are often used in academic research (Rahman et al., 2022). As such, these technologies aim to produce and process a lot of 3D data, aiming to produce an exact picture of every movement of the mandible in 3D space. This means that these technologies are overly complicated and bloated for pragmatic day-to-day use by surgeons and therapists. So the situation we have here is that on one end of the spectrum, the measuring instruments currently used by the general clinician are too basic for more meaningful analysis, and on the other end other sophisticated technologies that would provide more value to daily care are far too complex as they are specialised for another domain.

One research team has sought to address this gap in the research and market, by producing a purpose-made measuring device that reduces error in interincisal and lateral excursion measurements, as well as offers a method for roughly estimating jaw open-close movement on the coronal plane (Yoshitake, 2018). Other research teams have proposed using cameras capable of recording depth (such as the Microsoft Kinect or newer phones) as cheaper yet high-value means of tracking jaw movement (Tanaka et al., 2016), although these may not be suitable for obese patients.



As such, there is the opportunity to improve the diagnostic and assessment ability for therapists and so this design project was expanded to investigate this space.

# RESEARCH DESIGN

## **AN OVERVIEW.**

Both primary and secondary research was conducted in parallel, with each informing the other as they progressed. Secondary research methods included a literature review, whereas primary research with relevant stakeholders was conducted in the form of 3 in-depth expert interviews and 2 online surveys. Preliminary research as part of the literature review was conducted initially, which provided focus for early interviews, then advising direction for the completion of the literature review and objectives for the online surveys.


The initial major focus questions were:

-  **How can trismus therapy devices be optimised to improve therapeutical success for patients?**
  
-  **How can therapy methods be improved to cater for outing patients?**

The literature review addressed these questions by gaining an overview of the stances recording officially academic literature, which is primarily focused on quantitative analysis on the efficacy of different methods which is important for providing evidence-based research in health education (Watkins, 2012).

Then, qualitative primary research was aimed towards gaining personal insights into issues at hand and learn what are common problems identified in day-to-day practice by clinicians. This adds an important perspective by considering the element of context (Bryman et al., 1996), which is often overlooked or assumed in the literature.

The in-depth interviews revealed the challenges surrounding jaw movement measurements, thus the follow question was added to the literature review scope:

-  **How are jaw measurements made and jaw movements tracked clinically?.**

## **LITERATURE REVIEW.**

A literature review conducted to understand what the academic views on trismus therapies and measurement practices are, and on which relevant available technologies exist. Over 80 articles were reviewed - with the domains of trismus and TMDs being widely researched – with key research topics and keywords being:

- **Measurement of the Jaw**
- **Jaw Tracking Devices**
- **Trismus + Trismus Therapy**
- **Trismus + Etiologies**
- **Trismus Therapy Devices**
- **Mandibular Movement**
- **Jaw Anthropometrics**
- **TMD Diagnostics**

These articles were reviewed for relevant knowledge, with findings being recorded in a Miro Mindmap (Appendix G), mapping out key learnings from roughly 110 sources to the above topics. This assisted in logical linking of relevant findings formulate a strong basis of understanding of the current literature. Sources that are referenced in this report were then collated in Zotero for further analysis and referencing.

## **EXPERT INTERVIEW METHODOLOGY.**

Expert in-depth interviews were chosen as a research method because it is a proven method to gaining a lot of contextual information in a short amount of time (Watkins, 2012), with the added benefit of creating contacts with local clinicians with whom the ongoing design work can be collaborated. To ease the flow of conversation and offer the opportunity for novel insights and opinions from the participants, a semi-structured interview format was chosen consisting of a list of questions to address, but allowing the participant to talk freely around these, with the researcher guiding conversation to ensure key topics are addressed. Five participants were contacted for these interviews– three maxillofacial surgeons and one speech therapist from the RBWH; one ST from Hervey Bay Hospital – chosen for their intuitive understanding of the daily goings on and pain points involved with trismus therapy and maxillofacial issues in urban hospitals. The expert interview with a rural Central Queensland speech pathologist was organised but could not proceed due to an emergent situation. Whilst this is a shame, ongoing consultation with this clinician and their contacts is possible throughout the next design phase.

Building on learnings from the preliminary literature review, a series of guiding questions were made for each interview to ensure key points were discussed. This interview guideline was modified after each interview as different gaps in knowledge were identified, and specified for each specialist (see Appendices A-C).

Due to lack of appropriate ethics approval and the active hospital setting, the interviews could not be recorded. Whilst audio-recorded interviews, are widely used and touted for their accurate records of vast quantities of data (Fasick, 1977), the use of field notes is widely regarded as an effective qualitative reporting process especially when interview time is short (Fasick, 1977; Hill et al., 2022; Sanjek, 2019). Extending these notes shortly after the interview whilst the impressions are vivid provides the opportunity for the interviewer to elaborate on the participants' points while ideas and memories from the interview are fresh (Sanjek, 2019; Tessier, 2012).

For this reason, a "fair note" methodology was undertaken, with the researcher taking field notes throughout the interview in real time and then expanding these notes (Appendices D-F) from memory immediately after the interviews (Hill et al., 2022), for later use in coding and thematic analysis.



## **SURVEY METHODOLOGY.**

The second data collection method consists of two surveys that were produced from learnings from preliminary literature review research and the expert interviews. The first survey was provided to people who have received therapy or surgery for various jaw conditions, and 10 patients were reached via social media and online forums. The second survey was provided to 7 speech therapists based between Sydney and Hervey Bay.

The surveys took between 10 – 15 minutes to complete, comprising of a mixture of short-response, multiple choice, and Likert scale questions. Both patients and STs perspectives were sought to provide both perspectives of the topics of therapy, measurement methods, and the market. (Appendices L + M).

## **SUMMARY.**

This project's topic is the current state and methods of therapy of trismus and measurement of the jaw and its movements. A preliminary literature review was conducted on this topic to create a contextual overview of the issues at hand, which generated a series of questions which informed interview questions. The learnings from the interviews fuelled completion of the literature review and informed survey questions.

# RESULTS + ANALYSIS.

## **EXPERT IN-DEPTH INTERVIEWS.**

### **ANALYSIS.**

Data was analysed by reviewing the expanded fair notes for each interview, codifying these into 7 common codes and then categorising these into three major categories. The prevalence of comments and codes was identified alongside the prevalence of each category in proportion to each other. Furthermore, prevalence of each code occurrence within each category was also analysed to identify which topics were most talked about. Significant and novel quotes that stood out to the researcher were also identified and highlighted separately. All these learnings are summated and tabulated into their distinct categories in Appendices H-K.

## RESULTS.

The codes identified and the categories they fall under are described below and on the next page Broad definitions for each category are as follows:



### **Market & Business Considerations**

Major factors that contribute to making a successful medical product for this context

- **Patient Compliance**
- **Price**
- **Demand/Market**



### **Medical/Healthcare**

Current practices in healthcare and medical contexts, including medical devices, therapy, anatomical variants, and the trismus condition.

