DETERMINING THE RELATIONSHIP BETWEEN HARD AND SOFT TISSUE MOVEMENTS IN ORTHOGNATHIC SURGERY PATIENTS USING MULTIPLE IMAGING MODALITIES

by

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This is dedicated to my loving wife Erin and two amazing children, Ethan and Audrey. Both kids were born during this research, and without the support of my wife, none of this would have been possible. I love all of you more than I can put into words.

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Abstract

Orthognathic surgery encompasses various surgical procedures used for the correction of dentofacial deformities from malocclusions, prognathism, retrognathism, obstructive sleep apnea, to TMJ disorders and others. While the primary objective of orthognathic surgery is to optimize the occlusion and improve overall masticatory function, enhancement of the facial aesthetics is also an outcome of concern. However, tissue manipulation can result in unpredictable and sometimes, unfavorable outcomes. Thus, it is important to understand the impact hard tissue movement has on the soft tissue.

Purpose: The primary outcome of this study was to determine the hard to soft tissue ratio following orthognathic surgery. Secondary outcomes focused on evaluating changes in soft tissue.

Methods: Pre and post-operative cone beam computed tomography (CBCT) scans were taken prior to surgery and between 2 and 4 weeks post-operatively. 3D Photos were captured pre-operatively and at 3-months, 6-months and 12-months post-operatively. Image analysis was done using Dolphin® software. Three separate analysis were done: the magnitude of bony movement (HT), comparing hard to soft tissue movement (HT: ST), and changes in soft tissues (ST). The primary and secondary outcomes were then evaluated using these analyses stratified by time, sex, procedure type, age and BMI. Both a Wilcoxon signed-rank test and a regression model fit were used to evaluate the data. All patients planned for orthognathic surgery at Dalhousie University were screened and enrolled if they met the inclusion criteria.

Results: 12 total patients completed the 12-month follow up, 19 patients completed the 6-month follow up and 44 patients completed the 3-month follow up. There were 3 treatment groups: LF, BSSO and LF BSSO. There was no statistically significant change in the HT: ST ratio at 12-months post-operatively. There was a trend in the data that showed maximal increase in the HT: ST ratio at 6 months (1: 1.53, n=19, p=0.38), however it was not statistically significant. The nasolabial angle showed the greatest change with maxillary surgery (2.56mm, n=7, p=0.03) and in males (1.45mm, n=17, p=0.04). The mentolabial angle changed more in patients in the BSSO treatment group (5.08mm, n=11, p=0.03). The alar width increased after surgery (2.58mm, n=14, p=0.001), with the greatest changes in the LF treatment group (1.77mm, n=14, p=0.06). There were no significant differences seen in the mouth width, height of philtrum, and upper and lower lip thicknesses.

Conclusion: The hard to soft tissue ratio does not change significantly 12-months post-surgery. Minor soft tissue changes were seen at the level of the nasolabial angle, mentolabial angle and the alar width. The patient attrition rate was significant in this study, and the study findings should be interpreted accordingly.

List of Abbreviations

Abbreviation	**Description**
ANS	Anterior nasal spine
BMI	Body mass index
BSSO	Bilateral sagittal split osteotomy
HTST	Hard to soft tissue
HT	Hard tissue
IAN	Inferior alveolar nerve
LF	LeFort
ML	Mentolabial
NL	Nasolabial
OSA	Obstructive sleep apnea
ST	Soft tissue
TMJ	Temporomandibular joint
VSP	Virtual surgical planning

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CHAPTER I: INTRODUCTION

Subchapter I: Orthognathic surgery, a historical account and current applications

As a procedure dating back to 3000 BC, surgery was first used as a spiritual practice to rid the body of spirits by placing a small hole into the skull. Although this method was eventually abandoned, surgical techniques and procedures evolved from this common ancestor into what we know today as modern surgery. With the discovery of anesthetic and antiseptic drugs, what was once a daunting and horror filled experience, surgery has evolved into a tolerable and rather medically important constellations of procedures. From cesarean sections to craniotomies, over the last few decades, surgery has become one of the most fascinating and complex medical fields that has impacted the lives of countless patients. Today, there are numerous surgical specialties and subspecialties ranging from general surgery to oral and maxillofacial surgery.

History of orthognathic surgery

The beginnings of orthognathic surgery can be traced back to the times of Hippocrates and Aristotle who were first to document various dental and jaw-related procedures including wire fixation of loose teeth, treatment of gum disease and management of mandibular fractures[1]. It is from their native Greek language that orthognathic surgery gets its name, with *ortho* meaning “to straighten” and *gnathos* meaning “jaw”; thus, defining orthognathic surgery as a procedure used to straighten the misaligned jaw[2]. Despite the early evidence for operations resembling what we now refer to as orthognathic surgery, the first dedicated osteotomy designed for the correction of a dentofacial deformity was performed by an American surgeon, Simon P. Hullihen who pioneered the field of orthognathic surgery in 1849[3,4].

Since its inception, orthognathic surgery has gone through various modifications and improvements, most of which have led to the expansion of the technical repertoire of oral surgeons. The first modification came in 1907 from the father of modern orthodontics, Edward Angle and a general surgeon by the name of Vilray Blair. Together, Angle and Blair described the first horizontal osteotomy of the ramus[5,6]. The successful completion of this operation paved the way to his seminal article published in that same year, detailing a series of methods used to correct facial deformities[6]. His work was also captured in one of the first textbooks on oral and facial surgery written in 1912[7]. Blair's ingenuity and technique proved to be effective as attested by Max Ballin in 1908, who used the same surgical approach for the treatment of mandibular prognathism[8]. However, despite the initial success of these surgeries, complications arose, particularly in the context of surgical relapse. Over the next 3 decades, surgeons proposed various improvements to conventional orthognathic surgery across Europe and the United States, but it wasn't until the 1950s that the field of oral and maxillofacial surgery experienced a paradigm shift in its surgical offerings[9]. In 1955, Richard Trauner made significant contributions to the refinement of new orthognathic surgical procedures. His contributions were not limited to the confines of the operating room, but extended far beyond the hospital walls having a profound impact of how oral and maxillofacial surgeons practice today[9]. Having trained Heinz Kole and Hugo Obwegeser, two notable figures in the history and evolution of orthognathic surgery, Trauner is often credited for igniting a worldwide interest in orthognathic surgery. His once pupil and eventual successor, Heinz Kole went on to describe the first bimaxillary surgical procedure for the treatment of bimaxillary protrusion, an operation that was published in the first textbook on surgical orthodontics in 1964[10]. In addition, he also developed a new surgical technique to advance the chin, now commonly known as a genioplasty[11]. Alongside his student, Obwegeser, Trauner provided the first comprehensive description of the bilateral sagittal split osteotomy (BSSO) in 1955, a procedure which is still used today for the correction of mandibular dentofacial deformities and for the restoration of facial aesthetics[11,12]. Furthermore, Obwegeser continued to push the boundaries of what surgeons could offer patients with dentofacial deformities by developing a series of LFI osteotomies in 1969[13]. Much like the BSSO procedure described by Kole, the LFI osteotomy is still used today as a gold standard for the correction of malocclusions as well as being instrumental in cleft lip and palate and other dentofacial procedures[14].

Obwegeser was also the first surgeon who performed a simultaneous BSSO and LFI osteotomy in the same operation and by the 1970s, oral surgeons were performing “triple-jaw surgeries” involving the simultaneous mobilization of the maxilla, mandible and chin. Since the beginning of the twenty first century, oral and maxillofacial surgery has seen a significant increase in surgical options and techniques available to patients and has gained respect from the medical community, all of which have contributed to better patient care and outcomes. The surgical expertise of oral and maxillofacial surgeons can be used to treat patients who require dentoalveolar surgery, facial reconstructive surgery, dental anesthesia, management of cleft lip and palate, obstructive sleep apnea, the diagnosis and treatment of TMJ disorders and much, much more[15].

History of the Bilateral Sagittal Split Osteotomy

The BSSO is a type of surgery used for the correction of mandibular dentofacial deformities including mandibular excess, mandibular asymmetry and mandibular retrognathism[16]. The BSSO is currently considered the gold standard for mandibular surgery and is often referred to as the defining surgical procedure for oral and maxillofacial surgery. Since its introduction in 1955, the BSSO was subject to many modifications with varying degrees of success[17]. The first major improvement was accomplished by Dal Pont in 1961, shortly after the conception of the BSSO[18]. Initially, the BSSO involved an intraoral approach where two horizontal osteotomies were made on the lingual and buccal aspects of the mandibular ramus at a distance of approximately 25mm within one another[11,12]. The osteotomies were then connected at the level of the external oblique ridge; thus, separating the body of the ramus into a proximal and distal segment in a sagittal fashion. This technique allowed for the preservation of the inferior alveolar neurovascular bundle due to the gap formed in between the proximal and distal mandibular segments and the sliding action used to achieve bony movement. Maintaining the IAN intact was one of many challenges faced by oral surgeons when designing this mandibular osteotomy, and the evolution that led to its development. Dal Pont's modification consisted of further extending the lateral bone cut towards the distal aspect of the mandibular second molar[18]. Subsequent modifications were made by Hunsuck, Bell and Schendel, all of which aimed to decrease the possibility of nerve injury, unfavorable splits and relapse[19,20]. Currently, the BSSO technique involves making an intraoral incision spanning the external oblique ridge of the mandible and the anterior border of the ramus followed by the dissection of the mucosa from the anterior aspect of the ascending ramus[16]. The first osteotomy is achieved by placing the surgical saw or bur on the medial aspect of the ascending ramus, just superior to the lingula and parallel to the occlusal plane[16]. Once the cut has been made through the cancellous bone one half the mediolateral width of the ascending ramus, the osteotomy is continued anteriorly along the external oblique ridge until the level of the second molar along the course, and at the eventual termination of the external oblique ridge[16]. A final vertical osteotomy is placed along the buccal aspect of the mandibular body at the level of the second molar[16]. This cut is extended through the inferior border of the mandible and lingual cortex, aiming at the anteroposterior landmark of the termination of the external oblique ridge[16]. Upon completion of the osteotomies, the mandible is split while maintaining the integrity of the IAN, and placed in the desired position, often with the aid of an occlusal splint. The segments are then fixated with various forms of osteosynthesis.

History of the LeFort I Osteotomy

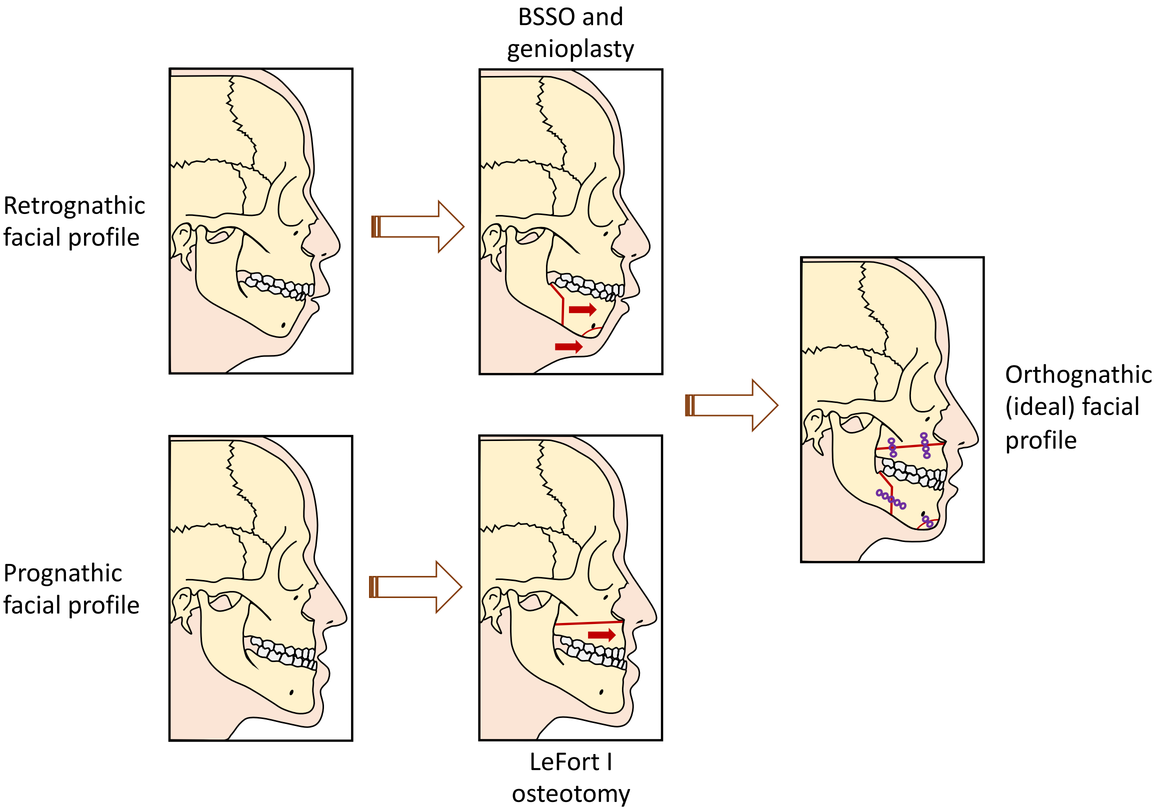
The LFI osteotomy is a surgical procedure aimed to correct maxillary dentofacial deformities including facial asymmetries, vertical maxillary excess and a retro-positioned maxilla which often result in the development of obstructive sleep apnea and various other presentations of Class II and III malocclusions. It is generally regarded as a effective and reliable intervention for such surgical corrections. This procedure takes its name from Rene LeFort who originally described three fracture patterns in his 1901 publication. A similar operation was initially performed in 1864 by David Williams Cheever for the removal of a nasopharyngeal tumor and later modified by Herman Wassmund in 1921[21,22]. However, it was not until 1969 that LFI osteotomies became a more widely accepted surgical procedure used to perform conventional maxillary surgery[23].

Nasotracheal intubation is a necessity when preforming LF1 osteotomy, as it is in all orthognathic surgery as the ability to control the occlusion remains the surgeons top priority[14]. An incision is made in the mucosa, leaving behind an adequate cuff of mobile gingiva which is later used to ensure proper closure of the surgical incision.[14] The incision is carried down to the level of the bone extending from first molar to first molar followed by a dissection that extends superiorly at the nasomaxillary buttress and laterally to the zygomatic buttress at the level of the pterygomaxillary junction[14]. The pterygomaxillary fissure is then dissected, completing dissection of the maxilla in its entirety. Once the maxilla is fully dissected, the LF1 osteotomy begins at the zygomatic buttress and continues medially to the ipsilateral piriform aperature[14]. The same osteotomy is repeated on the contralateral side, completing the LF1 laterally. A midline osteotomy through the bony and cartilaginous nasal septum must complete the osteotomy fully to allow for mobilization of the maxilla. This is often done with the use of a U-shaped osteotome[14]. This is followed by the down fracture of the maxilla and the separation of the posterior maxilla from the pterygoid plates[14]. The down fracture of the maxilla can be achieved in different ways: by using digital pressure, specialized spreaders or by means of dis-impaction forceps. This ultimately results in a maxilla free from the base of the skull that can be mobilized and fixated with plates and screws in the appropriate pre-planned position[14].

History of the Genioplasty

Genioplasty, or chin augmentation, is an orthognathic procedure used to enhance facial aesthetics and to restore the balance of one's face as it has no bearing on the patients final occlusion[24]. Depending on the position of the chin, a person can be perceived as weak, youthful, masculine, older or assertive, amongst other things. This why the chin is often referred to as "the basis for judging human character"[24–26]. Despite the primary focus on appearance and facial contour, the surgical manipulation of the chin can also be used to treat medical conditions such as obstructive sleep apnea[27,28]. Similar to the BSSO and LFI osteotomies described earlier, the art of genioplasty was pioneered by Dr. Obwegeser who, in 1957 performed the first osseous genioplasty using an intraoral approach on a live patient[11]. His technique continues to be used today in operating rooms worldwide. The surgery begins with an incision made inside the lower lip and the division of the mentalis muscles to expose the anterior aspect of the mandibular symphysis[29]. The midline and paramedian levels of the mandible are then marked with a surgical saw or bur[29]. Before initiating the osteotomy, care is taken to maintain a distance of at least 5 mm below the mental foramen in order to not violate the mental nerve[29]. It is useful to mark the area of the desire osteotomy before using the saw. The osteomized distal segment is then mobilized and repositioned, keeping its muscular attachments and periosteum inferior and lingual intact, in its desired post-surgical location[29]. Examples of these procedures and osteosynthesis using plates and screws can be seen in Figure 1 below:

Figure 1: **Illustration of different facial profiles and associated surgical procedures used to correct dentofacial deformities and achieve an ideal orthognathic profile.**



Intraoperative complications

Despite the numerous modifications and advancements made to further the safety and predictability of orthognathic procedures, intraoperative complications still pose a significant challenge to surgeons and continue to impact patient satisfaction (Table 1). Because the face and neck are highly innervated, one of the major risks associated with orthognathic surgery is nerve injury and the subsequent loss of sensation[30]. This becomes of particular concern when performing a BSSO. The IAN courses through the mandible and can be injured during a BSSO procedure resulting in temporary, or sometimes permanent neurosensory deficits. Temporary deficits have been reported to last up to a year following an operation. Studies have shown that IAN damage occurs in 2 to 3.5%, and even up to 10-15% of patients undergoing a BSSO[31]. This number increases to approximately 70% when the BSSO is performed in conjunction with a genioplasty[32,33]. Furthermore, the infraorbital and mental nerves are also at risk of injury during orthognathic surgery[34,35].

In addition to nerve damage, a constellation of intraoperative complications can occur while splitting the mandible, known collectively as a “bad split”. A bad split is the result of a mandibular osteotomy that has propagated in a less than ideal location, yielding further complications[36,37]. Two of the most common presentations of a bad split that can occur during a BSSO are a lingual plate fracture of the distal segment and a buccal plate fracture of the proximal segment[38–40]. An aberrant fracture pattern can also propagate to the coronoid process or the condylar neck resulting in a coronoid process or subcondylar fracture respectively, but these fractures are less common and rarely reported[41]. A bad split can not only result in longer surgical times, but may require additional or altered fixation of the bony segments as compared to the presurgical plan, resulting in increased risk for infection and the need for a second operation to correct the error. It is reported that a bad split occurs at a rate of 2.3%[42].

Lastly, severe bleeding or hemorrhage during orthognathic surgery can occur if there is damage to the facial artery, inferior alveolar artery, superior alveolar artery, internal maxillary artery, retromandibular and sublingual vessels[41,42]. The extent of bleeding during an operation varies from patient to patient and can be controlled with hemostatic materials and vessel ligation, as well as appropriate hypotensive anesthesia[43]. Rarely have procedures needed more invasive management like embolization.

Subchapter II: Post-operative implications and patient care

Patient recovery and quality of life

Following orthognathic surgery, a patient can experience swelling, facial bruising, pain, dysthesia, paresthesia and decreased facial mobility. The recovery time for orthognathic surgery patients is typically 6 weeks, but the return to normal function and complete bone healing can take up to 3 months. Immediately after the surgical procedure, patients are advised to apply ice to the affected areas and remain hydrated while getting an adequate amount of rest. Despite the recovery time and post-surgical discomfort, patients who undergo orthognathic surgery report an improvement in quality of life and general appearance[44–48].

The purpose of orthognathic surgery is to first restore normal function and then to improve facial aesthetics; the latter most often having a greater impact on an individual's self-image and emotional health. Studies have shown that patients with severe facial deformities behave in a shy, passive or defensive manner due to dissatisfaction with their appearance[49]. This has the potential to impact the types of jobs that an individual will opt for or be chosen for, as well as the kinds of relationships that they will maintain or be involved in[50]. A systematic review of literature from 2001 to 2012 revealed that individuals with dentofacial deformities have a significantly lower quality of life than those without facial deformities[51,52]. The phrase "the face is a mirror of the soul" is often used to describe how one's appearance can reflect their emotional and mental state, and in the case of orthognathic patients, this proves true as many individuals opt for surgery in efforts of improving their appearance and subsequently, their quality of life. A study surveying men and women in Malaysia found that 97% of all orthognathic patients underwent surgery for the purpose of improving their facial aesthetics[53]. Interestingly however, the authors also uncovered that 91% of females were seeking surgery as a means of enhancing their self-esteem whereas males were more interested in functional improvement[53]. These findings indicate that dentofacial deformities have a greater impact on the emotional state of women as compared to men. Furthermore, a research group in Brazil conducted a survey where they evaluated orthognathic patients on 8 different premises related to their overall satisfaction with the surgical results. The categories included questions regarding the patient's functional capacity, general health status, emotional state, social life, vitality and pain levels[47]. The authors found that women reported a higher overall improvement in their emotional state; thus, further emphasizing the discrepancy between the impact of facial deformities on males and females[47]. In addition, patient satisfaction following orthognathic surgery is in part dependent on the patient's realistic expectation of their surgical outcome[54]. This highlights the importance of the patient-surgeon relationship and having a mutual understanding of the patient's motivation for undergoing orthognathic surgery and more importantly, their expectations with the hopeful outcome of the procedure.

Postoperative complications

Although the majority of orthognathic surgery patients report an overall improvement in quality of life, a small subset of patients is still faced with the unfairness of postoperative complications (Table 1). Some of the complications associated with orthognathic surgery include, but are not limited to, infections (7%), anterior or posterior open bites, nerve injuries (50%), hearing issues (7%), temporomandibular joint (TMJ) disorders (14%), bleeding (9%) and surgical relapse (4%)[42,55–57]. Complications can also arise from the types of materials used to secure the bony fragments. For instance, a study conducted by Ahn *et al* found that more complications occur in patients with resorbable plates (18.3%) than those with titanium plates (8.6%)[58]. Although titanium fixation is considered the gold standard for orthognathic surgery, whether titanium plates are superior in every aspect of their functionality to resorbable plates remains debatable, though it is largely accepted that rigid internal fixation with titanium plates and screws is standard of care[59–61].

Regardless of all the improvements made to the surgical techniques used during orthognathic procedures, nerve injuries remain the most common postoperative complication. These mainly affect the infraorbital nerve, incisive nerve, IAN, mental nerve and, rarely, the facial nerve. These neurologic injuries manifest themselves as a reduction in touch sensation in the affected area or hypoesthesia, with the exception of facial nerve injury, which presets as a facial palsy on the ipsilateral side. It has been reported that younger patients generally recover more frequently and quicker from neurological injuries, however they can experience loss of sensation for up to a year, and in some cases, never fully recover. It is also thought that risk of permanent nerve injury is correlated with patient age. Although rare, facial nerve paralysis occurs in approximately 0.17% to 0.75% of patients[62–64]. This type of injury is often caused by physical damage to the nerve during instrumentation (e.g. chisel, drill or bur), improper injection of vasoconstrictors or compression of the nerve. If nerve function does not return to normal within 8 months, nerve grafting should be considered, although the window of opportunity for correction may be surpassed at this time. Other complications that have been previously reported include base of skull fracture, Adie pupil, unilateral oculomotor nerve palsy, maxillary sinusitis and other rare cranial neuropathies.

In addition to the functional complications that may arise following orthognathic surgery, aesthetic complications such as changes in nasal morphology (e.g. increased alar width, nasal tip projection) are often reported[65,66]. These become of particular concern during maxillary procedures when the repositioning of the maxilla and the subsequent suturing can cause nasal deviation and/or widening[65,67–69]. See Table 1

***Table 1*: Intraoperative and postoperative complications associated with orthognathic surgery.**

INTRAOPERATIVE	COMPLICATION	DEFICIT	SIGNS/SYMPTOMS
	Nerve injury[70]	IAN injury Oculomotor nerve palsy Facial nerve paralysis	Loss of sensation in the chin and lip Impaired eye movements, ptosis, diplopia Decreased salivation Facial weakness Muscle twitching
	Bad split	Fracture of mandible or maxilla at undesired sites	Delayed bone healing, pseudarthrosis, infection
	Insufficient gingival cuff	Inappropriate incision height	Incomplete closure of incision and hardware exposure

	COMPLICATION	DEFICIT	SIGNS/SYMPTOMS
	Hemorrhage[71,72]	Damage to major arterial blood supply to face (inferior alveolar, facial, internal maxillary, lingual)	Increased blood loss
POSTOPERATIVE	COMPLICATION	DEFICIT	SIGNS/SYMPTOMS
	Nasal morphology change[65,66,68,69]	Improper or lack of an alar base cinch suture Excess anterior nasal spine (ANS) Inadequate trimming of the nasal cartilage/ over-reduction of the ANS	Alar widening Change in nasal tip projection Nasal septum deviation
	Infection[56]	-	Pain at the surgical site, swelling of the face, difficulty breathing decreased opening of the mouth
	Hearing impairment*[55]	Blockage of the Eustachian tube or decreased opening of the Eustachian tube	Decreased hearing ability or loss of hearing *the exact cause is not well understood
	TMJ symptoms[57]	Mechanical overload or use of non-compressive screw fixation	TMJ pain, clicking, decreased opening of the mouth, etc. *underlying cause not well understood
	Relapse	-	Movement of mandible or maxilla out of position and development of malocclusion, open bite, etc.
	Maxillary Sunusitis[73,74]	Anatomic alterations of the nasal passages	Nasal congestion, sore throat, headache, cough, etc.
	Adie pupil[75]	Unknown	Dilated pupil in one eye, delayed light-induced pupillary constriction

Subchapter III: Surgical relapse

The stability of orthognathic surgical outcomes has seen major improvements over the last few decades, but the possibility of relapse is still a concern today. Post-surgical relapse can result in jaw and occlusal malalignment which is partially due to the repositioning of the muscles and bones during surgery as well as the physiologic adaptation of the body. Relapse can be categorized into two groups based on the causative agent(s): short term (early relapse) and long term (late relapse)[76]. As the name implies, early relapse occurs within a short time frame following the surgical intervention. Many consider this to be within three months of the operation. Errors and or miscalculations in the surgical plan and or intraoperative flaws are the major factors contributing to early relapse. This emphasizes the importance of accurate pre-operative models and well thought out surgical plans. Computer-based predictive models are becoming more widely used and aim at improving surgical accuracy and ultimately, treatment outcome. In contrast to aforementioned early relapse scenario, long-term relapse is primarily due to the continued growth and development of the patient following surgery. Therefore, the age and more importantly, the skeletal maturity of the patient must be taken into consideration prior to the surgical intervention.

Subchapter IV: Confounding variables affecting surgical outcome

While accurate predictive models can aid a surgeon in executing a flawless operation with a satisfactory outcome, there are other confounding variables that extend beyond the control of the surgeon which can have an impact on a patient’s functional and esthetic outcome. Such variables include age, body mass index and to an extent, the movement of ST in response to the predicted and coordinated HT movement. These factors will be addressed briefly in the following paragraphs.

Age

Patients seeking orthognathic surgery are often between the ages of 16 and 40, but in recent years, more patients on the upper end of the typical operative age have been seeking surgical care[77]. With increasing age comes the increased risk of intra-operative and post-operative complications. Studies have shown that patients over the age of 40 experience more intraoperative complications as well as longer hospital stays and post-surgical care during or following orthognathic surgery[77]. In addition, patients with an advanced age were more likely to suffer from neurosensory deficits and excessive intraoperative bleeding[78–80]. There is some thought that this is potentially due to the decreased elasticity of the bone with advancing age. Interestingly, younger patients experience their own complications with patients under the age of 40 being at a higher risk for mandibular fractures than those older than 40 years[80,81].

Body Mass Index (BMI)

In recent years, studies have reported that patients with a low body mass index experience increased intraoperative bleeding during orthognathic surgery[43] while patients with a BMI greater than 30 are at a higher risk for deep vein thrombosis[82]. Furthermore, patients with an elevated BMI are also at an increased risk of developing obstructive sleep apnea (OSA). Patients with OSA pose a risk for perioperative complications in the context of receiving a general anesthetic[83–85].

Hard and soft tissue movement

Appropriate presurgical planning can help the surgeon achieve the predicted HT movement during surgery with relative precision. However, predicting the response of the ST movement with confidence following this HT movement can, in some cases, be challenging. There is a lack of consensus on ST movement following a known HT movement. This highlights the importance of understanding the relationship between HT and ST changes with orthognathic surgery.

Throughout the years, studies have found that tissues generally follow the same course at an almost 1:1 ratio of HT to ST movement; however, there have been reports suggesting that the ratio is actually less than 1:1[86–89]. For instance, a study conducted by Storms *et al* found that the movements of the lower lip were much less predictable than those of the surrounding hard and soft tissues. However, the authors concluded that it is nearly impossible to determine whether this discrepancy is due to the procedure itself or to surgical relapse[90]. The authors also found that the nasolabial angle changes at a ratio of 0.5:1 as compared to the other tissues which transitioned at a 1:1 ratio[90]. In addition, the changes observed in ST following orthognathic surgery are influenced by a number of factors including lip thickness, ethnicity and sex among others[91]. The degree of movement is also influenced by the methods used to measure it. Depending on the accuracy of the method used, the HT: ST ratio [92–94]. Measurements were initially performed using two dimensional cephalometric radiographic tracings, but progress in medical technologies have made it possible to transition from x-rays to digital measuring tools such as cone beam computed tomography (CBCT) and 3D photography[95]. These newer modalities give the clinician the ability to better and more accurately measure facial parameters.

Subchapter V: Use of imaging programs to generate predictive models for surgical outcome

In the era of modern technology and personalized medicine, the use of predictive models for surgical outcome is an important aspect of treatment planning as well as patient reassurance and peace of mind when preparing for surgery. The ability of surgeons to accurately plan and predict the surgical outcome serves as a guide for better future care and patient satisfaction. Ultimately, these new technologies will eventually become the standard of care. Our abilities to better educate patients will also evolve using these advances in technology. Coupling the use of CBCTs and 3D photography with digital software analyzing programs has made it possible for surgeons to better predict surgical outcomes[96].

Current imaging software used for surgical planning

Virtual surgical planning is becoming increasingly popular and since its introduction, several software programs have been developed including Planmeca, CMF Surgery, Dolphin Imaging, VSP Orthognathics, ProPlan CMF, NemoFab, amongst others. Surgical planning using digital software generally revolves around two principles: first, the alignment or superimposition of the 3D images using a fixed reference point(s) (e.g. cranial base, floor of orbits) and second, the measurement of the difference between the pre- and post-operative images at specific points (e.g. A point, gnathion, etc.). The reference points are visually identified by the operator at the time of the analysis.

Although VSP is now widely accepted, it did not escape the unforgiving scrutiny of scientists and surgeons alike. Thus, several studies have been conducted to validate the reproducibility and reliability of digitally assisted surgical planning[97,98]. These studies have reported many advantages to using imaging software programs while also shedding light on their existing limitations which will be discussed in the following sections of this dissertation.

Advantages

One of the main advantages of digital imaging programs for the purposes of surgical planning is the ability to digitize cephalometric data and provide an accurate representation of the patient's facial structure. This can aid the surgeon in making a diagnosis and gaining a better overall understanding of the existing skeletal deformity, particularly when it comes to facial asymmetry[99–101]. VSP can also aid in diagnosis and treatment planning, thus allowing for better surgical planning[102,103]. The use of imaging software also allows the surgeon to create accurate predictive models which allow patients to appreciate the hopeful results of their surgery[104]. Patients can visualize what their surgical outcome could be and can assist them in deciding whether or not the proposed surgical plan is in keeping with their desired outcome. In addition, these software modalities help the surgeon determine the bony movements that must be completed to yield a desirable result. These software programs are also useful for patient follow up by allowing the surgeon to compare the movement of the HT and ST over extended periods of time. There exists an opportunity to acquire endless data through these programs. Overall, the use of VSP can positively impact the quality of patient care and patient satisfaction by maximizing the predictability of patients' surgical results.