- **Devices**
- **Anatomical Variants**
- **Trismus Cause**
- **Therapy**

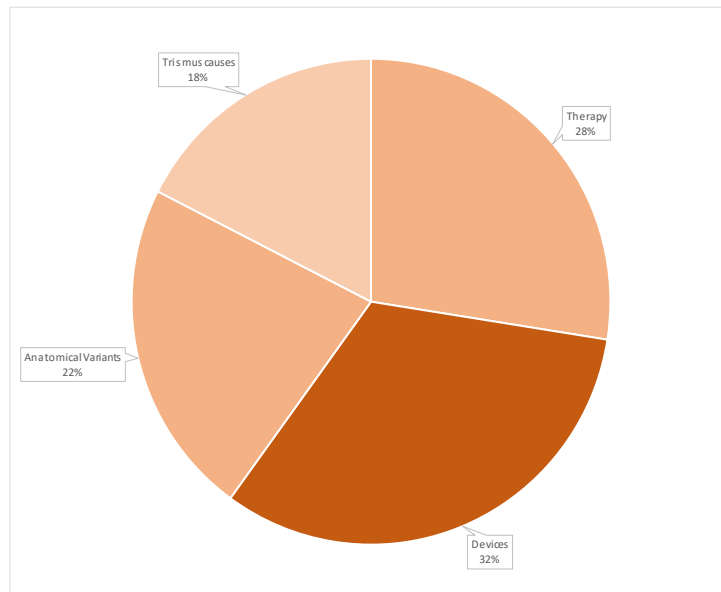


### **Product Features/Characteristics**

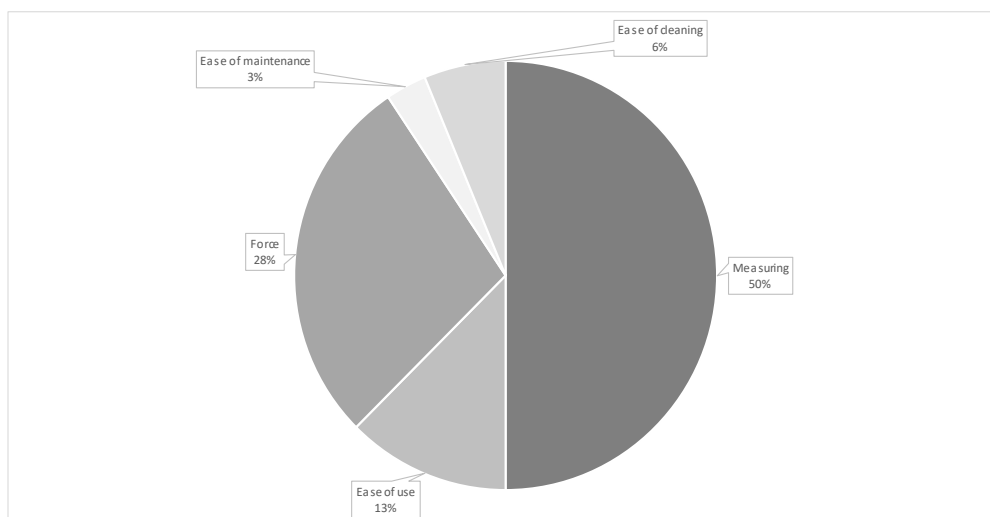
Key aspects of a product or device that are sought after in practice, detailing core features that will potentially define an effective and successful product.

- **Ease of Use**
- **Ease of Maintenance**
- **Ease of Cleaning**
- **Force**
- **Measuring**

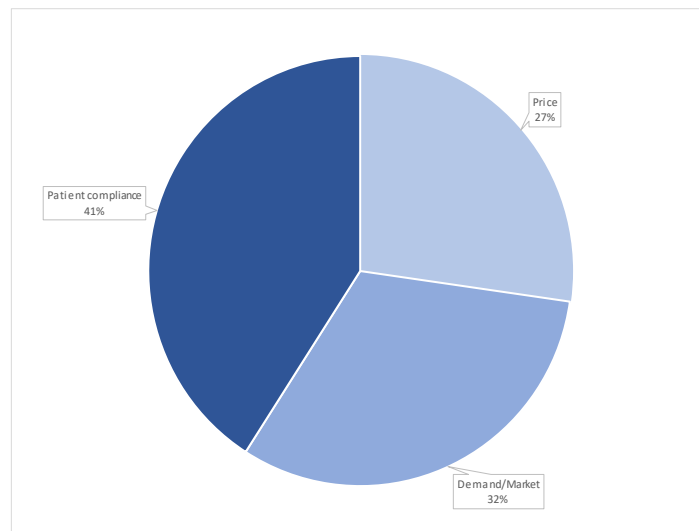
The **medical/healthcare category** was mentioned significantly more than other categories, although this is all not too surprising given that much of the interviews were spent discussing current therapy methodologies and the fundamentals of jaw conditions which are covered by this category. Within this category, devices and therapy were the most mentioned codes – logical given that this project revolves around improving therapy devices – though interestingly, anatomical variants comprised a large portion of this category although it isn't as intrinsic and covered by current therapy devices out there. This suggests that the issue of catering for anatomical variants is a significant concern of these clinicians.



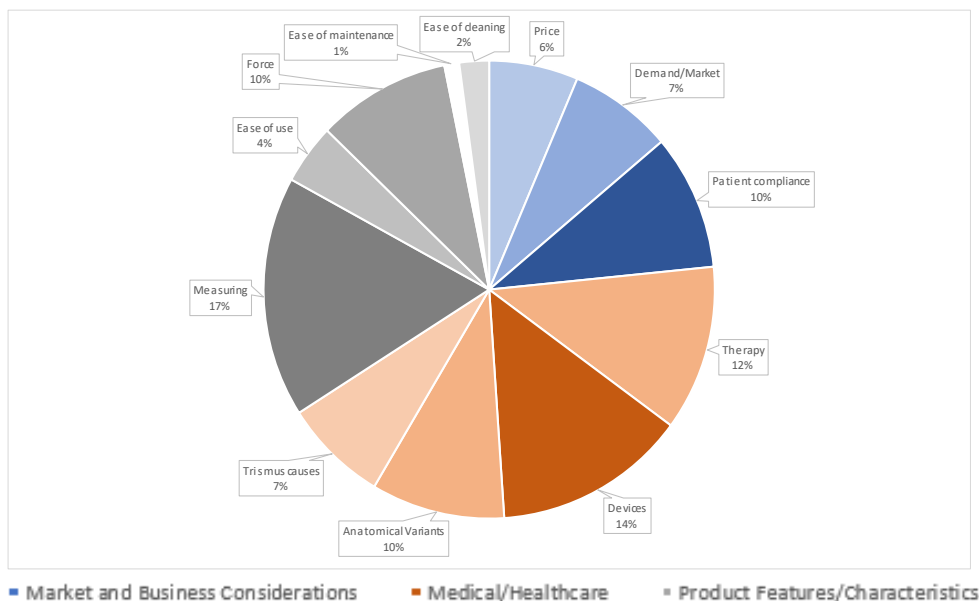
The **product features/characteristics category** was the second-most mentioned category, comprising of important design criteria for future products. Within this category, measuring dominated the conversations across the board, comprising 50% of all mentions. This is significant and a surprise, given that the project brief from HBI did not identify measuring as a major area for improvement. This data suggests that measurements of the jaw and its motions are major pain points for clinicians. The code of force was second (28%), being another key lacking area for clinicians, and ease of use in third. Ease of maintenance and ease of cleaning had significantly low scores, likely due to them being fundamental requirements for medical equipment.



The final, least mentioned category – **market & business considerations** – comprised the remaining 23% of all comments, 11% less than the previous. This is aided in part due to the fact that the clinicians interviewed were not in the position to make purchasing decisions and don't have experience in product viability so could only speak from their experience. Within this category, patient compliance, price, and demand/market were fairly evenly spread, with comments on patient compliance taking a larger place in conversation (42%). From this it can be gleaned that when it comes to product viability, patient compliance and their aptitude to want to use it is of most concern to clinicians. The reduced mentions on price are likely due to clinicians knowing that we are aware of the issues of price and of HBI's OpenTrismus project.



**Across all categories** the top two most mentioned codes were measuring and patient compliance, comprising 17% and 14% of all comments respectively. This reinforces the overarching significance of concerns regarding measuring mandibular and masticatory movements, and that optimising patient compliance is a major challenge for clinicians.



## SURVEYS.

### ANALYSIS.

As the survey questions were a mixture of a open- and close-ended nature, the data was analysed by separating the data into quantitative and qualitative data. Quantitative data was analysed and presented in graphs detailing the preferences and perspectives of respondents proportionally to each other. Qualitative responses were categorised and grouped to analyse major trends in perspectives from 10 patients and 7 speech therapists. Both types of data are presented in parallel to link their findings.

### RESULTS - PATIENT SURVEYS.

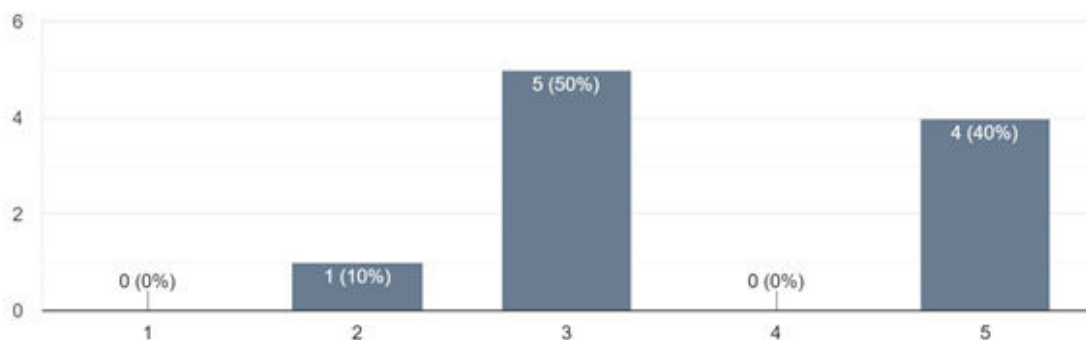
Patient respondents identified as having a wide range of different conditions, with 40% having diagnosed TMJ issues, 10% with trismus, 10% with jaw dislocations, and the remaining 40% with other jaw issues. 70% of respondents' issues were caused by clenching of the jaw – often due to stress –, 10% due to playing clarinet, and one due to other ENT issues.



In terms of effects to quality of life (QOL), 50% rated their symptoms' effect on their QOL at 3 out of 5, and 40% rated it the maximum at 5, and their duration of symptoms varied across the board from <2 weeks to 20+ years. Of these higher QOL scores, most respondents reported issues with eating, though other issues with breathing, ability to go to the dentist, and even a mandatory career change were noted. These point towards the fact that jaw issues significantly impact patient QOL by impacting their fundamental activities., careers, and health care.

How much did your symptoms affect your quality of life?

10 responses



Therapies that were undertaken included threaded cones, acupuncture, chiro adjustments, botox treatments, physiotherapy exercises, splints, retainers, mouth guards, dry needling, stretches, and massage. A driving theme in these short responses were that patients seem to need to actively take charge of their therapy and seek out different methods and specialists to find what works for them, which can be costly and uncovered. This is summed up in the following quote:

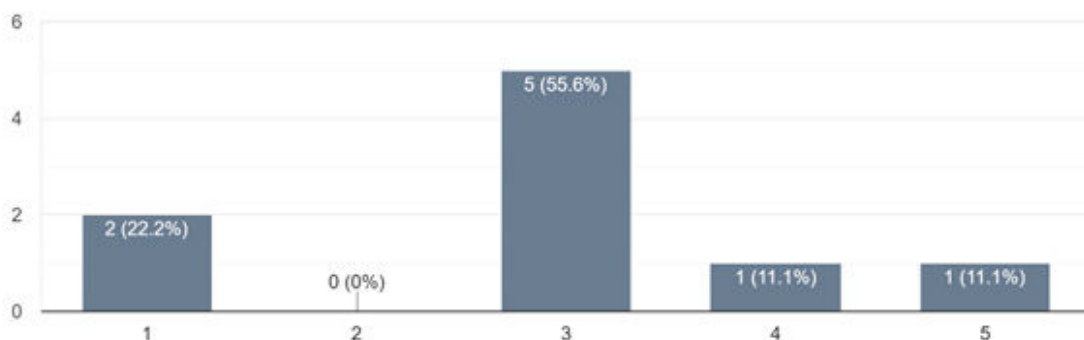
**“Numerous consultations on treatments that couldn’t be guaranteed to help and not covered by private health. Have managed it with physios, dry needling and remedial massage”.**

As such, practitioners seen varied as widely as the therapies undertaken. Devices used included stacked tongue depressors, Therabite, and the mouth screw, of which all patients were required to purchase.

Over half patients noted rated the ease of consistent therapy at a 3, with the other 50% rating on either side of the midline, and all patients but one noting that their symptoms have now improved with therapy. Key therapy reflections were that exercises and stretches were easy to do, with a preference for therapies that were easy to do in any location though it was also noted that it was “sometimes hard to track progress.”

How easy was it to do the therapy consistently?

9 responses



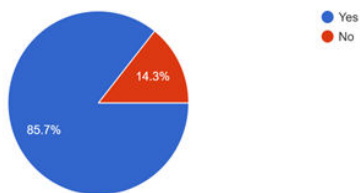


## RESULTS - SPEECH THERAPIST SURVEYS.

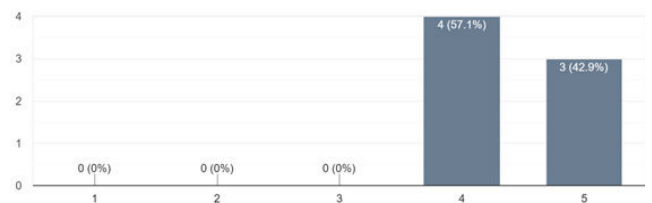
This survey was much more involved, so only select data will be mentioned here, drawing attention to notable insights.

Results here reflected a need for improvement in the space. 85% of respondents stated that they would find it useful to have a device that could accurately control the force applied to the patient's jaw for assessment purposes. Furthermore, all clinicians rated the importance of improving the current trismus therapies at least 4 of 5 with the cost of devices (29%) and patient motivation (43%) being the driving factors for success in treating trismus. Notably for this research report, poor manual strength was not listed as being a main limitation to therapy that these clinicians see often, even though 85% saw a need for a device operable by patients with low strength. From this it can be inferred that whilst there is a need, the demand is low.

Would it be useful to be able to use a device that accurately controls force to open the patient's jaw for assessment purposes?  
7 responses



How important is it that the therapy of trismus is improved?  
7 responses



When it comes to anatomical variants, there was misinterpretation in the question wording, with only two valid responses which indicated that placing of gum guards are used in therapy after surgical clearance. However, it was mentioned when providing thoughts on the Therabite a dislike for the bite pads, the non-ability of using the device with uneven teeth, the wide insertion plate, and that the plates don't "allow for altered dentition or mucosa" and all mouth shapes. 30% of respondents mentioned in short responses that the device is unable to be used by patients with minimal mouth opening – a point that is a novel addition to this research.

“ **Dislike that it cannot be used with minimal opening patients and those with uneven teeth.** ”

“ **It's not easy for patients with poor dexterity, its expensive, the mouth plates do not allow for altered dentition or mucosa** ”

“ **... doesn't accommodate all mouth shapes; need minimum mouth opening to use it** ”

Regarding taking measurements, they are taken by all clinicians, with 60% using the ruler cards, and 30% noting that they use the number of tongue depressors. All clinicians were happy with the reliability of the current measurement methods, which notably contrasts with in-depth interviews taken, though these respondents noted that they're only concerned with MIO. An important comment by one was that current measurement methods are "difficult with nil or missing teeth and when opening is less than 15mm". Major barriers were anecdotally noted as being the uncertainty in measurement with edentulous patients, no ability for force measurements, and the close proximity with a patient's space, and the lack of the ability to measure rotational movement for chewing which "is often deprioritised for opening alone". This same respondent suggested that a device "would possibly require dynamic biofeedback/measurement in simulated chewing".

*"With the measuring cards from Therabite or Orastretch"*

*"Yes, with Mio measure device from therabite"*

*"Via number of tongue depressors fit into the oral opening"*

## **SUMMARY.**

Through qualitative and quantitative analysis of two patient and speech therapist surveys, and qualitative analysis of three semi-structured in-depth expert interviews, truly valuable insights were gleaned into the reality of the therapy of trismus and jaw conditions. Notable areas to explore include the domains of jaw measurements, unsuitability for small mouth openings, and unsuitability for anatomical variants. The results also suggest that whilst non-manual force application to the jaw is deemed as important, there is not a great demand for it.

# DISCUSSION

## **AN OVERVIEW.**

This discussion brings together primary and secondary research, outlining where they reinforce and contradict each other and what gaps in the research and limitations are present.

## **QUALITATIVE RESULTS + THE LITERATURE = \_\_\_\_\_**

Preliminary research in the literature review revealed that there are no commercially available devices that can apply force to the jaw without the use of manual strength. This was reinforced up by the interviews and surveys which also highlighted the importance of such a technology, though the frequency of their comments on the subject suggest that there is not significant demand. The lack of literature on the effects of loss of manual ability to compliance to trismus therapy also indicate this. As such, the lack of such a device is likely a function of low demand and ability to commercialise such a product, yet this does not discount the few patients that suffer from this.

Furthermore, there is currently only one device that can apply a quantified force to the jaw (Charters et al., 2022), or at the very least an upper limit force. Further secondary research suggested that there was a need for this to avoid potential fractures during therapy as has been reported (Charters et al., 2022; Marunick et al., 2016). All qualitative research indicated a call for devices like this, to give greater control to surgeons for advising safe forces for therapists to prescribe to patients.

Regarding patients with oral anatomical variants, no research was found on therapy methods catered to these patients even though they are up to 8 times more likely to develop trismus (Martins et al., 2019). All qualitative participants specified challenges in providing therapy for these patients, and the unsuitability of current devices for these patients, especially when they only have half their teeth or can only open their mouth minimally. This points towards a device that can cater for these patients and provide valuable therapy to them, having perhaps higher demand than patients with insufficient manual ability.

A surprising pearl to come from interviews is the requirement for more sophisticated – yet accessible – measurement techniques for mandibular movements. Whilst surgeons in interviews indicated that they're looking for greater analysis of general movement pathways, speech therapists in the interview and surveys pointed towards analysing chewing movements and measuring rotational movements.