Limitations

Despite the advantages of VSP, advanced technology comes with a price. One of the inherent limitations of digital software programs in orthognathic surgery is their accuracy in predicting ST response, hence the importance in understanding the response of ST to changes in HT during orthognathic surgery. Another pitfall of these methods is apparent when assessing the pre- and post-operative images for patient follow up. A study found that 23% of the manually repeated reference points differed by at least 1 mm[98,105]. This is monumental when you consider that the modern orthognathic surgeon operates in millimeter increments. Moreover, there is currently no standardized method of analyzing pre- and post-operative images CBCTs and 3D photographs. This makes validating different studies challenging as there is no standards of how to analyze these data sets. The two-dimensional approach to measuring the differences between the superimposed pre- and post-surgery images does not maximize the benefits of the latest technology used in image evaluation[106]. Different research groups are now focusing on developing new methods of assessing orthognathic surgery patients using a combination of CBCT, 3D images and digital analyzing software programs, but no standard exists today.

Subchapter VI: Purpose of study

The primary outcome measured in this study was the HT: ST ratio, or change in ST thickness, following orthognathic surgery relative to patient's pre-operative relationship. The results of this study will aim to present a new analysis tool to assist surgeons in planning for orthognathic surgery. This analytic tool could easily be adapted to form a part of routine virtual surgical planning. In addition, the potential findings of this study may also provide insight into patient specific treatment planning, enabling patient's to understand and appreciate details and considerations of their surgery and influence their expected outcome. As our treatment and outcomes are becoming more and more patient driven, it is important that we provide our patients with the necessary information so that their decision to undergo surgery is as informed as possible.

Objectives

1. Determine the HT: ST ratio or change in ST thickness at 3, 6 and 12 months following orthognathic surgery, relative to patient's pre-operative position.
2. Determine the impact of orthognathic surgery on the nasolabial angle, mentolabial angle, alar width, mouth width, height of philtrum, upper lip thickness and lower lip thickness.

CHAPTER II: MATERIALS AND METHODS

Study design

The study was designed as a prospective case series. Patients who chose to enroll in the study were followed post-operatively up to 12 months to gather the appropriate imaging records. These records consisted of CBCT and 3D photos. The CBCTs were taken pre-operatively at the pre-admission appointment and post-operatively at the time of splint removal. The 3D photos were taken pre-operatively at the pre-admission appointment and post-operatively at 3, 6 and 12 months.

A radiologic review was done independently by the Department of Radiology at Nova Scotia Health and Dalhousie University where the additional radiation exposure from CBCT imaging was evaluated to ensure patient safety. Following approval from the radiologic review committee, ethics approval was sought and obtained through the Research Ethics Board at Nova Scotia Health (REB File Number 1024017).

Patient recruitment

Patients were recruited at the time of their preadmission appointment by a resident member of the OMFS team. The research requirements were explained to patients and their families and informed consent to participate was obtained. The preadmission appointment was used for collection of all pre-surgical records necessary for surgical planning. This included dental impressions, panoramic and cephalometric radiography, digital impressions and clinical photos, in addition to the necessary study records: a pre-operative CBCT and a pre-operative 3D photograph. All patients scheduled to undergo orthognathic surgery in the Department of Oral and Maxillofacial Surgery at Dalhousie University were screened for selection.

Inclusion criteria

All patients planned to undergo orthognathic surgery were offered study participation. This included any patient planned for LF1, BSSO, FG or any combination thereof.

Exclusion criteria

Patients were excluded if they had previous orthognathic surgery, a history of a craniofacial syndrome, a history of cleft lip, cleft palate, cleft lip and palate, patients with a history of maxillofacial trauma requiring open reduction and internal fixation, and patients from far reaching parts of Atlantic Canada in which returning for long term follow up not reasonably feasible.

Surgical planning

Patient's surgical plan was determined using a combination of clinical and radiographic evaluation. Cephalometric radiographs were traced according to "The Architectural and Structural Craniofacial Analysis of Delaire" written by D.S. Precious. This is the cephalometric analysis used routinely by Department of Oral and Maxillofacial Surgery at Dalhousie. Splints used during surgery to set the final occlusion were made by hand, using stone models set on a hand articulator to achieve the desired occlusion, and polymethylmethacrylate resin to fabricate each splint.

Surgical procedures

Bilateral sagittal osteotomy procedure

All BSSO procedures were completed in a conventional fashion under general anesthetic with a nasal intubation. Lindeman and fissure burs were used to osteotomize the mandible. Pre-fabricated final occlusal splints were used in all cases. Some surgeons chose to trim a full coverage splint to cover only the incisor teeth. 2.0 KLS Martin® reconstruction plates and 6-millimeter monocortical screws were used to provide fixation in all cases. There were no intra-operative complications encountered. The procedure was preformed in the same manner regardless if there were additional procedures preformed during the same operation.

LeFort I osteotomy procedure

LF surgery was also preformed conventionally. As with mandibular surgery, maxillary surgery was preformed the same, regardless if it was in isolation or in combination with another orthognathic procedure during the same operation. A reciprocating saw and nasal septal osteotome were used to complete the horizontal LF level osteotomies. Posteriorly, the osteotomies at the level of the pterygoid plates is completed with a spatula, mallet and Tessier spreaders. There were no pterygoid chisels used.

Patients who underwent LF received 2.0 KLS Martin ® reconstruction plates with 6-millimetre monocortical screws for fixation. Some patients underwent wire osteosynthesis at the level of the zygomatic buttress, as per surgeon preference. Nasolabial reconstruction was done with an alar cinch suture in all cases. V to Y closure of patient’s vestibular incision was also done in all cases.

Genioplasty procedure

A sliding functional genioplasty was preformed by using a reciprocating saw to osteotomize the distal anterior mandible. Fixation was achieved using 2.0 KLS Martin® pre-bent chin advancement plates with 6-millimetre monocortical screws in all cases. There were no genioplasty setbacks in the study population.

Post-operative care

All patients enrolled in the study were monitored following the standard clinical protocol at our centre. This consisted of, at minimum, follow up at weeks 2, 4 and 6, and sometimes beyond. Patients were typically sent home with analgesics and anti-inflammatory medications. Ibuprofen, acetaminophen and an opioid were normally prescribed. Patients were also asked to use chlorhexidine rinse for a period of two weeks in addition to standard oral hygiene measures.

Patients were placed on a puree liquid diet for the first two weeks following surgery, then slowly transitioned to a non-chew diet for the subsequent two weeks. Finally, patients resumed a normal diet at 6 weeks post-surgery. Post-operative imaging on patients enrolled in the study was obtained at the time of their follow up appointments.

Study Imaging

Types of imaging

Two imaging modalities were used in this study: a CBCT scan and a 3D photo. All CBCTs were taken using an iCat FLX® CBCT machine and all 3D photos were taken using a 3dMD FACE® camera. Each imaging modality was taken, as per the manufacturer positioning recommendations, to the standards outlined in their respective user manuals.

CBCTs were acquired using the QuickScan setting within iCat FLX ®. This imaging selection was used to limit patient's radiation exposure to the lowest achievable dose. Each QuickScan delivered an estimated 22 microsieverts of radiation, as per the manufacturer. There was no radiation emitted in capturing 3D photos using the 3dMD FACE® camera.

The ST captured using the QuickScan setting, particularly of the chin, was distorted due to the use of the positioning chin cup. Therefore, the 3D photo was needed to capture undistorted ST overlying the anterior mandible.

Timing of imaging

CBCT volumes were taken at patient's pre-admission appoint prior to surgery and post-operatively between weeks 2 and 4. Volumes were taken on the day of the patient's surgical splint removal, which varied between 2 and 4 weeks post-operatively.

3D photos were taken at patient's preadmission appointment, and at 3, 6 and 12 months post-operatively. These timelines are represented below in Table 2 and Figure 2:

Table 2: Summary of imaging modality acquisition timeline

Time point	**3D photo**	**CBCT**
Pre-operative	X	X
2-4 weeks post-op		X
3 months	X	
6 months	X	
12 months	X	

Figure 2: Imaging modality acquisition timeline.

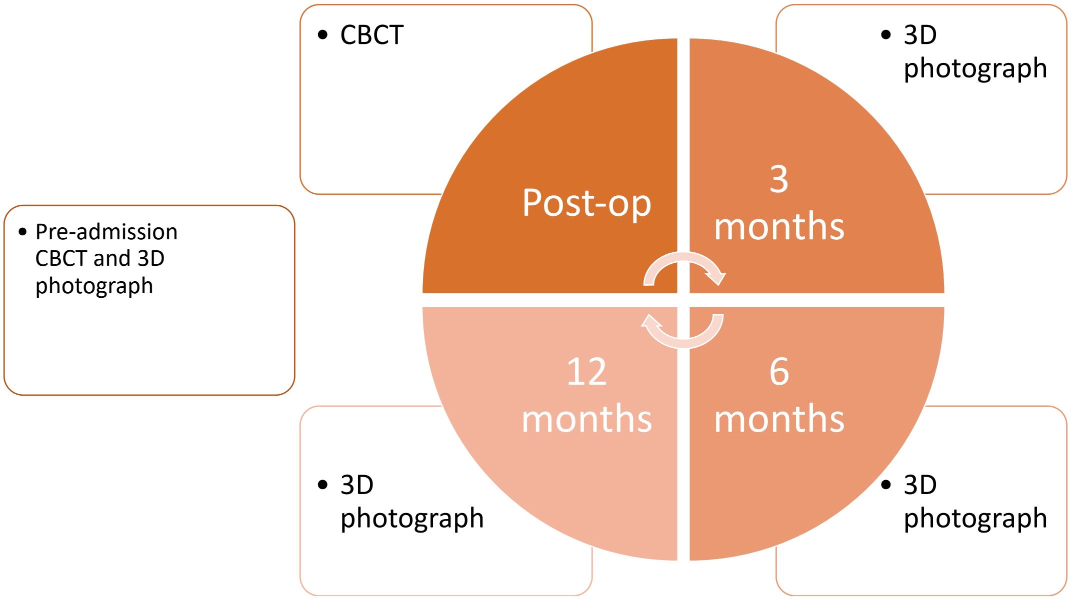


Image importing into Dolphin®

CBCT volumes imported into Dolphin® were in a multi-DICOM format. 3D photos imported into Dolphin® were in an .obj file format. Once the images were imported into Dolphin®, they were oriented using the bony Frankfurt horizontal plane (the superior aspect of the bony external auditory canal and the bony inferior orbital rim) and saved in the program. This saved file was then used in subsequent analysis with a standardized head position.

Data collection

There were three separate analysis done. First a change in ST thickness analysis was done on points M1 to M7. Secondly, a change in HT movement analysis was done, focusing on points M15 to M23. Lastly a surface ST analysis was done focusing on points M8-M14. These points are summarized in Table 3. Photo representation of these points can be seen in APPENDIX 1.

Table 3: Summary of anatomic landmarks used in all data analysis

Landmark	Description	Landmark	Description
M1	Bony A point to soft tissue A point	M13	Upper lip thickness
M2	CEJ of maxillary central incisor to upper lip	M14	Lower lip thickness
M3	CEJ of mandibular central incisor to lower lip	M15	A point
M4	Bony B point to ST B point	M16	B point
M5	Bony pogonion to ST pogonion	M17	Pogonion
M6	Bony gnathion to ST gnathion	M18	Gnathion
M7	Bony menton to ST menton	M19	Menton

Landmark	Description	Landmark	Description
M8	Nasolabial angle	M20	Lingual CEJ of mandibular incisors
M9	Mentolabial angle	M21	Lingual CEJ of maxillary incisors
M10	Alar width	M22	Superior genial tubercle
M11	Mouth width	M23	Anterior nasal spine
M12	Height of the philtrum		

Primary outcome analysis

To determine the HT: ST ratio, the magnitude of both HT and ST movement was calculated at different anatomic points including: A point, the upper lip, the lower lip, B point, pogonion, gnathion and menton (M1 – M7). As there is no published consensus as to the best way to evaluate HT to ST movements during orthognathic surgery, these points were selected as they are common anatomic points used across the existing literature[107–110].

HT movement was calculated through superimposition of the pre and post-operative CBCT volumes. First, pre and post-operative volumes were superimposed based on manually selecting and overlaying the frontozygomatic sutures on each volume within Dolphin®. Once manually superimposed using the frontozygomatic sutures as a reference, the built-in auto-superimposition function within Dolphin® was used to superimpose the same two volumes based on their bony base of skull. Observers have the ability to define the region of base of skull to superimpose through a click and drag function. In this case, the bony base of skull included the sella turcica, the lesser wings of the sphenoid bone and the cribriform plate. With the volumes superimposed, HT movement was calculated by directly measuring the difference in pre and post-operative volumes at each anatomic point in millimeters. This was calculated using the “Line” function in Dolphin®. An example of this calculation can be seen in APPENDIX 2.

ST movement was calculated by adding the HT movement to the change in ST thickness at each anatomic point. To calculate the change in ST thickness, pre and post-operative tissue thicknesses were compared. This was done through superimposition of 3D photos onto a CBCT volume at each desires time point. With both a CBCT volume and 3D photo imported into Dolphin®, manual superimposition was done using ST surface landmarks. The ST landmarks used for superimposition were the medial canthi and ST subnasale. Prior to manual superimposition, extraneous tissue from the ST image was trimmed using the “Sculpting” function in Dolphin®. This eliminated portions of the 3D photo that aren’t needed for analysis, but could affect the eventual auto-superimposition. Once superimposed manually, the built-in auto-superimposition function was used to optimize the volume superimposition. With the 3D photo and CBCT fused, the image was sectioned in the mid-sagittal plane at the anatomic base of skull using the “clipping splice” function. With the volume viewed in profile, the ST thickness measurements were calculated in millimeters using the “Line” function in Dolphin®. An example of this calculation can be seen in APPENDIX 3.

The HT: ST ratio was then calculated as the HT movement divided by the sum of the ST thickness change and the HT movement. All measurements were assumed to be linear. An example of this calculation is shown in Figure X: The HT: ST ratio calculation was repeated at all the anatomic points of interest (A point, upper lip, lower lip, B point, pogonion, gnathion and menton).

A 1:1 ratio implied that there was no change to the ST thickness, or that the HT and ST move to the same magnitude during orthognathic surgery. A ratio less than 1:1 implied that the ST thickness decreased, and a ratio greater than 1:1 implied that the ST thickness increased. An example of this calculation can be seen in APPENDIX 4.

Secondary Outcome Analysis

To perform the ST analysis, the .obj 3D photo was imported and superimposed onto the time appropriate CBCT volume in the same fashion as previously described. Once superimposed, direct measurements were taken of the desired ST landmarks using the same “Line” function within Dolphin®. These included measurements of the NL and ML angles in degrees and the alar and mouth width, height of the philtrum, and vertical thickness of the upper and lower lips in millimeters. Because of a lacking standardized method of tissue evaluation in the literature, these points were again selected based on anatomic points consistently used within the existing literature. Data for each time point (pre-operatively and 3, 6 and 12 months post-operatively) was generated for each patient using the method described above. An example of these calculations can be seen in APPENDIX 5.

Observers, intra and inter-relater reliability

There were two independent observers. Each observer generated data for the primary and secondary outcomes at each of the four time points. Images were analyzed twice by each observer at each time point, allowing a comparison of the data within and between the observers. Data analysis by each observer was done independent of the other observer. Time points were not analyzed twice within the same session.

Data sets generated by each observer were compared against the same observer using a Wilcoxon signed-rank test to determine intra-relater reliability. The same test was applied to establish inter-relater reliability for both primary and secondary outcomes at every time point.

Statistical Analysis

Based on study design, a one-way ANOVA power analysis was done and found that to achieve study power, 80 patients overall were needed.

The data consisted of three groups: the HT to ST measurements at 4 time points (ST thickness), the change in HT measurements pre and post-surgery and the ST measurements along 4 time points. The time points were again, pre-operatively, 3 months after surgery, 6 months after surgery and 12 months after surgery. Two observers obtained data at each time point, and measured the observations twice.