There is a vast body of research into tracking jaw movements with various high-end technologies to create highly precise 3D models of the mandible for orthodontic/dental procedures and for research into the efficacy of various surgeries. However, there is very limited research into the application of such a technology in a way that is pragmatic to clinicians and therapists in taking general jaw movement measurements and tracking movement pathways. Qualitative research revealed contradicting views on the accuracy of MIO measurements with the ruler, with lateral movements and measuring edentulous patients being significantly less accurate. On the other hand, secondary research indicates a high level of accuracy of MIO measurements yet no research on the accuracy of measuring lateral movements and MIO for edentulous patients. Only one article has explored the possibility of such a practical device, in the form of a ruler instrument designed to make accurate MIO and lateral excursion measurements, and approximations of movement pathways.

Whilst the creation of a budget trismus device is outside this project's scope, cost remains a major factor – heavily documented in the literature and a major topic for all qualitative participants and important for both patients and hospitals' wallets. Thus, it is important to strive to keep acquisition costs low for any devices to assist in commercial and investor buy-in

## **LIMITATIONS.**

The surveys only have 7 and 10 participants, which is quite low comparatively to other qualitative online surveys (Braun et al., 2021). This means that there is a high potential for anomalous responses to greatly affect the quantitative data. However, this isn't a major issue as the qualitative nature of most of the data offers deeper insights that allow the researcher to discount erroneous data and glean insights.

Another major limitation is that all patient survey respondents were based in Brisbane, Queensland, and all clinical participants were based between Brisbane and Hervey Bay. This is a limited range of perspectives when the goal of this device is national distribution for the entire spectrum of patients and clinical settings.

Further limitations include the lack of physical observations of devices being used on patients – being circumstantial – and recording of audio and transcriptions not being possible. Recorded data may be subject to selection bias and subconscious omission.

# DESIGN IMPLICATIONS

## **AN OVERVIEW.**

This section describes the application of the research's findings to future concepts, defining a set of design implications to guide the ongoing design process. Whilst these are summative of the formal initial research stage of this project, due to the ongoing and evolving nature of the design process it is expected that these design implications will evolve over time with the presence of concept feedback, prototyping, and further research.

The following design criteria describe the 5 various implications for concept development, whether in the domains of jaw movement diagnostics & assessment or trismus therapy.

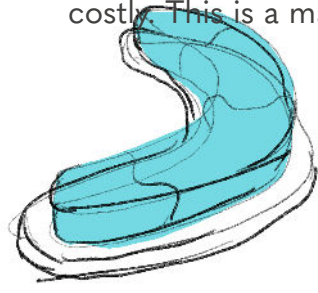
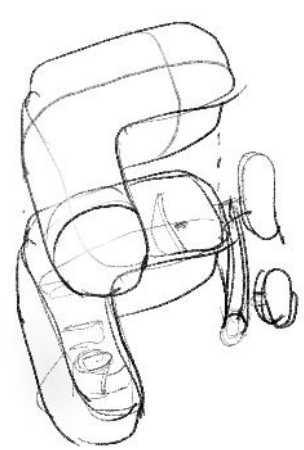
- 1** Keep Costs Down
- 2** All-Anatomies Inclusivity
- 3** Ease + Speed of Use
- 4** Ease of Cleaning + Servicing
- 5** Accurate-Enough Imaging Technologies

# 1

## KEEP COSTS DOWN.

For both purchase decision-makers in health services and patients at home paying out of their own pocket, it comes down to the bottom line when making purchasing decisions on medical equipment. To get buy-in from hospital management, value for money needs to be proven. As practical day-to-day measurement of mandibular movements is a current challenge, hospitals may wear higher costs, though as it isn't an urgent need it will be easy for them to prioritise other, more pressing purchases.

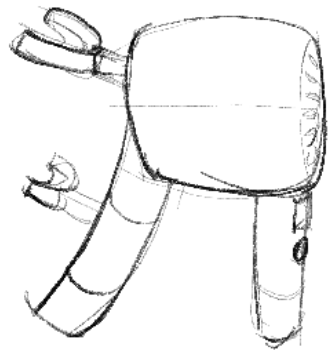
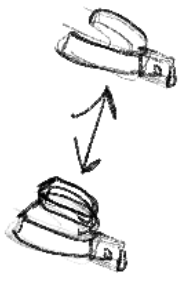
Regarding patients, as insurances don't cover these costs and it comes out of their back pocket, keeping costs as economical as possible is preferable to increase access. However, with the reduced demand for more sophisticated trismus therapy devices, achieving economy of scale will be difficult, and such devices may end up quite costly. This is a major design challenge.

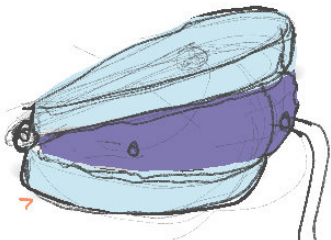


# 2

## ALL- ANATOMIES INCLUSIVITY.

From the research, it is seen to be imperative that any concepts are suitable for a wide range of oral anatomies, aiming for full inclusivity. This includes making provisions for patients that may be missing teeth, or parts of their maxilla or mandible. This could come in the form of customisable bite plates, modular parts to adjust the device for different biomechanics, mouldable bite pads, or extra-oral devices that act on the outside of the skin.

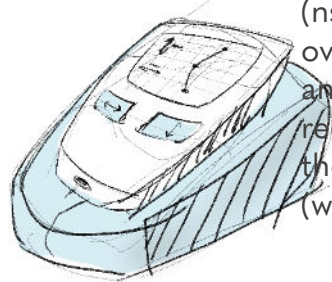
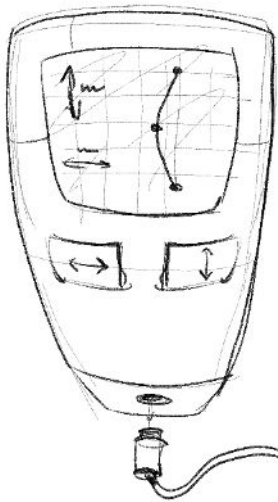




# 3

## EASE + SPEED OF USE.

To become a part of a clinician's daily practice, any medical device needs to be simple and quick to use. All clinicians are fighting for time in medical settings, and if a device is onerous with high amounts of setup time – and not a crucial part of the process – then they will opt for a faster “good enough” solution. This also applies to patients using therapy devices.



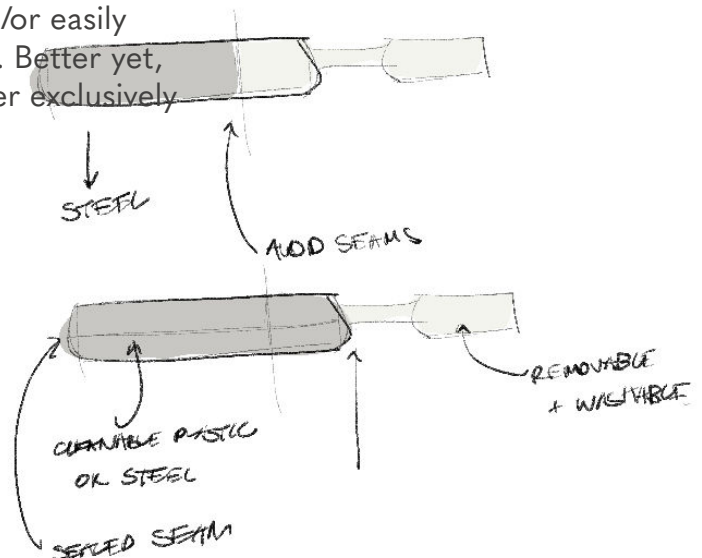
For devices aimed towards clinical assessment, this criterion may include data readout methods (instant user interface read-outs may be preferable over or in addition to a computer or app); power and charging requirements if needed be; set-up requirements, calibration; speed of technology; and the procedural requirements of the measurement (what movements the patient needs to do).



# 4

## EASE OF CLEANING + SERVICING.

Part of the ease of use as well as a general requirement for a medical device, is how easy it is to sterilise. This is particularly important as the device is involving the jaw and oral cavity, with many devices on the market – both scanning devices and therapy devices – working intraorally. The use of single-use components, modular attachments, and/or easily wipeable surfaces may be essential here. Better yet, solutions may be devised that work either exclusively or optionally outside of the oral cavity.



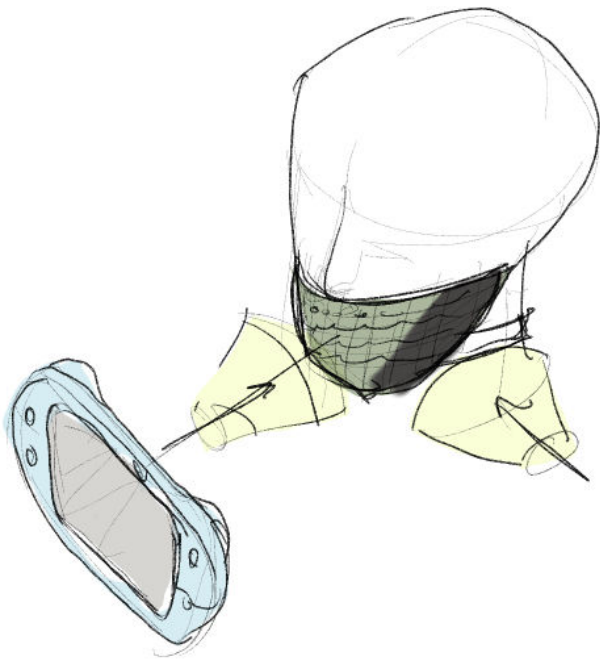
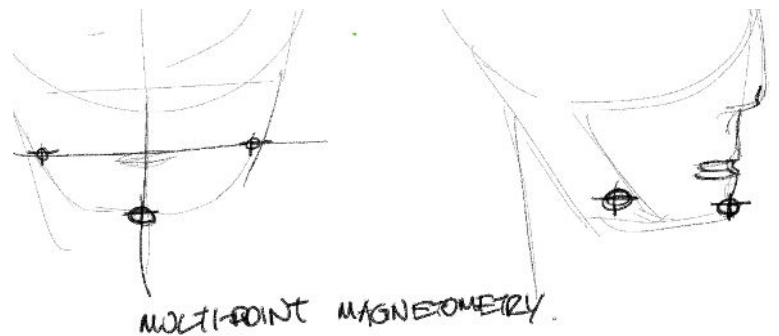


# 5

## ACCURATE-ENOUGH IMAGING TECHNOLOGIES.

The vast amount of imaging technologies available offer valuable insights into imaging possibilities, though the major challenge here is implementing a technology whilst also meeting the demands of the above domains of ease of use, and economic feasibility.

Here, the age-old tug of war exists between using a sophisticated and compact technology at an economically viable manufacturing cost. Fortunately, the need for measurements only accurate to a millimetre allows for the application of sophisticated measuring methods to lesser degrees of accuracy, or the use of less sophisticated technologies.



# CONCLUSION.

## **LOOKING BACK.**

The purpose of this research report is to inform future development of a product that can improve the quality of treatment patients of trismus and TMDs receive.

To do this, this report provided informed insights into the daily reality facing patients and their clinicians by means of a literature review, two in-depth semi-structured interviews with three maxillofacial surgeons from the RBWH, one in-depth semi-structured interview with a RBWH speech therapist, and two online surveys – one provided to rural and urban speech therapists and the other to previous and current patients of TMDs and trismus.

Preliminary secondary research for the literature review was conducted to gain a basis of understanding of the broader issues, before commencing interviews which in turn advised further in-depth secondary research before finalising the literature review.

From there, the synthesis of these findings was discussed before applying these discussion points to practical design implications to guide further concept iterations.

## **LOOKING FORWARD.**

These design implications will be used to guide ongoing concept ideations, and will be subject to evolve over time with greater knowledge, feedback from stakeholders, prototyping, and user testing.

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# APPENDICES

## APPENDIX A - 1st Maxillo-Facial Surgeon Semi-Structured Interview Guiding Questions

INTERVIEW STRUCTURE FOR CAPSTONE RESEARCH PROJECT 1 <sup>st</sup> Surgeon Interview
Development of the <b>MechaTrismus</b> – A Device for Use in the Therapy and Assessment of Trismus

### Questions & Structure

#### The Practitioner

##### In practice

- What are the common causes for Trismus that you encounter?
- What does the current common therapy practice involve in terms of medical intervention and physical therapies?
- Who conducts the therapy program?
- What is the functional relationship between surgeons and Speech Pathologists / Physiotherapists in treating for Trismus?
- Is jaw movement measured over time to track progress? How?

#### The Patient/User

- Where are physical therapy devices used?
- How are they used?
- Is there a fair amount of patient fear and anxiety in using these devices?
- What are current take-home practices?
- What are the main current limitations to the physical therapy of Trismus?

#### Anatomy

##### Forces

- What kinds of forces are involved in opening the jaw?
- Are you aware of resources or data on this?

##### Anthropometrics

- Are you aware of resources or data on oral anthropometric data?
- What outliers and atypical oral anatomies need to be considered?

##### Biomechanics

- Are you aware of resources or data on the movement pathways of the jaw?
- What movement pathways are affected by Trismus?
- How is patient jaw movement currently measured?

#### The Market

##### Existing Products

- Do you use or prescribe any existing products? Why / why not?
- What are limitations to these products, or other therapy methods?

##### Demand

- What is demand for another device like?
- Where can you see devices being used? SP clinics? Hospitals? At home?

##### General

- What is your vision for the future of managing and treating Trismus?

## APPENDIX B - 2nd Maxillo-Facial Surgeons Semi-Structured Interview Guiding Questions

INTERVIEW STRUCTURE FOR CAPSTONE RESEARCH PROJECT 2 <sup>nd</sup> Surgeon Interview
Development of the <b>MechaTrismus</b> – A Device for Use in the Therapy and Assessment of Trismus

### Questions & Structure

#### The Practitioner

##### In practice

- What are the common causes for Trismus that you encounter?
- What does the current common therapy practice involve in terms of medical intervention and physical therapies?
- What is the functional relationship between surgeons and Speech Pathologists / Physiotherapists in treating for Trismus?
- Is jaw movement measured over time to track progress? How? How important is this?
- Do you use the Therabite often? What do you like and don't like about it?

#### The Patient/User

- Where are which physical therapy devices used? At home, in hospital, in the clinic?
- How are they used in the hospital and at home?
- What are current take-home practices?
- What are the main current limitations to the physical therapy of Trismus?
- Which physical conditions can prevent these patients from doing the therapy?
- How does the patient know how much force to apply?
- Is there a fair amount of patient fear and anxiety in using these devices? How does this present itself?
- What is the process for patients using therapeutical equipment, either in the case of trismus or other conditions? Do they hire from the hospital? Do they buy from hospital or 3<sup>rd</sup> parties?

#### Oral Anatomy

##### Forces

- What are safe forces for opening the jaw?
  - Are you aware of resources or data on this?
- Are you aware of any methods/equipment to safely measure force applied to the jaw in trismus therapy?

##### Anthropometrics

- Are you aware of resources or data on oral anthropometric data? Data on mouth sizes and general oral movement measures?
- What common atypical oral anatomies do you encounter that may affect trismus therapy?

##### Biomechanics

- Are you aware of resources or data on the movement pathways of the jaw?
- What movement pathways are affected by Trismus? Both along the sagittal and coronal planes?
- How is patient jaw movement currently measured? Along both planes? How precise does this need to be?
- Would it be beneficial to improve this?

#### The Market

##### Existing Products

- Are there any other products you're aware of that you like aspects of?

##### Demand

- What is the demand for innovations in trismus therapy?
- Where can you see devices being used? SP clinics? Hospitals? At home?

##### General

- What is your vision for the future of managing and treating Trismus?
- Who makes the purchasing and usage decisions in the hospital?
- What is the hallmark of a successful medical product?
-

# APPENDIX C - Speech Therapist Semi-Structured Interview Guiding Questions

<p>INTERVIEW STRUCTURE FOR CAPSTONE RESEARCH PROJECT Interview with Speech Pathologists</p> <p><b>Development of the MechaTrismus – A Device for Use in the Therapy and Assessment of Trismus</b></p>
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**Questions & Structure**

Read the consent form points and get a verbal agreement. State that your statements will be audio recorded but that your personal details won't be shared

**The Practitioner**

**In practice**

- What are the common causes for Trismus that you encounter?
- Do you treat both acute and chronic trismus?
- What does the current common therapy practice involve in terms of medical intervention and physical therapies?
- Who conducts the therapy program? Who is in charge of following up the patient?
- What is the functional relationship between surgeons and speech pathologists in the patient's treatment?
- Is jaw movement measured over time to track progress? If so, how?
- In your opinion, is the treatment of trismus a domain that requires improvement?
- If so, what are the major challenges that you face in the process of trismus therapy?
- Do you have any experience with private therapy of trismus? If so, how does this differ from the treatment in the public system?
- If a patient's condition does not improve, what is the course of action?