To establish intra-relater reliability, a Wilcoxon signed-rank test was applied to each observer's data. This was used because of data set outliers and the non-normal distribution of the variables within the data. The Wilcoxon signed-rank test is used to compare two sets of data that come from the same participant. It is the non-parametric equivalent of the paired t-test, and overall is not a powerful test. This same test was used to establish inter-relater reliability between observers for the same reason.

The primary and secondary outcomes were analyzed using mixed-effect model to capture the variability within and across patients. This was utilized instead of a simple linear regression as the overall sample size was too small to fit a linear regression. Because the maxillary HT movements were all highly correlated with each other and the mandibular HT movements were all highly correlated with each other, all maxillary and mandibular HT points were normalized to a single point in the respective jaw in using the mixed effect model. Maxillary HT points were normalized to M21 (CEJ of the maxillary central incisor) for maxillary movement and mandibular HT points were normalized to M22 (CEJ of the mandibular central incisor) for mandibular movements. The mixed effect model allowed observation of the data over time as it related to age, gender, BMI, and procedure type. All statistical analysis was performed by the Department of Statistics at Dalhousie University.

CHAPTER III: RESULTS

Demographics

A total of 120 patients enrolled in the study and acquired their pre-operative CBCT and 3D photograph. Of those, 44 total patients (37%) completed the post-operative CBCT and 3-month 3D photo. Of those 44 patients, 19 patients (16%) completed their 6-month 3D photo and 14 patients (12%) completed their 3D photo at 12 months. The remaining description of the demographics represent the total number of patients who completed at least the pre-operative CBCT and 3D photo, and the post-operative CBCT and at least one 3D photo: 44 patients.

Of the 44 patients who completed pre-operative and the first post-operative time point data collection, there were 27 males (61%) and 17 females (39%).

Of the 44 total patients, 7 underwent an isolated LF1 (11%), 9 underwent an isolated BSSO (20%) 22 patients had a combined LF1 and BSSO (50%), 4 patients had a LF, BSSO and FG (9%) and 2 patients underwent BSSO and FG (5%). There were 6 total patients who underwent an FG: 2 patients with BSSO FG and 4 patients with LF BSSO and FG. Because of the small sample size of patients who underwent FG, the data was aggregated into three groups: The two patients who underwent a BSSO FG were amalgamated into the BSSO group for a total of 11 patients and the four patients who underwent a LF BSSO FG were amalgamated into the LF BSSO group, for a total of 26 patients. Therefore the three procedure groups were LF (7 patients), BSSO (11 patients) and LF BSSO (26 patients).

Age was distributed with 30% of patients in the 2nd decade, 30% of patients in the 3rd decade, 30% of patients in the 4th decade, 7% of patients in the 5th decade and 7% of patients in the 6th decade of life.

BMI was distributed with 2 patients (5%) between a BMI of 10 and 19, 28 patients (64%) with a BMI between 20 and 29, 12 patients (27%) with a BMI between 30 and 39, one patient (2%) with a BMI between 40 and 49 and one patient (2%) with a BMI between 60 and 69.

These demographics are summarized below in Table X. Information about each patient including procedure, age, sex, height, weight, BMI and ASA classification can be found in APPENDIX 6.

Table 4: Patient demographic summary

Demographic	**Time Point**				**Overall Percentage**
	3 months	**6 months**	**12 months**	**Total**	
Total patients	44	19	14	44	
Sex					
M	17 (39%)	9 (20%)	5 (11%)	17	39%
F	27 (61%)	10 (23%)	9 (20%)	27	61%
Procedure					
LF	7	2	4	7	16%
BSSO	9	5	2	9	20%
FG	0	0	0	0	0%
LF/BSSO	22	10	6	22	50%
LF/BSSO/FG	4	2	4	4	9%
BSSO/FG	2	0	0	2	5%
LF/FG	0	0	0	0	0%
Age					
15-19				13	30%
20-29				13	30%

Demographic	**Total**	**Overall Percentage**
Age		
30-39	12	27%
40-49	3	7%
50-59	3	7%
BMI		
10-19	2	5%
20-29	28	64%
30-39	12	27%
40-49	1	2%
50-59	0	0%
60-69	1	2%

Note. Patient demographics who completed pre and at least 1 post-operative time point by sex, procedure, age and BMI

Intra-relater reliability

There were three separate analysis done: A change ST thickness analysis, a change in HT movement analysis and a change in surface ST analysis. The change in ST thickness analysis was done through the superimposition of CBCT volumes and 3D photos. The HT movement analysis was done through the superimposition of pre and post-operative CBCT volumes. Finally, the ST analysis was done by comparing changes directly using pre and post-operative 3D photos. The ST thickness and HT movement analysis were used to determine the primary outcome. The ST analysis was used to determine the secondary outcomes.

Primary Outcome

Having two independent observers analyze the data allowed the researchers to compare the consistency of the data within and between observers. Inter-observer reliability, or the consistency of the data generated by each observer was determined using a Wilcoxon signed-rank test, which compares different data sets across time that come from the same observer. This test is similar to a nonparametric T-test, but overall holds a low power. Using the mean, standard deviation and a confidence interval of 0.95, the two data sets generated by each observer for the primary outcome were examined.

The primary outcome included a ST thickness analysis and a HT movement analysis, at points M1-M7 and M15-M23, respectively. Each observers' data sets were found to have no statistically significant difference using a 0.95 confidence interval as all p-values were greater than 0.05. This showed that both observers generated consistent ST thickness and HT movement data. These are shown in the following Tables 5-8. Graphic representation of the intra-relater reliability for both observers can be found in APPENDICES 7 – 10.

***Table 5*: Intra –relater comparison of soft tissue thickness analysis by observer 1**

Point	Mean				Standard Deviation				P Value			
	Pre-op	*3 M*	*6 M*	*12 M*	*Pre-op*	*3 M*	*6 M*	*12 M*	*Pre-op*	*3 M*	*6 M*	*12 M*
M1	0.4	0.25	0.311	0.014	2.008	1.005	0.606	0.366	0.686	0.54	0.52	0.982
M2	0.598	0.202	0.258	0.2	1.745	0.883	0.515	0.254	0.402	0.835	0.693	0.872
M3	0.314	0.209	0.095	-0.157	2.302	0.937	0.594	0.311	0.649	0.692	0.977	0.836
M4	0.943	0.725	0.547	-0.05	2.282	4.544	1.126	0.274	0.363	0.339	0.726	0.908
M5	1.323	0.48	0.163	0.014	2.758	1.275	0.513	0.311	0.144	0.556	0.8115	0.909
M6	1.58	0.882	0.479	0.221	2.935	1.91	1.823	0.421	0.087	0.374	0.861	0.73
M7	0.839	0.943	0.384	-0.007	2.084	2.176	1.67	0.381	0.248	0.576	0.793	0.963

Table 6: **Intra-relater comparison of soft tissue thickness analysis by observer 2**

Point	Mean				Standard Deviation				P Value			
	Pre	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*
M1	-0.393	-0.166	-0.023	-0.064	1.013	0.924	0.787	0.438	0.507	0.815	0.737	0.945
M2	-0.141	0.061	0.011	0.093	0.711	0.492	0.314	0.264	0.77	0.861	0.942	0.872
M3	-0.275	0.055	0.037	-0.164	0.779	0.482	0.302	0.369	0.567	0.904	0.919	0.783
M4	0.036	-0.202	0.289	-0.379	0.992	0.707	0.944	1.064	0.871	0.764	0.827	0.73
M5	0.082	-0.039	0.326	-0.079	0.944	0.519	0.566	0.435	0.914	0.973	0.693	0.854
M6	0.473	0.059	-0.032	-0.143	1.385	0.865	1.261	0.713	0.504	0.793	0.988	0.836
M7	-0.102	-0.005	0.289	0.086	0.959	0.658	1.043	0.602	0.9	0.977	0.838	0.927

Table 7: **Intra-relater comparison of hard tissue change analysis by observer 1**

Point	Mean	Standard Deviation	P Value
M15	-0.123	0.489	0.778
M16	-0.152	0.682	0.773
M17	-0.089	0.675	0.874
M18	0.036	0.822	0.920
M19	-0.086	0.85	0.098
M20	-0.143	0.77	0.764
M21	-0.032	0.701	0.946
M22	0.043	1.075	0.917
M23	-0.089	0.717	0.876

Table 8: **Intra-relater comparison of hard tissue change analysis by observer 2**

Point	Mean	Standard Deviation	P Value
M15	0.023	0.626	0.990
M16	0.252	0.500	0.707
M17	-0.098	0.737	0.973
M18	-0.082	0.656	0.983
M19	-0.298	0.774	0.673
M20	0.061	0.800	0.933
M21	0.116	0.697	0.990
M22	0.000	0.868	0.957
M23	0.114	0.525	0.707

Secondary Outcome

The same Wilcoxon signed-rank test was used to evaluate the consistency of the two data sets generated by each observer for the secondary outcome: the ST analysis. The ST analysis was the only data set required to examine the secondary outcomes. There was no statistical difference within observers using a confidence interval of 0.95 and the mean and standard deviation of the ST data. This is shown in the following Tables 9 and 10. This is also represented graphically in APPENDICES 11 and 12.

***Table 9*: Intra-relater comparison of soft tissue analysis by observer 1**

Landmark	Mean				Standard Deviation				P Value			
	Pre	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*
M8	-0.65	-1.539	-0.289	0.1	4.359	3.284	2.63	2.747	0.739	0.593	0.8115	0.909
M9	-1.514	-1.143	-0.384	0.164	1.514	3.487	3.068	2.791	0.593	0.614	0.683	0.908
M10	0.193	0.13	-0.195	0.036	0.193	0.486	0.517	0.3	0.799	0.799	0.77	0.945
M11	0.125	-0.275	0.158	0.221	0.125	2.71	0.941	0.664	0.78	0.94	0.726	0.872
M12	0.214	0.093	0.558	-0.15	0.214	0.874	0.914	1.106	0.809	0.815	0.579	0.73
M13	0.525	0.425	0.332	0.114	0.525	0.926	0.661	0.674	0.098	0.106	0.447	0.945
M14	0.241	0.198	0.111	-0.15	0.241	0.703	0.632	0.591	0.523	0.646	0.838	0.818

***Table 10:* Intra-relater Comparison of soft tissue analysis by observer 2**

Landmark	Mean				Standard Deviation				P Value			
	Pre	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*
M8	-0.85	-1.22	-1.474	0.043	2.844	2.691	3.307	2.7	0.698	0.71	0.502	0.89
M9	-1.225	-1.543	-2.353	0.214	4.92	5.352	3.995	3.956	0.499	0.448	0.525	0.927
M10	0.12	-0.359	-0.374	-0.136	0.863	0.603	0.847	0.733	0.806	0.658	0.683	0.927
M11	0.259	-0.452	-0.326	-0.429	1.008	1.157	1.017	0.932	0.767	0.416	0.693	0.836
M12	0.264	-0.052	-0.363	0.071	1.09	0.943	0.617	0.702	0.713	0.943	0.704	0.982
M13	-0.161	-0.241	0.095	-0.144	0.704	0.568	0.531	0.303	0.442	0.43	0.559	0.8
M14	-0.161	-0.014	0.121	0.093	0.69	0.719	0.708	0.336	0.877	0.818	0.672	0.836

Inter-relater reliability

Averages of the two data sets from each observer were compared to establish intra-relater reliability. The Wilcoxon signed-rank test was used to compare the averages of both observer's data sets using the mean, standard deviation and a confidence interval of 0.95 for both the primary and secondary outcomes.

Primary outcome

There was no statistical difference between data sets from each observer comparing HT movement. There was a statistically significant difference between observers in the change in ST thickness analysis, particularly at the pre-operative time point, and at tissue points M1 and M7 (A point and menton) post-operatively. Measurements were repeated twice for this analysis to mitigate potential measurement error, however, the statistical difference persisted. Because of this statistical difference between observes, only one observer's data set was used in the statistical analysis. The mean, standard deviation and p values showing this statistical correlation is summarized in *Tables 11 and 12*. A graphical representation can be found in APPENDICES 13 and 14.

Table 11: Inter-relater comparison the soft tissue thickness changes between observers

Landmark	Mean				Standard Deviation				P Value			
	Pre	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*
M1	1.06	1.67	2.34	0.88	1.66	1.72	2.53	1.45	0.071	0.002	0.002	0.183
M2	1.20	1.27	1.42	0.40	1.25	1.54	1.56	1.44	0.030	0.036	0.125	0.662
M3	1.52	1.10	1.61	0.77	1.83	2.23	1.87	1.88	0.005	0.086	0.136	0.280
M4	1.80	1.21	1.37	1.02	2.94	3.18	2.88	2.10	0.009	0.098	0.237	0.435
M5	1.98	1.26	1.87	1.49	2.34	2.81	2.69	1.78	0.009	0.059	0.204	0.352
M6	1.89	1.52	1.67	0.67	3.85	2.72	3.19	2.17	0.025	0.065	0.111	0.748
M7	3.56	3.32	5.03	2.62	1.23	3.31	3.27	1.87	0.001	0.001	0.001	0.022

Table 12: Inter-relater comparison of the hard tissue movement between observers

Point	Mean	Standard Deviation	P Value
M15	0.48	2.01	0.221
M16	0.55	3.20	0.861
M17	1.08	3.16	0.374
M18	0.93	3.39	0.582
M19	0.62	3.59	0.973
M20	0.41	2.26	0.874
M21	0.77	2.54	0.171
M22	1.33	3.72	0.335
M23	0.12	2.38	0.757

Secondary Outcome

There was no statistically significant difference in the ST changes measured by both observers. This is shown below in *Table 13.*

***Table 13*: Inter-relater comparison of the soft tissue changes between observers**

Landmark	Mean				Standard Deviation				P Value			
	Pre	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*	*Pre*	*3 M*	*6 M*	*12 M*
M8	1.96	1.16	2.20	3.39	3.61	2.65	4.06	5.41	0.385	0.686	0.726	0.476
M9	-0.66	-0.36	3.66	0.65	5.71	7.11	9.72	10.00	0.825	0.960	0.271	0.908
M10	-0.26	-1.05	-1.51	-3.59	2.10	3.55	3.61	6.10	0.960	0.540	0.430	0.323
M11	0.74	0.70	0.89	3.26	2.52	2.78	3.47	6.33	0.411	0.540	0.651	0.175
M12	0.72	0.34	1.19	1.61	1.23	0.99	0.95	1.40	0.299	0.570	0.255	0.124
M13	0.15	0.34	0.43	0.49	0.87	1.00	0.72	1.25	0.713	0.291	0.293	0.301
M14	0.56	0.16	-0.13	0.07	0.95	1.14	1.56	1.19	0.220	0.924	0.569	0.854

Primary outcome – HT: ST ratio

There was no statistically significant change in the HT: ST tissue ratio at any time point post-surgically in comparison to patients' pre-operative relationship. At 3, 6 and 12 months, the HT: ST ratio was 1: 0.96 ($p = 0.13$), 1: 1.53 ($p = 0.38$) and 1: 1.04 ($p = 0.60$), respectively. A trend in the HT: ST ratio was seen, showing an increase to 1: 1.53 at 6 months post-surgery, however, this was not statistically significant. This is represented in Figure 16. Two p-values that showed a statistically significant in changes to the HT: ST were patients older than 40 years of age at 12 months (p = 0.02) and patients in the LF group at the 6-month time point (p = 0.01). There was one patient older than 40 years at the 12-month time point, and two patients in the LF group at the 6-month time point. There were no statistically significant differences in the HT: ST ratio when comparing males and females. These findings are summarized in *Table 14*.