**The Patient/User**

- Where are physical therapy devices used?
- How are they used?
- What are current take-home practices and regimes?
- What are the most important factors in treating trismus in patients?
- What are main limitations to patient's current therapy?
- What are the major inhibitors to patient compliance?
- Is it common for patients to have fear and anxiety in doing therapy?

**Anatomy**

**Forces**

- What kinds of forces are involved in opening the jaw?
- What do you instruct patients as per forces to apply to open the jaw?
- Are you aware of resources or data on this?

**Anthropometrics**

- Are you aware of resources or data on oral anthropometric data?
- What outliers and atypical oral anatomies have you encountered?
- What measures do you take to cater for atypical anatomies, whether variations in teeth, gums, maxilla or mandible

**Biomechanics**

- What movement pathways are affected by Trismus?
- Are you aware of resources or data on the movement pathways of the jaw?
- How is patient jaw movement currently measured? Is movement measured along multiple planes?

**The Market**

**Existing Products**

- Do you use or prescribe any existing products? Why / why not?
- What are limitations to these products, or other therapy methods?
- Are there any devices that you would like to use but don't have access to?
- Do you use the Therabite? What are your experiences with this product?

**Demand**

- What is the demand like for a trismus therapy device that can suit a wide range of oral anatomies?
- What is the demand like for a device that accurately measures to movement of the jaw and force required to move the jaw?

**General**

- What is your vision for the future of managing and treating Trismus?

# APPENDIX D - Notes from Interview with Speeth Therapist

MEETING WITH SARAH

24.08.23

RoL therapy → tightness + atrophy.  
↳ sometimes resolved.

Surgical → flexor  
muscle muscle used up → stretched.

HPV + ALL  
CANCEL.

- Not so well out. Love ... can be

- Some 1st time maintenance, others not so. (3-6 months? after management)  
↳ other maintenance

• Long term → Late onset radiation effects.  
↳ Certain types of cancer ... not always. Various depends on type of cancer.

• Some times Trismus → not after surgery.  
↳ tears some don't heal.

• Non-compliance → severity & motivation.

• HPV?

• Tongue depressors → Satisfying feedback on improvement.  
↳ 7 to 8!

• Similar to good pain + bad pain.  
↳ To point when you can just open past it.  
↳ To maintain the stretch.  
↳ Marked.

• LIFEHOUSE  
↳ SYDNEY DEVICE  
• PASSIVE + ACTIVE.



# APPENDIX D - Notes from Interview with Speeth Therapist (cont.)

## MEETING WITH SPEATH

24.08.23

- **ATYPICAL:**
  - NO FRONT TEETH → Guns.
  - Only teeth on outside →
  - Maxilla functional only → Teeth/Guns
  - Talk/Teeth →
  - Gun/Gun. →
  - Opposing forces @ front. →
- **MEASUREMENT** → Flex card → NO teeth = bad.
  - Improving by "hum" \*
  - Tooth to tooth = good.
  - if not =
  - Sp + rd.
- **PHIWHITE** → Vglz Perkins
  - Not huge demand - old.
  - Sales → longer print demand.
  - Sing coast kind Red things.
- **Follow some protocols**
  - 30 mg to 30 ms → 3-5x a day \*
  - Go in + at diff clinics → need for resolution

**EXACT CUSTOMER**

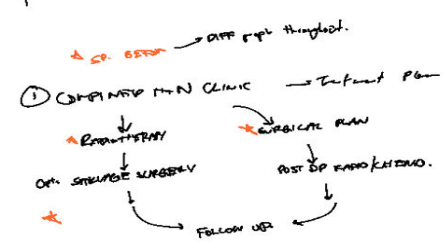
- Cost to visit \$3

**\*REXT**

- ALL OUT OF POCKET.
- HOSPITAL PACKAGE

**LEARNING**

- ↳ Can devices
- ↳ Place references → \*
- ↳ Somewhere + collect/8 sign up



# APPENDIX E - Notes from Interview with 2 Maxillofacial Surgeons

<p>INTERVIEW STRUCTURE FOR CAPSTONE RESEARCH PROJECT 2nd Surgeon Interview</p> <p>Development of the <u>MechaTrismus</u> - A Device for Use in the Therapy and Assessment of Trismus</p>
--

### Questions & Structure

#### The Practitioner

##### In practice

- What are the common causes for Trismus that you encounter?
  - o Cancer-related + surgical
- What does the current common therapy practice involve in terms of medical intervention and physical therapies?
  - o Surgery, depressors, fingers
- What is the functional relationship between surgeons and Speech Pathologists / Physiotherapists in treating for Trismus?
  - o Refer to Speech Paths & Occupational Therapists, Speechies
- Is jaw movement measured over time to track progress? How? How important is this?
- Do you use the Therabite often? What do you like and don't like about it?
  - o No they don't
  - o Too expensive
  - o The arc is wrong for some - doesn't suit some class 2 and class 3 bites
  - o No ability to change bite plates

#### The Patient/User

- Where are which physical therapy devices used? At home, in hospital, in the clinic?
- How are they used in the hospital and at home?
- What are current take-home practices?
- What are the main current limitations to the physical therapy of Trismus?
  - o High price, getting patients to actually do their therapy
  - o Don't comply due to reasons listed further below
  - o Compliance:
    - Depressors seem worthless, lose them, unsanitary, fear of splintering/actual breakage
    - Too hard and onerous
    - Either goes too hard or not hard enough
  - o Having a device which is easy to use and also easy to designate exactly what force is applied would reel back those that go too hard (at risk of damage), and make it easier for those that have fear, don't try as it is too onerous, or are fearful to go harder
    - A set force to use would be easier. Ideal if you can "set the device and go!"
- Which physical conditions can prevent these patients from doing the therapy?
  - o Elderly or cancer patients with low strength
    - Hydraulics/Air/Mechanics would be great for them!
    - Look to Medela Breast Pumps - Sleek, clean, home and hospital version with interchangeable parts
- How does the patient know how much force to apply?
  - o They go by pain
  - o Or limitation of movement due to bone structure, impingements, growths
- Is there a fair amount of patient fear and anxiety in using these devices? How does this present itself?
  - o Gagging due to the texture and taste of the timber depressors
  - o Large devices that are quite intrusive and intimidating
- What is the process for patients using therapeutical equipment, either in the case of trismus or other conditions? Do they hire from the hospital? Do they buy from hospital or 3rd parties?
  - o NEED TO VERIFY THIS! - I believe they buy externally

# APPENDIX E - Notes from Interview with 2 Maxillofacial Surgeons (cont.)

## The Market

### Existing Products

- Are there any other products you're aware of that you like aspects of?
  - Sydney product
    - Positives:** Cheap, can change the force and the force has been quantified, passively stretches the jaw
    - Negatives:** Incorrect movement arc, no customisable bite plates and only pushes on a few teeth

### Demand

- What is the demand for innovations in trismus therapy?
  - Significant demand, but best for device to be suitable for more issues (TMDs)
    - Do other issues require therapy? Research
  - With TMDs, measurement would be very **handy**
- Where can you see devices being used? SP clinics? Hospitals? At home?
  - All

### General

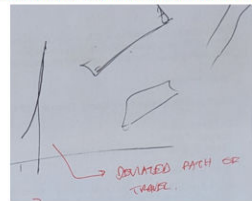
- What is your vision for the future of managing and treating Trismus?
- Who makes the purchasing and usage decisions in the hospital?
  - The Department Head, then the Director of Medicine, then the CEO
- What is the hallmark of a successful medical product?
  - Wide acceptance
  - Minimal competition
  - Cheap to purchase for both hospital and patients
  - Easy to manufacture, service, replace parts
  - Easy to clean (cleaning can be done by wipes)
    - Eg:** Nasal Endoscopes used to be very onerous to sterilise, now company has developed a series of wipes to clean them on site without taking to cleaning department – this is now done by junior doctors on site

### OTHER NOTES:

- A measuring device could identify changes in movement patterns and point towards conditions and **abnormalities**
  - It could also build up a database on conditions, symptoms, improvement after particular therapies, and mandibular movement **anthropometrics**
- There are no easy-to-use measuring devices out there to measure mandibular **movement**
  - Though there are a few devices in **research**
- Arcs of travel differ with each person, and in no devices can you modify/customise this arc of travel
  - Class 1, 2, 3 have different bite anatomies and thus arcs



- Different sized mouths have diff arcs – some shorter, some **steeper**
- Potentially we could measure and print custom arcs?
- Potentially there are 3 different-sized arc movement guides that are sent out to suit different anatomies?
- Sometimes paths of travel laterally also differ **substantially**



- Example of a TMD regarding a longer-than-normal coronoid process

# APPENDIX F - Notes from Interview with First Maxillofacial Surgeon

## INTERVIEW NOTES

ALITARIQ - MAX-FAC SURGEON

22.08.23

### The Practitioner

#### In practice

- What are the common causes for Trismus that you encounter?
- What does the current common therapy practice involve in terms of medical intervention and physical therapies?
- Who conducts the therapy program?
- What is the functional relationship between surgeons and Speech Pathologists / Physiotherapists in treating for Trismus?
- Is jaw movement measured over time to track progress? How?