***Table 14*: Summary of the HT: ST ratio stratified by time, gender, age and procedure type.**

Parameter	**3 Months**		**6 Months**		**12 Months**	
	HT:ST	p value	HT:ST	p value	HT:ST	p value
Time	0.94	0.13	1.53	0.38	1.04	0.6
Gender						
Male	0.6	0.77	1.77	0.08	1	0.48
Female	1.16		0.32		1.06	
Age						
15-19	1.15	control	1.97	control	0.92	control
20-29	1.21	0.96	1.23	0.69	1.01	0.48
30-39	0.6	0.14	1.37	0.63	1.39	0.83
Older than 40	0.54	0.63	1.06	0.06	0.06	0.02
Procedure						
BSSO	0.55	control	2.16	control	1.04	control
LF	0.09	0.5	0.87	0.01	0.75	0.72

Parameter	**3 Months**		**6 Months**		**12 Months**	
Procedure						
LF BSSO	1.34	0.2	1.38	0.26	1.18	0.85

Secondary Outcomes

Secondary outcomes included a ST analysis examining changes in the NL angle, ML angle, alar width and mouth width, height of the philtrum, upper lip thickness and lower lip thickness. These parameters were evaluated with respect to time, gender procedure and BMI.

There were no statistically significant changes to the NL angle over time across all patients. There was a statistically significant difference in the change in NL angle when the data was segregated by sex. Males showed a greater change in their NL angle versus females (1.45˚ versus -0.37˚) with a p value of 0.04. The NL angle also showed the greatest change in patients who underwent a LF procedure (2.56˚; p value = 0.03). Modelling also showed that an increase in the BMI by 1 was correlated with a predicted change in the NL angle by 0.32˚. Graphic representation of the changes to the NL angle can be found in APPENDIX 17.

There was no statistically significant change in the ML angle in all patients when stratified by time. Likewise, there was no statistical difference in the ML angle when the data was stratified by gender. There was statistical significance when the ML angle data was stratified by procedure, with the BSSO group showing the greatest change in the ML angle (5.08°; p value = 0.03). Graphical representation of changes to the ML angle can be found in APPENDIX 18.

The alar width showed a statistically significant change across all patients at all post-operative time points. At 3 months, the change was 1.47mm (p = 0.001), at 6 months the change was 1.26mm (p = 0.01) and at 12 months the change was 2.58mm (p = 0.001). The alar width also changed more in patients who underwent maxillary surgery (LF BSSO = 1.36mm, p = 0.01; LF = 1.77mm, p = 0.06). There was no statistically significant difference in the change in alar width when the data was stratified by gender. Graphic representation of these changes can be found in APPENDIX 19

There was a statistically significant changes seen in the mouth width with respect to time at each time point. These changes were all less than 1mm. There were not differences seen in the mouth width with respect to gender or procedure.

There was no statistically significant difference in the height of the philtrum with respect to time or procedure type. There was a statistically significant difference in the philtrum height between sexes of 0.21mm and 0.08mm (p = 0.03). However, these are submillimeter differences.

The upper lip thickness decreased slightly with LF surgery (-0.12mm; p = 0.05). There were no statistically significant changes to the upper lip thickness with respect to time and gender.

There was a statistically significant change in the height of the lower lip across all patients at 3, 6 and 12 months post operatively (-0.73mm, p = 0.001; -0.7mm, p = 0.001; -0.80mm, p = 0.01).

Secondary outcome results are summarized below in Table 15.

Table 15: Secondary outcomes summary

Outcome	3 Months		6 months		12 months	
	change	p value	change	p value	change	p value
Nasolabial angle						
Time	1.07	0.34	1.25	0.73	-2.03	0.23
Gender						
Male					1.45	0.04
Female					-0.37	0.04
Procedure						
BSSO					-1.39	baseline
LF					2.56	0.03
LF BSSO					0.44	0.07
Mentolabial angle						
Time	2.36	0.3	3.21	0.51	5.27	0.09
Gender						
Male					3.91	0.55
Female					0.70	0.55
Procedure						
BSSO					5.08	baseline
LF					2.42	0.03
LF BSSO					0.60	0.03
Alar width						
Time	1.47	0.001	1.26	0.01	2.58	0.001
Gender						
Male					1.28	0.56
Female					0.87	0.56
Procedure						
BSSO					-0.31	baseline
LF					1.77	0.06
LF BSSO					1.36	0.01
Mouth width						
Time	-0.21	0.71	0.12	0.82	-1.92	0.04
Gender						
Male					-0.54	0.31
Female					-0.11	0.31
Procedure						
BSSO					-0.77	baseline
LF					-0.27	0.80
LF BSSO					-0.08	0.76

Outcome	**3 Months**		**6 Months**		**12 Months**	
	change	p value	change	p value	change	p value
Philtrum height						
Time	0.31	0.21	0.19	0.88	-0.11	0.89
Gender						
Male					0.21	0.03
Female					0.08	0.03
Procedure						
BSSO					-0.19	baseline
LF					0.02	0.95
LF BSSO					0.29	0.44
Upper lip thickness						
Time	0.13	0.37	0.09	0.53	0.14	0.38
Gender						
Male					0.06	0.14
Female					0.09	0.14
Procedure						
BSSO					0.23	baseline
LF					-0.12	0.05
BSSO LF					0.07	0.49
Lower lip thickness						
Time	-0.73	0.001	-0.87	0.001	-0.80	0.01
Gender						
Male					-0.34	0.51
Female					-0.59	0.51
Procedure						
BSSO					-0.44	baseline
LF					-0.23	0.86
LF BSSO					-0.59	0.20

CHAPTER V: DISCUSSION

Primary Outcome

There was a statistically significant difference in the HT: ST ratio when the data was stratified by age, with patients over 40 years of age showing a slight increase in their HT: ST (1: 1.06; p = 0.02). Though this provided statistical significance, the sample size in this age cohort at this time point was only 1 patient. Due to this sample size, this finding should not be interpreted as clinically significant. There was also a statistically significant difference in the HT: ST ratio when the data was stratified by procedure, with patients undergoing LF only having a 1: 0.87 ratio at the 6-month time point (p = 0.01). However, there were only two patients in this treatment group at the 6-month time point. Again, with a sample size of only two patients, it is challenging to credit the statistical significance provided by the model with any clinical significance.

There were no statistically significant differences seen in the HT: ST ratio at any time point post surgically in comparison to the pre-operative ST thickness. There was a trend seen within the data that showed a maximal increase in the HT: ST at 6 months post op (1: 1.53, p = 0.38), with a return of the ratio to almost baseline at 12 months (1: 1.04, p = 0.60). Even though this did not provide statistical significance, it is important to consider reasons for this trend. One would not expect there to be post-operative inflammation contributing to increased tissue thickness at this time point. A typical course of post-operative inflammation is peaks within 3-5 days and is largely regressed at the two week mark, therefore we would not expect typical post-operative inflammation to be contributing to increased tissue thickness at 6-months post-operatively. Another consideration would be to any long-term effects of the perioperative steroid dosing regimen and its potential contributions to long term ST changes. Jean et al. in 2017 conducted a systematic review on steroid use in orthognathic surgery and found that the use of perioperative steroids was associated with a decrease in facial edema and there were no long term complications reported associated with perioperative steroid use in orthognathic surgery[111]. With that in mind, it is still a consideration, but an unlikely explanation for this trend. Fluctuations in patient weight, and weight-loss associated with surgery is also a consideration for this trend. As surgeons, we know that patients undergoing orthognathic surgery generally lose between 5 and 15 pounds after surgery. Patients are generally instructed to return to a normal diet between weeks 6 and 8, and despite this, patients can potentially have challenges progressing their diet back to their pre-operative baseline. It is a possibility that the effects of post-operative weight loss are reflected in the 3-month HT: ST ratio (1: 0.94) and that the 6-month HT: ST ratio (1: 1.53) is reflective of rebound weight gain by patients. One must also consider long term tissue remodeling, particularly of the peri-alar musculature and ST. After an alar cinch suture and V to Y closure of the vestibular incision, there could be long term tissue remodeling contributing to this trend. Lastly, and the more likely explanation for this trend is the small overall sample size and the patient attrition that occurred over the course of the study. The data set decreased from 44 patients at 3 months, to 19 patients at 6 months, and finally to 14 patients at 12 months post-operatively. There are likely outliers skewing the data at the 6-month mark which account for the increasing trend in the HT: ST ratio at that time. One may ask why the HT: ST ratio would then show a relative decrease close to its pre-operative relationship at the 12-month mark. This is likely due to losing some of the outliers skewing the data at the 6-month time point. The total number of patients who completed the study subjects this trend to sample size bias. It is also important to note that this trend was just that, a trend, and provided no statistical significance.

Secondary Outcome

The greatest change in NL angle was seen in patients in the LF procedure group. Interestingly we saw a decrease in the NL angle in the BSSO procedure group. These are intuitive findings given that one would expect there to be the greatest change in the NL angle when the maxilla is operated on. Likewise, a decrease in the NL angle in the BSSO group reflects an increase in upper lip support provided by a more appropriate positioned mandible following surgery. Though these findings were statistically significant, the absolute difference in the change in NL angle is small comparing LF and BSSO groups (2.56˚ vs -1.39˚). Therefore, despite these statistical differences, it is unlikely to impact treatment planning in a clinically meaningful way.

For every increase in a patients BMI by 1, the change in the NL angle was predicted to increase by 0.32˚. This is again an intuitive finding. One would expect patients with a higher BMI to have a higher overall volume of subcutaneous tissue evenly distributed throughout their body, including in the face. Typically, people with an elevated BMI will have areas of their bodies that have relatively more subcutaneous fat, but overall, one would expect a patient with a relatively higher BMI to have a relatively larger volume of facial subcutaneous fat, in comparison to a patient with a lower BMI. With an elevated BMI, one could therefore reasonably expect that the increased volume facial subcutaneous fat is more susceptible to post-surgical changes. The correlation between BMI and changes to the NL angle found in this data set is reflective of that.

The statistically significant change to the ML angle in the BSSO treatment group (5.08˚, p = 0.03) is again intuitively what one would expect to observe. With all other things being equal, one would expect the ML angle to increase the most when the mandible is operated on. Although this finding was statistically significant, the overall difference in the change in ML angle is less than 5˚. Some observers may argue that a difference of 5˚ is clinically apparent, while others may feel that a 5˚ change provides little clinical difference. The authors feel that a 5˚ difference would be on the cusp of what is detectable clinically, and therefore believe that this statistical finding provides some clinical benefit as to the expected post-operative changes associated with BSSO.

The alar width showed a statistically significant increase 3, 6 and 12 months post-operatively (1.47mm, p = 0.001; 1.26mm, p = 0.01; 2.58mm, p = 0.001, respectively). It is interesting that change was still seen 1-year mark post-surgically, and that this time point showed the greatest amount of change. There are several reasonable thoughts that could provide explanation for this finding. First, we expect there to be some long-term remodeling of the bone at the level of the LF osteotomies. Further, we would expect some remodeling at the interdental osteotomies if the maxilla was segmentalized. Depending on the nature of the surgery performed and the bone healing, a callous could be formed at any or all of these sites (horizontal and interdental osteotomies), contributing to an increased underlying HT volume. With an increased volume of bone deep to the ST alae of the nose, one would expect to see widening of the alar base, all other things being equal. In this study, no maxillary surgery (whether in the LF only group or the LF BSSO group) was stratified based on a segmental versus one-piece LF. This would perhaps be an interesting parameter to examine in future studies. There is also a possibility of bony remodeling at the level of the nasal pillar and lateral bony pyriform aperture. In the case of maxillary advancement or slight down grafting, a bony step would exist at this tissue level in one or more vectors. Again, with secondary intention bone healing at these bony gaps, a callous is formed, and can ultimately contribute to the widening of the alar base. Lastly, the application of fixation hardware can have an effect on the alar width. Post-surgically, there is potential for capsule formation surrounding part, or all of the fixation hardware. A screw that is not intimately adapted can be a source of long term, low-grade inflammation, leading to chronic granulation tissue deep to the alae of the nose. Patients can potentially experience ectopic bone formation, covering the hardware, leading to changes in the alar base width. And finally, without any changes overlying the hardware, the hardware itself adds to the tissue volume deep to the alae, even though they are designed to be as low profile as possible. All of these potential explanations come down to on underlying principle: that is any increase in the tissue volume deep to the dissected and raised ST envelope can have a potential to widen the alar base once the ST drape is re-approximated and the wound is closed. This increase in volume could be from bony steps in the surgical planning, the fixation hardware, any reaction to the hardware in the form of a ST capsule, and any combination thereof. Therefore, the observed statistically significant increase in alar width post-surgery can be correlated to these clinical scenarios.

There was a statistically significant difference in the mouth width across all patients at the 12-month time point of -1.92mm ($p = 0.04$). Again, a small sample size at 12 months challenges the clinical significance of this finding. There are also potential sources of error in mouth width measurement and 3D photo acquisition that further question the overall validity of this finding.

We observed statistically significant, sub-millimeter differences in the philtrum height when comparing males to females (M = 0.21mm, F = 0.08mm, $p = 0.04$). With this difference being only a fraction of a millimeter, its clinical significance is minimal, if any. The change in upper lip thickness saw a similar difference when stratified by procedure. The LF group showed a statistically significant decrease of upper lip thickness of -0.12mm ($p = 0.05$). Again, with such a small absolute measurement, the clinical significance is minimal, if any.

The lower lip thickness also showed statistically significant decrease over time across all patients. At 3, 6 and 12 months, the lower lip thickness decreased -0.73mm, -0.87mm and -0.80mm, respectively ($p <0.01$).

The changes seen in the mouth width, philtrum height and upper and lower lip thicknesses likely reflect an error in analysis within Dolphin® or an error in image capturing using the 3D camera. With all of these differences being less than a millimeter, they bear minimal clinical significance.

Overall, there were no statistically significant findings associated with the primary outcome. There was an interesting trend seen in the HT: ST ratio, with maximal changes being seen at 6 months post-surgery, and we have outlined some thoughts as to why this trend exists. Given the limitations, it would be interesting to observe changes in this trend, and any statistical significance derived from the primary outcome data with a larger sample size. Without a larger sample size in this study, we cannot say whether or not this trend would bear any scientific or clinical significance. We did observe statistically significant findings at the NL angle, ML angle and the alar width. All of the findings at these anatomic locations are not only intuitive, but supported statistically as well. Though there was some statistical significance found other variable including mouth width, philtrum height, upper lip thickness and lower lip thickness, we cannot conclude that they provide clinical significance. This is due to a combination of small sample size and measurement error bias associated with the use of the analysis software.

CHAPTER VI: LIMITATIONS AND FUTURE DIRECTIONS

Limitations

After completing the study, there were several obvious shortcomings that impacted the research including: the small sample size, patient attrition over time, error involved in imaging acquisition, image importing and superimposition into Dolphin®, image analysis within Dolphin® and the differences in inter-relater reliability of the data generated for the primary outcome.

Sample size and patient attrition

A one-way ANOVA power analysis was conducted during the study design phase which indicated a total of 80 participants was necessary to achieve statistical power. Of the 120 patients who initially enrolled in the study, 37% (44/120) completed their 3-month data acquisition, 16% completed their 6-month data acquisition and only 12% completed their 12-month data acquisition. Not all patients who followed up at 12 months honored their 6 months follow up, which further provides inconsistency to the data set. The small sample size is certainly the most obvious shortcoming with the study. Longitudinal studies are inherently difficult from a patient recruitment and retention perspective. The patient attrition we experienced was not through lack of effort of the research team, however, better overall organization of patient follow up by the research team could have improved the sample sizes at the post-operative time points. Consideration of a full-time research assistant to contact patients for follow up could have provided benefit. Another consideration for the significant patient attrition is that the research team did not provide participants with any form of incentive to participate. Initial interest in participation was high, with 120 participants initially enrolled. However, the stark drop off at the 3-month time point (37% retention) and further attrition at later time points reflects the impact of not offering patients with participation incentive. Incentive could have been provided perhaps through a financial incentive, incentive the form of provision of post-operative analgesic medication, or a complimentary oral cancer screening 1-year post-op. Without any form of incentive, it is clear that patient's willingness to complete their study requirements was low.

Although the attrition rate was significant, we asked ourselves, given the data we collected, how many patients would have been required for the data to provide statistical power? We once again performed a one-way ANOVA power analysis on our data gathered at the 3-month time point stratified by procedure. Given the variability in the data at this time-point and using a power of 0.9 and a p-value of 0.05, we found that a total of 60 patients at all 3 post-operative time points would have been needed or, at minimum, 20 patients in each treatment group (BSSO, LF and LF BSSO) to achieve power.

The last major challenge associated with sample size and patient retention pertains to the COVID-19 pandemic. Much of this data was impacted by public health restrictions within both the province of Nova Scotia, and further within the Nova Scotia Health Authority governing in-hospital care. There were a significant number of participants who enrolled in the study in 2019. This is both where we saw patients completing all of the requirements at post-operative time points, but at the same time, where much of the patient attrition occurred. This is of no fault of the pandemic. Patients who were recruited in the last quarter of 2019 and the first quarter of 2020 were most significantly impacted by the lack of long-term follow-up, through personal, public health or health authority recommendations. Many of these patients were not able to meet study requirements. Following March 2020, there were periods of time where there was no orthognathic surgery being performed at our center, thus we experienced a stark reduction in initial patient participation and ongoing patient follow up. Although the pandemic had a negative impact on the study, it was by no means the main contributing factor to the small sample size and patient attrition.

Image Acquisition

Two imaging modalities were used in this study: CBCT and 3D photography. These both have inherent challenges associated with acquisition of consistent images at different time points.

Because the CBCT involved exposing patients to ionizing radiation, the images were prone to artifact. Artifact can come from different sources in the exposure field, particularly metals and other dense materials. During this study, patients wore either orthodontic appliances in the form of conventional orthodontic brackets or surgical hooks and buttons placed by the orthodontist peri-operatively. These appliances were present in both pre and post-operative exposures. Post-operative CBCT exposures also captured the fixation hardware placed at the time of surgery. Lastly, a CBCT can be influenced by existing dental restorations, particularly dental amalgam. Each of the sources of metal can produce artifact in image acquisition, ultimately affecting the accuracy and precision of the CBCT. There is nothing we can due to mitigate this artifact other than understand that it will influence the accuracy of our imaging.

A 3D camera does not emit ionizing radiation to capture an image, it simply uses a combination of 6 static cameras to produce a three-dimensional image. However, we rely heavily on patient compliance in taking images. For example, all patients are asked to be in centric relation (the first contact of the teeth). This was of particular importance in the pre-operative photo before the correction of any malocclusion. It was also challenging to ensure patients were not posturing their lips, particularly in cases where patients had pre-operative lip incompetence. Lip posturing could have not only affected the mouth width and lip thickness from a frontal view, but also the NL and ML angles from a profile view.

Lastly, patient head positioning in each imaging machine could have influenced artifact. In CBCT acquisition, a chin cup and glabellar strap were used in conjunction with laser markers to position patients head appropriately in the machine. While this is functional from a patient alignment perspective, there is a potential for the chin cup to influence mandibular position if untoward pressure is placed on the mandible by the chin cup, or if the head is not in its natural resting position. This is a source of potential error. Furthermore, the head positioning in capturing the 3D photo was critical, as any unnatural head flexion could have exaggerated the amount of ST thickness, particularly at the level of the mandible. With multiple images being taken at different time point by different clinical assistants, consistency of images is challenging, and thus a source of error.

Image importing and overlay in Dolphin®

To analyze the images, they were imported in a third-party software, Dolphin®. All CBCTs were oriented prior to image analysis. Two types of image overlays were preformed to conduct this study: CBCT-CBCT overlay for the HT movement analysis, and the 3D photo-CBCT overlay to perform the ST thickness analysis and the surface ST analysis. Each of these superimpositions required a manual selection of anatomic points by each observer and an auto-superimposition function built into the software. Furthermore, the CBCT-CBCT superimposition was done using the auto-superimposition function on a manually defined area of the base of skull. Both of these overlay processes had multiple steps involved, thus the potential for the introduction of error, and the potential for compounding smaller error into potentially larger error.

Analysis

Another limitation to the study is the fact that only a two dimensional analysis was performed on the three dimensional images captures. All measurement were assumed to be linear, or in one axis. Measurements were not calculated based on an X-Y-Z coordinate system. The study simply looked at the magnitude of movement, and did not consider the direction of movement. A three-dimensional analysis would have been ideal, however, with lack of standardized tissue measurements available, this analysis was not undertaken.

Another limitation with respect to the analysis pertains particularly to ST thickness analysis, where all tissue thickness measurements were taken at the anatomic midline. The anatomic midline was based on the sella turcica, the perpendicular plate of the ethmoid bone and the cribriform plate. It would perhaps had been advantageous to take some ST thickness measurements off of the anatomic midline. However, this proves quite difficult to establish consistency in choosing a consistent HT point across patients. Again, there is no standardized method of tissue evaluation in the literature. There are some other publications that use a heat map to study changes in ST thickness, but because we calculated the thickness in a linear fashion with direct measurement between a HT and corresponding ST landmark, this was not feasible[107–110].

Having no standardized method of tissue evaluation is both a reason for undertaking the study and a shortcoming of the study. Having no consistency within the literature to influence study design is reflected in some of the shortcomings of the analysis.

Inter-relater reliability

The final major weakness of the study is the fact that there was a statistically significant difference in the ST thickness analysis, particularly at points M1 and M7 (A point and menton). This analysis was used in evaluation of the primary outcome: the HT: ST ratio. When this statistical difference was first encountered, the data was re-analyzed twice in an effort to eliminate this statistical discrepancy. Despite the efforts of the research team, the difference persisted. We were thus faced with a decision to accept the statistical differences and amalgamate the ST thickness data sets between observers, or simply use only one observers' data set of the final analysis. In consultation with our statisticians, it was decided that using a single observers' ST thickness data set to analyze the primary outcome was the best course of action.

This impacts the validity of the primary outcome analysis, and is certainly a shortcoming worth highlighting in this study.

Future Directions

There are several takeaways from this study that could help improve its clinical relevance. Improving the sample size and reducing the volume of patient attrition is the most obvious are for improvement. For this study to hold statistical power and to potentially influence treatment decisions in the future, better patient retention and a more even distribution of procedure groups would be needed. The lack of incentive, financial or otherwise, could have easily influenced this factor. However, more organization and efforts with a full-time research assistant could have proved beneficial, particularly from a patient attrition perspective.

It would have also been interesting to track patient's BMI at their post-operative follow ups. Their BMI was calculated on the day of surgery as part of their permanent surgical record. Had we tracked BMI post-operatively, it could have shed some light on the thought that post-operative weight loss could contribute to the variability in soft tissue thickness at different post-operative time points.

Lastly a better overall understanding in using Dolphin® software could have improved this study. This was the writer's first experience with the software, and the first time any surgeon or resident in the department used the software for research purposes. Though on-line learning sessions with the manufacturer was done to gain a fundamental understanding of the software, a more thorough understanding of its capabilities may have provided the research team with a better study design, and more clinically relevant findings. The primary outcome analysis was overall challenging to understand and inefficient. The research team would hope to improve on the use of Dolphin® in any future research.

CHAPTER VII: CONCLUSIONS

The HT: ST ratio does not change significantly following orthognathic surgery, that is, the HT and ST move by the same magnitude during orthognathic surgery.

The NL angle showed the greatest change with maxillary surgery and in males. For every increase in patient's BMI of 1, the change in the NL angle was predicted to increase by 0.32°.

The ML angle changed more in patients in the BSSO treatment group. The alar width increased up to 12 months after surgery, and increased more in patients who underwent LF 1 procedures.

There were minimal changes seen with respect to mouth width, height of the philtrum, and upper and lower lip thicknesses.

REFERENCES

1. Güven Y. Scientific basis of dentistry. *J Istanbul Univ Fac Dent*. 2017;51(3): 64-71.
2. Gandhi, V and Malek F. Orthognathic Surgery and Facial Changes- A Review. *J Orthod Endod*. 2018;4(1):1-3.
3. Hullihen S. Case of Elongation of the under Jaw and Distortion of the Face and Neck, Caused by a Burn, Successfully Treated. *Am J Dent Sci*. 1849;9(2):157-165.
4. Aziz SR. Simon P. Hullihen and the origin of orthognathic surgery. *J Oral Maxillofac Surg*. 2004;62(10):1303-1307.
5. Angle E. Double resection of lower maxilla. *Dent Cosm*. 1898;40:635.
6. Blair V. Operations on the Jaw-bone and Face. *Surg Gynecol Obs*. 1907;4:67.
7. Blair V. Surgery and Diseases of the Mouth and Jaws. In: *Surgery and Diseases of the Mouth and Jaws*. St. Louis Mosby; 1912.
8. Ballin M. Double resection for treatment of mandibular protrusion. *Dent Items*. 1908;30:422.
9. Bell RB. A History of Orthognathic Surgery in North America. *J Oral Maxillofac Surg*. 2018;76:2466-2481.
10. Köle H. Surgical operations on the alveolar ridge to correct occlusal abnormalities. *Oral Surgery, Oral Med Oral Pathol*. 1959;12(5):515-529.
11. Trauner R, Obwegeser H. The surgical correction of mandibular prognathism and retrognathia with consideration of genioplasty. Part I. Surgical procedures to correct mandibular prognathism and reshaping of the chin. *Oral Surgery, Oral*

Med Oral Pathol. 1957;10(7):677-689.

12. Obwegeser, HL and Trauner R. Zur Operationstechnik bei der Progenie und anderer Unterkieferanomalien. *Dtsch Zahn Mund Kieferheilkd*. 1955;23(1).
13. Obwegeser HL. Surgical correction of small or retrodisplaced maxillae: The "dish-face" deformity. *Plast Reconstr Surg*. 1969;43(4):351-365.
14. Buchanan EP, Hyman CH. LeFort i osteotomy. *Semin Plast Surg*. 2013;27(3):149-154.
15. Laskin DM. Contemporary Oral and Maxillofacial Surgery. *Alpha Omegan*. 2009;102(2):45.
16. Monson LA. Bilateral sagittal split osteotomy. *Semin Plast Surg*. 2013;27(3):145-148.
17. Böckmann R, Meyns J, Dik E, Kessler P. The modifications of the sagittal ramus split osteotomy: A literature review. *Plast Reconstr Surg - Glob Open*. 2014;2(12):271.
18. Dal Pont G. Retromolar osteotomy for the correction of prognathism. *J Oral Surg Anesth Hosp Dent Serv*. 1961;12:42-47.
19. Hunsuck EE. A modified intraoral sagittal splitting technic for correction of mandibular prognathism. *J Oral Surg*. 1968;26(4):250-253.
20. Bell WH, Schendel SA. Biologic basis for modification of the sagittal ramus split operation. *J Oral Surg (Chic)*. 1977;35(5):362-369.
21. Cheever D. Displacement of the upper jaw. *Med Surg Rep Bost City Hosp*. 1870;1:156.

22. Wassmund M. Frakuren und Luxationen des Gesichtsschadels. *Leipzig, Ger Meusser*. 1927.

23. Converse JM, Horowitz SL. The surgical-orthodontic approach to the treatment of dentofacial deformities. *Am J Orthod*. 1969;55(3):217-243.

24. Lee EI. Aesthetic alteration of the chin. *Semin Plast Surg*. 2013;27(3)155-160.

25. Hoenig JF. Sliding osteotomy genioplasty for facial aesthetic balance: 10 Years of experience. *Aesthetic Plast Surg*. 2007;31(4):384-391.

26. Rosen HM. Aesthetic guidelines in genioplasty: The role of facial disproportion. *Plast Reconstr Surg*. 1995;95(3):463-469.

27. Alvarez CM, Lessin ME, Gross PD. Mandibular advancement combined with horizontal advancement genioplasty for the treatment of obstructive sleep apnea in an edentulous patient. A case report. *Oral Surgery, Oral Med Oral Pathol*. 1987;64(4):402-406.

28. Bruno Carlo B, Mauro P, Silvia B, Enrico S. Modified Genioplasty and Bimaxillary Advancement for Treating Obstructive Sleep Apnea Syndrome. *J Oral Maxillofac Surg*. 2008;66(9):1971-1974.

29. Nadjmi N, Van Roy S, Van De Casteele E. Minimally Invasive Genioplasty Procedure. *Plast Reconstr Surg - Glob Open*. 2017;5(11):1575.

30. Park JW, Choung PH, Kho HS, Kim YK, Chung JW. A comparison of neurosensory alteration and recovery pattern among different types of orthognathic surgeries using the current perception threshold. *Oral Surgery, Oral Med Oral Pathol Oral Radiol Endodontology*. 2011;111(1):24-33.

31. D’Agostino A, Trevisiol L, Gugole F, Bondí V, Nocini PF. Complications of orthognathic surgery: The inferior alveolar nerve. *J Craniofac Surg*. 2010;21(4):1189-1195.

32. Van Sickels JE, Hatch JP, Dolce C, Bays RA, Rugh JD. Effects of age, amount of advancement, and genioplasty on neurosensory disturbance after a bilateral sagittal split osteotomy. *J Oral Maxillofac Surg*. 2002;60(9):1012-1017.

33. McLeod NMH, Bowe DC. Nerve injury associated with orthognathic surgery. Part 2: Inferior alveolar nerve. *Br J Oral Maxillofac Surg*. 2016;54:366-371.

34. Gianni AB, D’Orto O, Biglioli F, Bozzetti A, Brusati R. Neurosensory alterations of the inferior alveolar and mental nerve after genioplasty alone or associated with sagittal osteotomy of the mandibular ramus. *J Cranio-Maxillofacial Surg*. 2002;30(5):295-303.

35. Alolayan AB. Neurosensory Recovery of the Infra-Orbital Nerve Following Maxillary Orthognathic Surgery. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2015;120(5):202.

36. Mensink G, Verweij JP, Frank MD, Eelco Bergsma J, Richard Van Merkesteyn JP. Bad split during bilateral sagittal split osteotomy of the mandible with separators: A retrospective study of 427 patients. *Br J Oral Maxillofac Surg*. 2013;51(6):525-529.

37. Chrcanovic BR, Freire-Maia B. Risk factors and prevention of bad splits during sagittal split osteotomy. *Oral Maxillofac Surg*. 2012;16(1):19-27.

38. O’Ryan F, Poor DB. Completing sagittal split osteotomy of the mandible after

fracture of the buccal plate. *J Oral Maxillofac Surg*. 2004;62(9):1175-1176.

39. Witherow H, Offord D, Eliahoo J, Stewart A. Postoperative fractures of the lingual plate after bilateral sagittal split osteotomies. *Br J Oral Maxillofac Surg*. 2006;44(4):269-300.

40. Steenen SA, Becking AG. Bad splits in bilateral sagittal split osteotomy: Systematic review of fracture patterns. *Int J Oral Maxillofac Surg*. 2016;45(7):887-897.

41. Teltzrow T, Kramer FJ, Schulze A, Baethge C, Brachvogel P. Perioperative complications following sagittal split osteotomy of the mandible. *J Cranio-Maxillofacial Surg*. 2005;33(5):307-313.

42. Kim YK. Complications associated with orthognathic surgery. *J Korean Assoc Oral Maxillofac Surg*. 2017;43(1):3-15.

43. Thastum M, Andersen K, Rude K, Nørholt SE, Blomlöf J. Factors influencing intraoperative blood loss in orthognathic surgery. *Int J Oral Maxillofac Surg*. 2016;45(9):1070-1073.

44. Bertolini F, Russo V, Sansebastiano G. Pre- and postsurgical psycho-emotional aspects of the orthognathic surgery patient. *Int J Adult Orthodon Orthognath Surg*. 2000;15(1):16-23.

45. Murphy C, Kearns G, Sleeman D, Cronin M, Allen PF. The clinical relevance of orthognathic surgery on quality of life. *Int J Oral Maxillofac Surg*. 2011;40(9):926-930.

46. Rustemeyer J, Gregersen J. Quality of Life in orthognathic surgery patients: Post-

surgical improvements in aesthetics and self-confidence. *J Cranio-Maxillofacial Surg*. 2012;40(5):400-404.