**RARELY MEASURED.**

ASKS TO DO EXERCISES FOR 3 WEEKS THEN SEE IF POSSIBLE.

- OFTEN DOESN'T MEASURE, JUST USES 3 FINGERS + FING. WIDTH TO MEASURE.

POST SURGERY / MOSTLY ACUTE  
STROKE / TRAUMA.

- FINGERS + THUMB
- SYRINGE + DEPRESSORS
- DOESN'T LIKE JUST DEPRESSORS.
- THERABITE.

SURGEONS, RARELY REFERRED BUT SHOULD BE

### The Patient/User

- Where are physical therapy devices used?
- How are they used?
- Is there a fair amount of patient fear and anxiety in using these devices?
- What are current take-home practices?
- What are the main current limitations to the physical therapy of Trismus?

↓ A → ABOVE, NO FOLLOW UP, NO THERABITES TO TAKE HOME + NO FOLLOW UP.

- ALL PERCEIVED EFFORT + PAIN.

NEED TO ASK → WHO MEASURES → USER

- PRICE
- MOTIVATION
- EASE OF ACCESS
- EASE + ABILITY OF MEASURING.

NO, BUT LACK OF MOTIVATION MEANS SOME DON'T DO ANYTHING.

SOME MAY NEED SOMETHING TO GIVE MORE INSTRUCTION / GUIDANCE

DECISIONS?

DO YOU USE OFTEN OR NOT?



# APPENDIX F - Notes from Interview with First Maxillofacial Surgeon (cont.)

## INTERVIEW NOTES

22-08-23

### TARIG ALI - MAX-FAX SURGEON

#### Anatomy

##### Forces

- What kinds of forces are involved in opening the jaw? **X**
- Are you aware of resources or data on this? **X**

UNKNOWN, PERCEIVED MIN/EXERTION.  
NO.

##### Anthropometrics

- Are you aware of resources or data on oral anthropometric data? **X**
- What outliers and atypical oral anatomies need to be considered? **X**

NO. POSSELT'S ENVELOPE = STANDARD.

##### Biomechanics

- Are you aware of resources or data on the movement pathways of the jaw? **X**
- What movement pathways are affected by Trismus? **X**
- How is patient jaw movement currently measured? **X**

MISSING TEETH  
THERAPY USUALLY ISNT CONSIDERED FOR MAJOR SURGERY PATIENTS.

ALL MOVEMENTS BUT HARD TO MEASURE FRONT/BACK + LATERAL MOVEMENT.

BY USING MEASUREMENT CARDS/RULERS.

FINGER-WIDTH!

#### The Market

##### Existing Products

- Do you use or prescribe any existing products? Why / why not? **X**
- What are limitations to these products, or other therapy methods? **X**

AS BEFORE.

- CHEAP.
- ACCESSIBLE
- EASY.

##### Demand

- What is demand for another device like? **X**
- Where can you see devices being used? SP clinics? Hospitals? At home? **X**

NEED FOR SOMETHING CHEAPER W/ CONSISTENCY.

- LACK OF MEASUREMENTS.
- LACK OF CONSISTENCY
- MANUAL OPERATION.

HOME, HOSPITALS.

- INCORRECT JAW MOTION + FORCE ON TEETH

##### General

- What is your vision for the future of managing and treating Trismus? **X**

NO ANSWER/TIME.

- SIMPLE + MINIM
- EASY MEASUREMENTS

MAYBE PRIVATE HOSPITALS WILL PRESCRIBE THERAPIES AND/OR

## QUICK NOTES.

22-08-23

### MEETING W/ ALI-TARIG

#### IDEAS

- DEVICE THAT MEASURES FULL MOVEMENT.

- REPLACES THERABYTE CARDS.
- AUTOCLEANABLE

- SIMILAR TO CALIPERS/FORCEPS.

- CLEANABLE BUT MEASURES FULL MOVEMENT.
- QUICK TO USE.

- APP THAT TRACKS MOVEMENT THROUGH SPATIAL FACIAL TRACKING.

- CURRENT DEVICE

MONTH UNIT + MOTION GUIDE CUSTOMISED FOR EACH ORAL ANATOMY.

MANUAL ACTION AT HOME → THERAPY  
DIGITAL SIDE AT HOSPITAL → DIAGNOSTICS

→ IDEAS AS NEXT ISSUE.

#### OTHER IDEAS

- TRACKING SURGERY SPOTLIGHTS
- CORDLESS RULERS + EQUIPMENT.

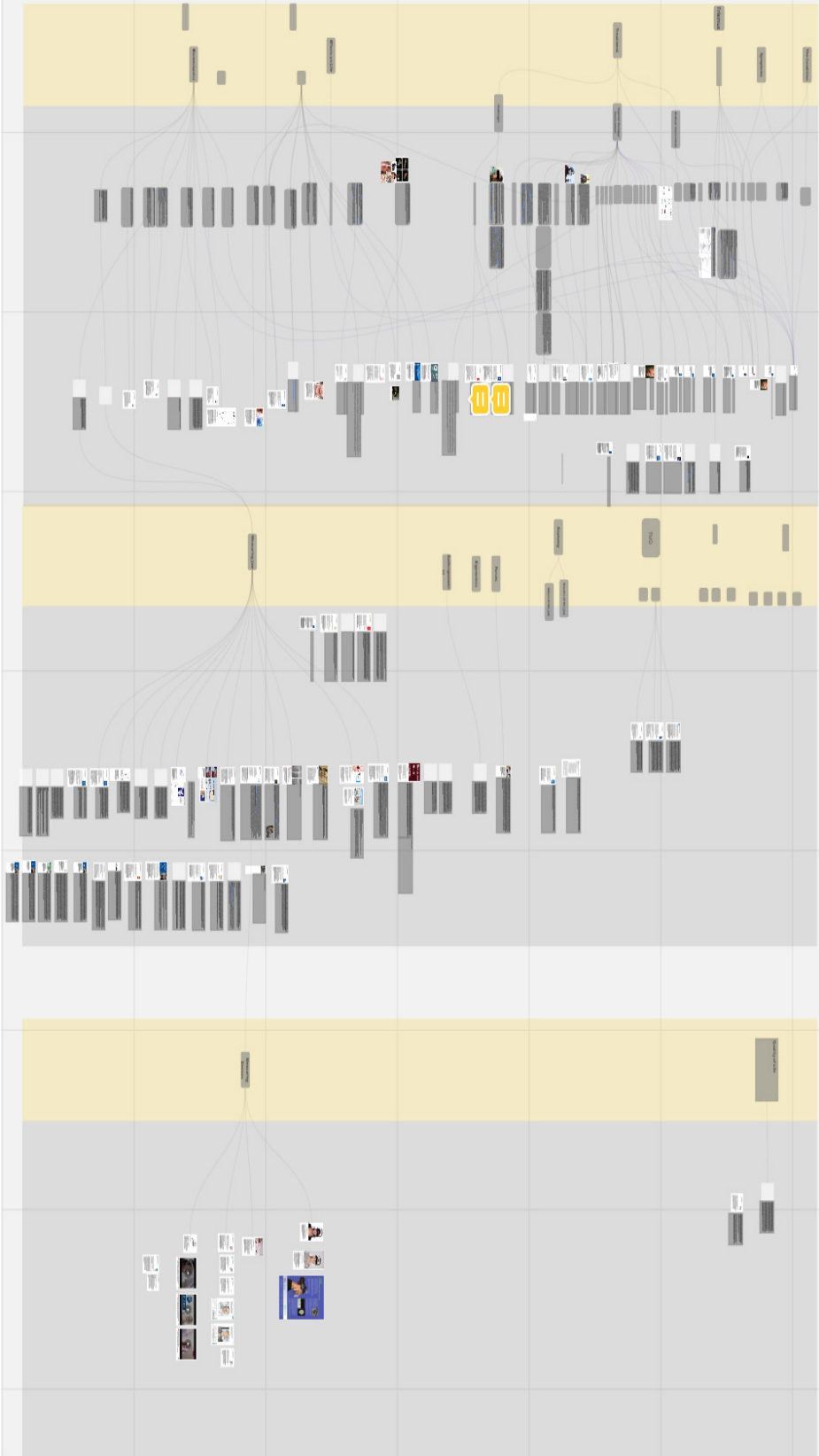
- PREFERS



+ MOTORS OVER THE TOP. THERABYTE RIP OFF IS TOO MUCH.