47. Nicodemo D, Pereira MD, Ferreira LM. Effect of orthognathic surgery for class III correction on quality of life as measured by SF-36. *Int J Oral Maxillofac Surg*. 2008;37(2):131-134.

48. Motegi E, Hatch JP, Rugh JD, Yamaguchi H. Health-related quality of life and psychosocial function 5 years after orthognathic surgery. *Am J Orthod Dentofac Orthop*. 2003;124(2):138-143.

49. Bui KK, Rinchuse DJ, Zullo TG, Cozzani M. Perception of facial attractiveness following modification of the nose and teeth. *Int Orthod*. 2015;13(2):195-209.

50. Macgregor FC. Facial disfigurement: problems and management of social interaction and implications for mental health. *Aesthetic Plast Surg*. 1990;14(4):249-257.

51. Soh CL, Narayanan V. Quality of life assessment in patients with dentofacial deformity undergoing orthognathic surgery - A systematic review. *Int J Oral Maxillofac Surg*. 2013;42(8):974-980.

52. Kaur P, Singh S, Mathur A, et al. Impact of dental disorders and its influence on self esteem levels among adolescents. *J Clin Diagnostic Res*. 2017;11(4):5-8.

53. Siow KK, Ong ST, Lian CB, Ngeow WC. Satisfaction of orthognathic surgical patients in a Malaysian population. *J Oral Sci*. 2002;44(3-4):165-171.

54. Modig M, Andersson L, Wårdh I. Patients' perception of improvement after orthognathic surgery: Pilot study. *Br J Oral Maxillofac Surg*. 2006;44(1):24-27.

55. Algudkar A, Lim B, Fan K, Bentley R. Sustained bilateral middle ear effusions post orthognathic surgery successfully treated with grommet insertion. *JRSM Short Rep*. 2013;4(9):1-4.

56. Davis CM, Gregoire CE, Steeves TW, Demsey A. Prevalence of surgical site infections following orthognathic surgery: A retrospective cohort analysis. *J Oral Maxillofac Surg*. 2016;74(6):1199-1206.

57. Dujoncquoy JP, Ferri J, Raoul G, Kleinheinz J. Temporomandibular joint dysfunction and orthognathic surgery: A retrospective study. *Head Face Med*. 2010;6(1):27.

58. Ahn YS, Kim SG, Baik SM, et al. Comparative Study Between Resorbable and Nonresorbable Plates in Orthognathic Surgery. *J Oral Maxillofac Surg*. 2010;68(2):287-292.

59. Agnihotry A, Fedorowicz Z, Nasser M, Gill KS. Resorbable versus titanium plates for orthognathic surgery. *Cochrane Database Syst Rev*. 2017;11:1-27.

60. Kanno T, Sukegawa S, Furuki Y, Nariai Y, Sekine J. Overview of innovative advances in bioresorbable plate systems for oral and maxillofacial surgery. *Jpn Dent Sci Rev*. 2018;54(3):127-138.

61. Yoshioka I, Igawa K, Nagata J, et al. Comparison of material-related complications after bilateral sagittal split mandibular setback surgery: Biodegradable versus titanium miniplates. *J Oral Maxillofac Surg*. 2012;70(4):919-924.

62. Consolo U, Salgarelli A. Transient facial nerve palsy following orthognathic

surgery: A case report. *J Oral Maxillofac Surg*. 1992;50(1):77-79.

63. de Vries K, Devriese PP, Hovinga J, van den Akker HP. Facial palsy after sagittal split osteotomies. A survey of 1747 sagittal split osteotomies. *J Cranio-Maxillofacial Surg*. 1993;21(2):50-53.

64. Choi BK, Goh RCW, Chen PKT, Chuang DCC, Lo LJ, Chen YR. Facial Nerve Palsy After Sagittal Split Ramus Osteotomy of the Mandible: Mechanism and Outcomes. *J Oral Maxillofac Surg*. 2010;68(7):1615-1621.

65. Khamashta-Ledezma L, Naini FB, Manisalı M. Review of nasal changes with maxillary orthognathic surgery. *J Istanbul Univ Fac Dent*. 2017;51(3):52-61.

66. Dantas WRM, da Silveira MMF, do Egito Vasconcelos BC, Porto GG. Evaluation of the nasal shape after orthognathic surgery. *Braz J Otorhinolaryngol*. 2015;81(1):19-23.

67. Yamada T, Mishima K, Moritani N, et al. Nasolabial morphologic changes after a le fort i osteotomy: A three-dimensional anthropometric study. *J Craniofac Surg*. 2010;21(4):1089-1095.

68. DeSesa CR, Metzler P, Sawh-Martinez R, Steinbacher DM. Three-dimensional nasolabial morphologic alterations following Le Fort I. *Plast Reconstr Surg - Glob Open*. 2016;4(8):1-9.

69. Jeong HI, Lee HS, Jung YS, Park HS, Jung HD. Nasal Soft Tissue Change Following Bimaxillary Orthognathic Surgery. *J Craniofac Surg*. 2017;28(7):605-608.

70. Bendor-Samuel R, Chen YR, Chen PT, Miller NR. Unusual complications of the le

fort i osteotomy. *Plast Reconstr Surg*. 1995;96(6):1297.

71. Lanigan DT, West RA. Management of postoperative hemorrhage following the Le Fort I maxillary osteotomy. *J Oral Maxillofac Surg*. 1984;42(6):367-375.

72. de Mol van Otterloo JJ, Tuinzing DB, Greebe RB, van der Kwast WAM. Intra- and early postoperative complications of the le fort I osteotomy. A retrospective study on 410 cases. *J Cranio-Maxillofacial Surg*. 1991;19(5):217-222.

73. Kramer, FJ., Baethge, C., Swennen, G., Teltzrow, T., Schulze, A., Brenten, J., Brachvogel P. Intra and perioperative complications of the Le Fort I osteotomy: a prospective evaluation of 1,000 patients. *J Craniofac Surg*. 2004;15:971-977.

74. Valstar MH, Baas EM, Te Rijdt JP, De Bondt BJ, Laurens E, De Lange J. Maxillary sinus recovery and nasal ventilation after le Fort i osteotomy: A prospective clinical, endoscopic, functional and radiographic evaluation. *Int J Oral Maxillofac Surg*. 2013;42(11):1431-1436.

75. Sirikumara M, Sugar AW. Adie's pupil following le fort i maxillary osteotomy. A complication or coincidence? *Br J Oral Maxillofac Surg*. 1990;28)5):306-308.

76. Proffit WR, Turvey TA, Phillips C. The hierarchy of stability and predictability in orthognathic surgery with rigid fixation: An update and extension. *Head Face Med*. 2007;3(1):1-11.

77. Peacock ZS, Lee CCY, Klein KP, Kaban LB. Orthognathic surgery in patients over 40 years of age: Indications and special considerations. *J Oral Maxillofac Surg*. 2014;72(10):1995-2004.

78. Verweij JP, Mensink G, Fiocco M, Van Merkesteyn JPR. Incidence and recovery of neurosensory disturbances after bilateral sagittal split osteotomy in different age groups: A retrospective study of 263 patients. *Int J Oral Maxillofac Surg*. 2016;45(7):898-903.

79. Ylikontiola L, Kinnunen J, Oikarinen K. Factors affecting neurosensory disturbance after mandibular bilateral sagittal split osteotomy. *J Oral Maxillofac Surg*. 2000;58(11):1234-1239.

80. Brecher, E., Viswanath, M., Finkelman, M., Papageorge M. Is age a risk factor for orthognathic surgery complications? *Int J Oral Maxillofac Surg*. 2019;48:247.

81. Olate S, Sigua E, Asprino L, De Moraes M. Complications in Orthognathic Surgery. *J Craniofac Surg*. 2018;29(2):158-161.

82. Parkin L, Sweetland S, Balkwill A, Green J, Reeves G, Beral V. Body mass index, surgery, and risk of venous thromboembolism in middle-aged women: A cohort study. *Circulation*. 2012;125(15):1897-1904.

83. Romero-Corral A, Caples SM, Lopez-Jimenez F, Somers VK. Interactions between obesity and obstructive sleep apnea: Implications for treatment. *Chest*. 2010;137(3):711-719.

84. Den Herder C, Schmeck J, Appelboom DJK, De Vries N. Risks of general anaesthesia in people with obstructive sleep apnoea. *Br Med J*. 2004;329(7472):955-959.

85. Dority J, Hassan ZU, Chau D. Anesthetic implications of obesity in the surgical patient. *Clin Colon Rectal Surg*. 2011;24(04):222-228.

86. Erbe C, Mulié RM, Ruf S. Advancement genioplasty in Class i patients: Predictability and stability of facial profile changes. *Int J Oral Maxillofac Surg*. 2011;40(11):1258-1262.

87. Lo LJ, Weng JL, Ho CT, Lin HH. Three-dimensional region-based study on the relationship between soft and hard tissue changes after orthognathic surgery in patients with prognathism. *PLoS One*. 2018;13(8):1-15.

88. Chen CM, Lai S, Lee HE, Chen KK, Hsu KJ. Soft-tissue profile changes after orthognathic surgery of mandibular prognathism. *Kaohsiung J Med Sci*. 2012;28(4):216-219.

89. Tiwari R, Chakravarthi PS, Kattimani VS, Lingamaneni KP. A Perioral Soft Tissue evaluation after Orthognathic Surgery Using Three-Dimensional Computed Tomography Scan. *Open Dent J*. 2018;12(1):366-376.

90. Storms AS, Miclotte A, Grosjean L, et al. Short-term hard and soft tissue changes after mandibular advancement surgery in Class II patients: A retrospective cephalometric study. *Eur J Orthod*. 2017;39(5):567-576.

91. Yeo BY, Kim JS, Kim J, Kim JY, Jang WW, Kang YG. Submandibular soft tissue changes after mandibular set-back surgery in skeletal Class III patients. *J Stomatol Oral Maxillofac Surg*. 2019;120(4):301-309.

92. Knoops PGM, Borghi A, Ruggiero F, et al. A novel soft tissue prediction methodology for orthognathic surgery based on probabilistic finite element modelling. *PLoS One*. 2018;13(5):1-15.

93. Almeida RC, Cevidanes LHS, Carvalho FAR, et al. Soft tissue response to

mandibular advancement using 3D CBCT scanning. *Int J Oral Maxillofac Surg*. 2011;40:353-359.

94. Lines PA, Steinhauser EW. Diagnosis and treatment planning in surgical orthodontic therapy. *Am J Orthod*. 1974;66(4):378-397.

95. Hammoudeh JA, Howell LK, Boutros S, Scott MA, Urata MM. Current status of surgical planning for orthognathic surgery: Traditional methods versus 3D surgical planning. *Plast Reconstr Surg - Glob Open*. 2015;3(2):1-10.

96. Swennen GRJ, Mollemans W, Schutyser F. Three-Dimensional Treatment Planning of Orthognathic Surgery in the Era of Virtual Imaging. *J Oral Maxillofac Surg*. 2009;67(10):2080-2092.

97. Shaheen E, Sun Y, Jacobs R, Politis C. Three-dimensional printed final occlusal splint for orthognathic surgery: design and validation. *Int J Oral Maxillofac Surg*. 2017;46(1):67-71.

98. Stokbro K, Thygesen T. A 3-Dimensional Approach for Analysis in Orthognathic Surgery—Using Free Software for Voxel-Based Alignment and Semiautomatic Measurement. *J Oral Maxillofac Surg*. 2018;76(6):1316-1326.

99. Efanov JI, Roy AA, Huang KN, Borsuk DE. Virtual surgical planning: The Pearls and pitfalls. *Plast Reconstr Surg - Glob Open*. 2018;6(1):1-10.

100. Magro-Filho O, Magro-Érnica N, Queiroz TP, Aranega AM, Garcia IR. Comparative study of 2 software programs for predicting profile changes in Class III patients having double-jaw orthognathic surgery. *Am J Orthod Dentofac Orthop*. 2010;137(4):1-5.

101. Marchetti C, Bianchi A, Muyldermans L, Di Martino M, Lancellotti L, Sarti A. Validation of new soft tissue software in orthognathic surgery planning. *Int J Oral Maxillofac Surg*. 2011;40(1):26-32.

102. Jaisinghani S, Adams NS, Mann RJ. Virtual Surgical Planning in Orthognathic Surgery. *Interesting Case Series.* 2017;36(Fig 1):127-132.

103. Farrell BB, Franco PB, Tucker MR. Virtual surgical planning in orthognathic surgery. *Oral Maxillofac Surg Clin North Am*. 2014;26(4):459-473.

104. Ahmad Akhoundi MS, Shirani G, Arshad M, Heidar H, Sodagar A. Comparison of an imaging software and manual prediction of soft tissue changes after orthognathic surgery. *J Dent (Tehran)*. 2012;9(3):178-187.

105. Hwang JJ, Kim KD, Park H, Park CS, Jeong HG. Factors influencing superimposition error of 3D cephalometric landmarks by plane orientation method using 4 reference points: 4 point superimposition error regression model. *PLoS One*. 2014;9(1):1-10.

106. Weiss R, Read-Fuller A. Cone Beam Computed Tomography in oral and maxillofacial surgery: An evidence-based review. *Dent J*. 2019;7(2):1-23.

107. Baik HS, Kim SY. Facial soft-tissue changes in skeletal Class III orthognathic surgery patients analyzed with 3-dimensional laser scanning. *Am J Orthod Dentofac Orthop*. 2010;138(2):167-178.

108. Betts NJ, Dowd KF. Soft tissue changes associated with orthognathic surgery. *Atlas Oral Maxillofac Surg Clin North Am*. 2000;8(2):13-38.

109. Lo LJ, Weng JL, Ho CT, Lin HH. Three-dimensional region-based study on the

relationship between soft and hard tissue changes after orthognathic surgery in patients with prognathism. *PLoS One*. 2018;13(8):1-15.

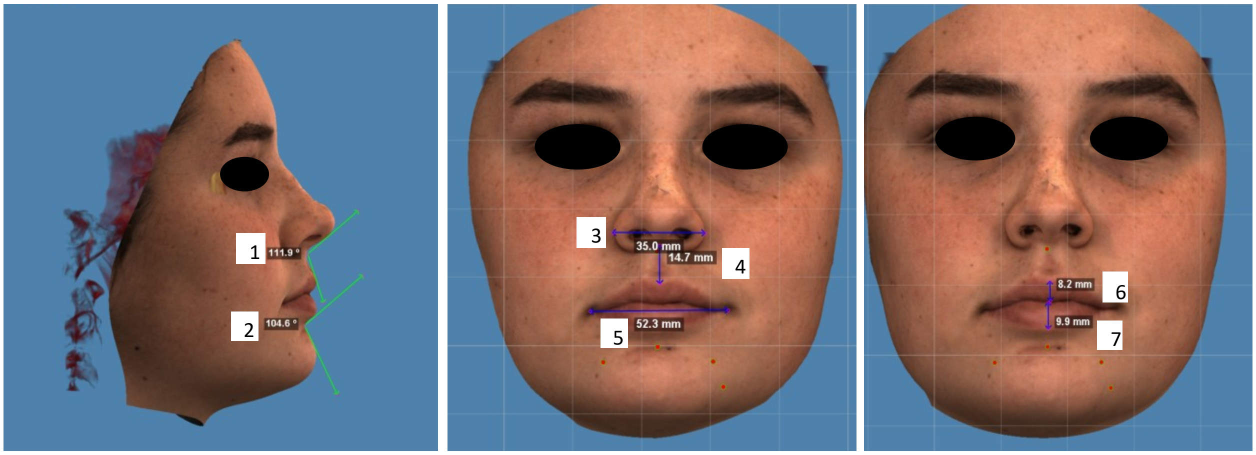
110. Ferrario VF, Sforza C, Schmitz JH, Santoro F. Three-dimensional facial morphometric assessment of soft tissue changes after orthognathic surgery. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*. 1999;88(5):549-556.