# APPENDIX G - Miro Recording + Mapping of Secondary Research

(Can be supplied on request)



# APPENDIX H - Tabulation of Notes from Interview with First Maxillofacial Surgeon

Expanded notes: Interview 1 - One MaxFac Surgeon							Qty	% of All
Market and Business Considerations	Patient compliance	Price Need for cheaper therapy devices	Intrinsic motivation	ease of access	lack of instruction and guidance		4	13%
Market and Business Considerations	Price	Home & hospitals could be markets for therapy devices	prescribe more higher-priced devices				1	3%
Market and Business Considerations	Demand/Market	Rarely refers patients to speech therapists but feels like should be standard practice,	Exercises for 3 weeks, if no improvements come back	Therapy often isn't considered for major surgery patients as they have greater issues			2	6%
Medical/Healthcare	Therapy	Fingers + thumbs, therabite rarely if ever used	syringe + depressors	doesn't like just using depressors	Devices lack measurements		3	9%
Medical/Healthcare	Devices	Some patients are missing all or some teeth	Devices often are the incorrect for different jaw motions and put undue force on teeth				4	13%
Medical/Healthcare	Anatomical Variations	Post-surgery	shock/trauma	mostly acute			2	6%
Medical/Healthcare	Trismus causes	Opening distance rarely measure	Often just uses 3 finger-widths as objective	All jaw movements are affected by trismus but front/back and lateral movement is hard to measure with current methods	All measuring is done with rulers, therabite ruler cards, or finger-widths	Measurements must be easy to perform	6	19%
Product Features/Characteristics	Measuring	Devices require manual operation	Devices must be simple and minimal				2	6%
Product Features/Characteristics	Ease of use	Devices have a lack of consistency	Use perceived effort + pain as a goal	Need for consistent device	No resistance measured		4	13%
Product Features/Characteristics	Force	Devices must be easy to clean or even autoclavable					0	0%
Product Features/Characteristics	Ease of maintenance						1	3%
Product Features/Characteristics	Ease of cleaning						32	
							32	

# APPENDIX I - Tabulation of Notes from Second Interview with Two Maxillofacial Surgeons

Expanded notes: Interview 2 - Two MaxFac Surgeons							Qty	% of All
Market and Business Considerations	Price	Devices are too high priced	Successful products must be low price both for hospitals and patients				2	5%
Market and Business Considerations	Demand/Market	Significant demands for innovations in trismus therapy	Best for a device to be suitable for more issues like TMDs	With TMDs, a measurement device would be very handy	Tongue depressors seem worthless, easily lost, unsanitary, fear of breakage	Director of Medicine, and CEOs make purchasing decisions on various equipment	4	10%
Market and Business Considerations	Patient compliance	High cost	Getting patients motivated				6	15%
Medical/Healthcare	Therapy	Surgery as a therapy	Often refers to STG, Otr				2	5%
Medical/Healthcare	Devices	Using fingers	Tongue depressors	Doesn't often use therabite due to cost and unsuitability for some patients' jaw movements	Tongue depressors seem worthless, easily lost, unsanitary, fear of breakage	Gagging due to texture and taste of wood depressors	5	13%
Medical/Healthcare	Anatomical Variations	Therabite isn't suitable some jaw opening arcs	Therabite also doesn't suit some class 2 and class 3 bites	Current devices don't have ability to change bite planes	Would be great if devices could cater for not only all oral anatomies but also all oral biomechanical variations	Sydney device is cheap, and force-adjustable, but doesn't cater for anatomical variants, moves in the incorrect arc, and pushes only on a few teeth	6	15%
Medical/Healthcare	Trismus causes	Cancer-related	Surgical cases			One example of another TMD issue is the surgery of someone with a longer-than-normal osseous process which is out back	2	5%
Product Features/Characteristics	Measuring	Both movement pathways are affected but only focus on vertical movement to increase MID for trismus	In TMDs, they take into account lateral movement	Currently measured with ruler/calipers or therabite ruler cards commonly - these are all imprecise and subjective especially along the lateral direction	They require accuracy to the millimetre level - not overly precise	An accessible device that can easily record and map out jaw movement would be an amazing tool for assessing all sorts of jaw conditions	6	15%
Product Features/Characteristics	Ease of use	A device that is easy to use will encourage patients to take more charge of their therapy	Elderly patients or cancer patients with low strength struggle with therapies	A hydraulic/pneumatic/mechanical device would be great for patients with low strength	SON considered maximal force for their masticator devices	Unaware of other measuring devices but suspect there are others	2	5%
Product Features/Characteristics	Force	The ability for clinicians to set the force at the practice would be best				able to advise speech paths on what force suitable for each patient given their unique condition	5	13%
Product Features/Characteristics	Ease of maintenance	Devices must be easy to clean - preferably done simply with wipes					1	3%
Product Features/Characteristics	Ease of cleaning						1	3%
							TOTAL	% of All
							40	

# APPENDIX J - Tabulation of Notes from Interview with First Maxillofacial Surgeon

Market and Business Considerations		Expanded notes: Interview 3 - Speech Therapist								0	0%
Market and Business Considerations	Price	Not a huge private demand for speech therapists in Qld. In NSW & Vic there is larger demand	Hospitals do not loan out therapy equipment commonly, all comes out of patient's pocket							2	10%
Market and Business Considerations	Demand/Market	With increased symptom severity, patients are more motivated to do therapy								1	5%
Market and Business Considerations	Patient compliance									1	5%
Medical/Healthcare	Therapy	Sometimes people require lifetime maintenance, ophthrs between 3 and 6 months	Others it's more management, and then maintenance of their new ability	Current therapy is to stretch the jaw to a the border of good and bad pain, then insert enough depressors until your mouth is a bit less open than its maximum	Current therapy of 30 reps x 30 seconds holding the mouth open with tongue depressors	Different STs will be seeing the patient over their journey	They often first see the patient post-operatively to assess condition and advise on therapy			6	30%
Medical/Healthcare	Devices	Sometimes use therabites, but patients don't buy often	Has been years since has used a therabite	Likes the aspect of tongue depressors where each tongue depressor is a different stage	Likes the Lifehouse Sydney device as it is actively stretches the jaw					4	20%
Medical/Healthcare	Anatomical Variants	Some patients have no front teeth - just gums there - but they have molars								1	5%
Medical/Healthcare	Trismus causes	Radiotherapy typically which leads to tightening and atrophy - sometimes one-sided and at times it onsets later, months down the track	Sometimes after free flap surgery masseter muscles seize up and the issue is more structural							2	10%
Product Features/Characteristics	Measuring	MJO measurements are made between functional opening area which is used for chewing, whether teeth-teeth, teeth-gums, or gums-gums	Therabite cards and rulers are hard to use when patients are lacking teeth - tooth to tooth is much easier	With long-term patients and when going to other clinics, it's important for consistent measurements to gauge overall progress	Looking for millimetre improvements					4	20%
Product Features/Characteristics	Ease of use									0	0%
Product Features/Characteristics	Force									0	0%
Product Features/Characteristics	Ease of maintenance									0	0%
Product Features/Characteristics	Ease of cleaning									0	0%
<b>TOTAL</b>										<b>20</b>	<b>% of All</b>

# APPENDIX K - Results from Codified Data

Categories	Codes	Occurrences	% Occurance	% of Category
Market and Business Considerations	Price	6	6%	27%
Market and Business Considerations		7	7%	32%
Market and Business Considerations	Patient compliance	9	10%	41%
Medical/Healthcare	Therapy	11	12%	28%
Medical/Healthcare	Devices	13	14%	33%
Medical/Healthcare	Anatomical Variants	9	10%	23%
Medical/Healthcare	Trismus causes	7	7%	18%
Product Features/Characteristics	Measuring	16	17%	50%
Product Features/Characteristics	Ease of use	4	4%	13%
Product Features/Characteristics	Force	9	10%	28%
Product Features/Characteristics	Ease of maintenance	1	1%	3%
Product Features/Characteristics	Ease of cleaning	2	2%	6%
		<b>94</b>		

Column1	% of All	Occurrences
<b>Product Features/Characteristics</b>	34%	32
<b>Market and Business Considerations</b>	23%	22
<b>Medical/Healthcare</b>	43%	40
	<b>100%</b>	<b>94</b>