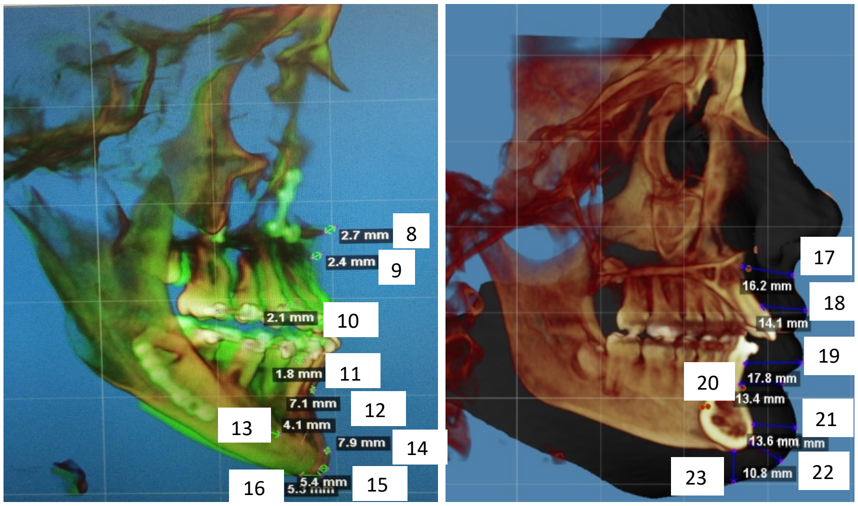
111. Jean S, Dionne PL, Bouchard C, Giasson L, Turgeon AF. Perioperative Systemic Corticosteroids in Orthognathic Surgery: A Systematic Review and Meta-Analysis. *J Oral Maxillofac Surg*. 2017;75(12):2638-2649.

APPENDICES

APPENDIX 1: Anatomic points used in data analysis with numbering legend

The anatomic points used in the soft tissue thickness, hard tissue movement, and soft tissue changes analyses by numeric reference.

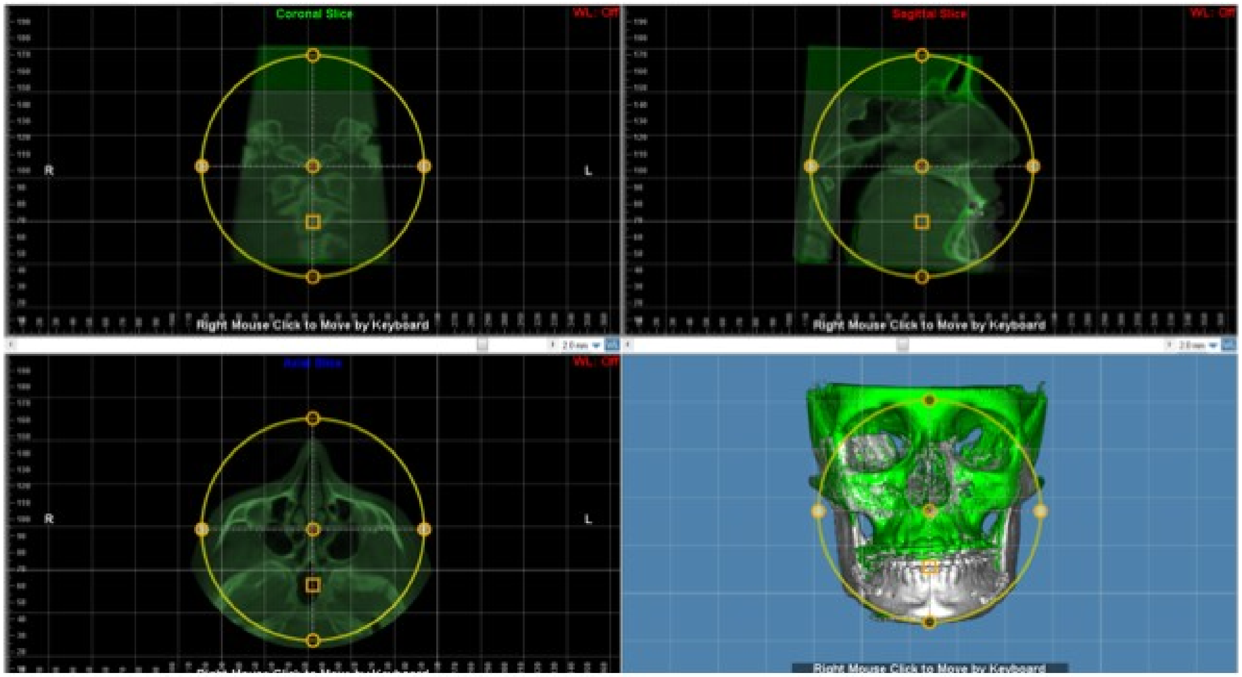


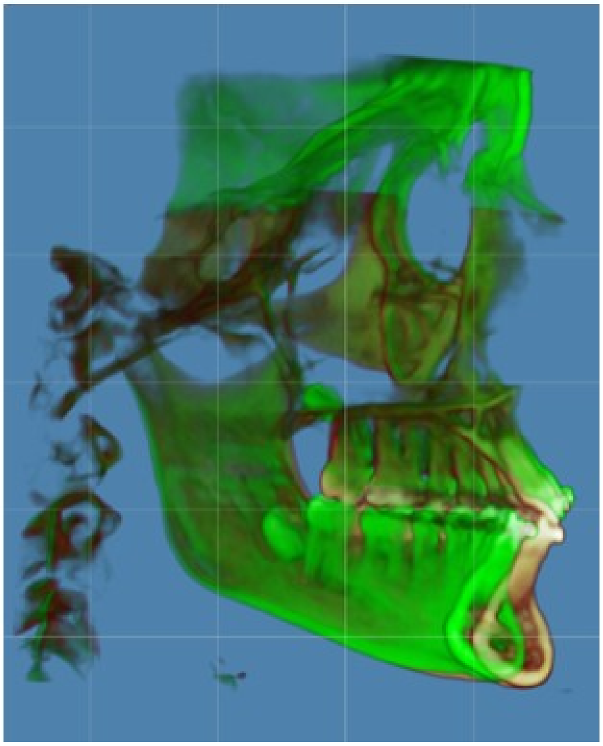


1. Nasolabial angle
2. Mentolabial angle
3. Alar width
4. Philtrum height
5. Mouth width
6. Upper lip thickness
7. Lower lip thickness
8. Anterior nasal spine
9. HT A Point
10. Maxillary CEJs
11. Mandibular CEJs
12. HT B Point
13. Mandibular tubercles
14. Pogonion (Po)
15. Gnathion (Gn)
16. Menton (Me)
17. HT A Point → ST A Point
18. HT Max CEJ → ST labrare superius
19. HT Man CEJ → ST labrare inferius
20. HT B Point → ST B Point
21. HT Po → ST Po
22. HT Gn → ST Gn
23. HT Me → HT Me

APPENDIX 2: HT superimposition in Dolphin Imaging Software.

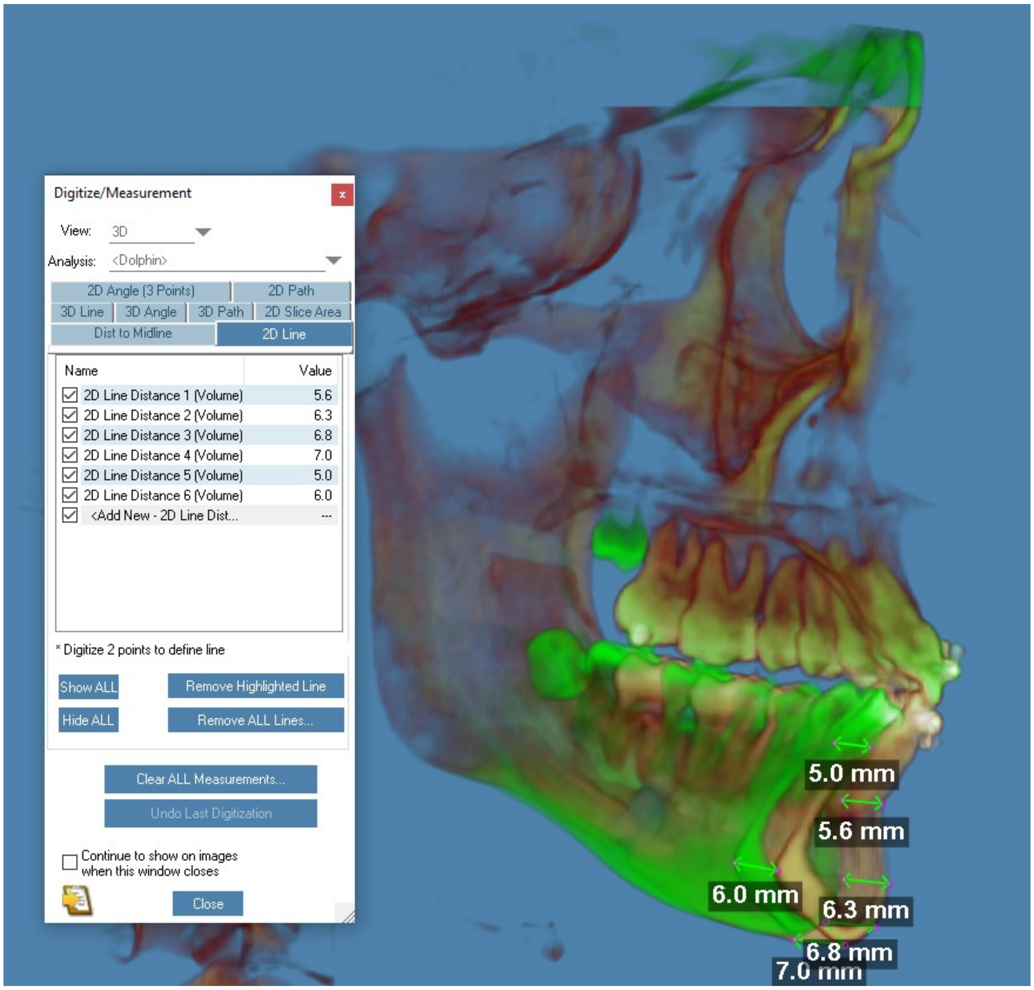
The preoperative CBCT was superimposed over the post-operative CBCT using the auto-superimposition function and the patient's base of skull.





APPENDIX 3: HT movement calculation

This diagram shows the hard tissue measurement calculations for the mandibular hard tissue points



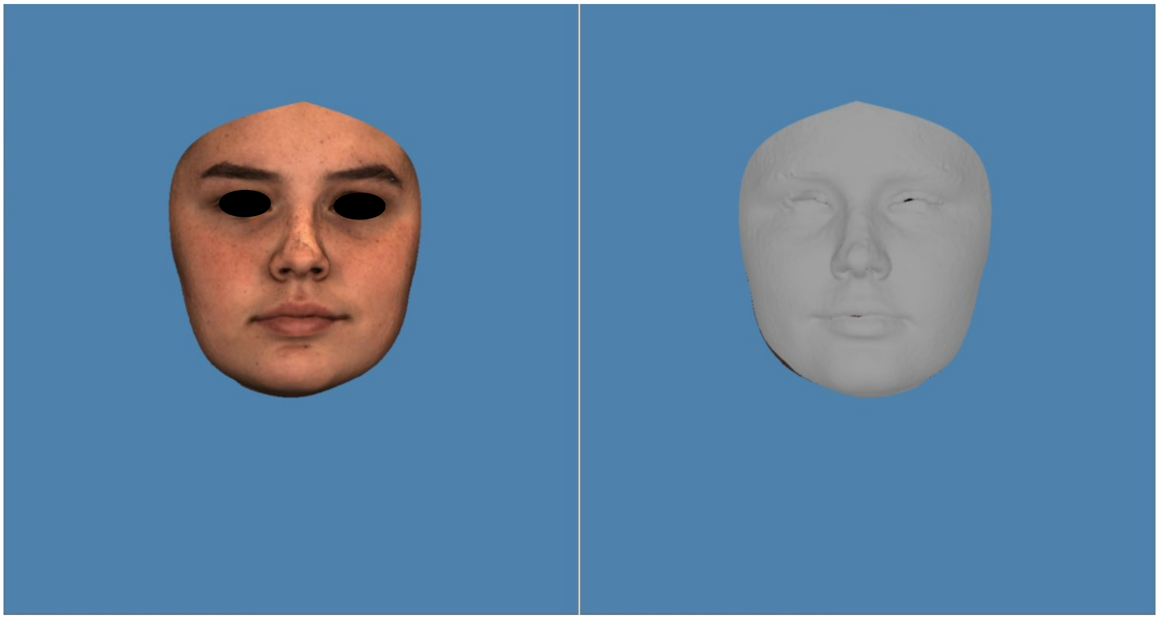
View: 3D

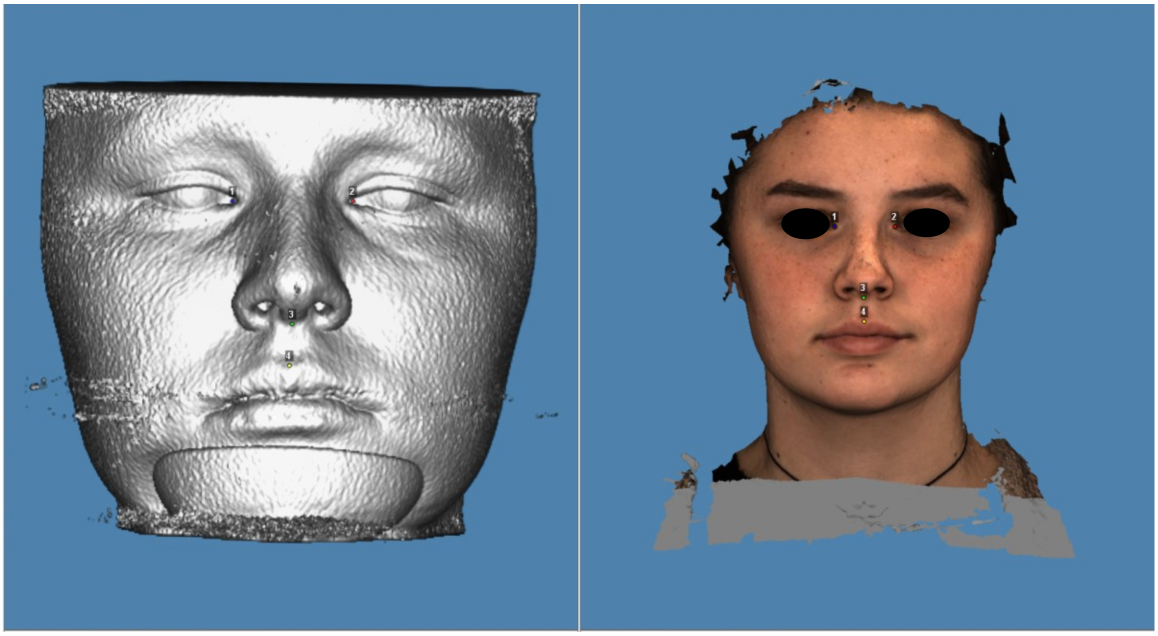
Analysis: <Dolphin>

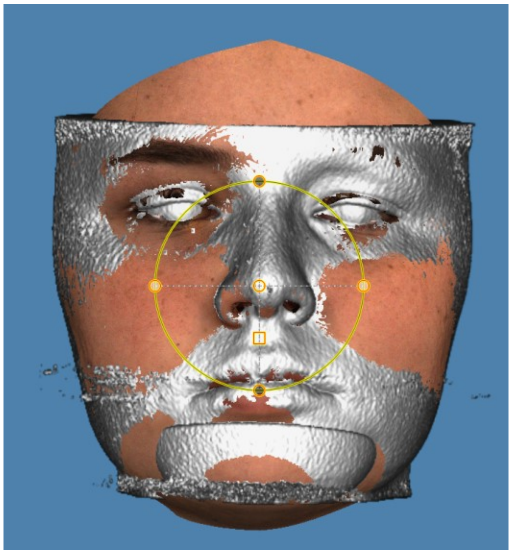
Name	Value
☑ 2D Line Distance 1 (Volume)	5.6
☑ 2D Line Distance 2 (Volume)	6.3
☑ 2D Line Distance 3 (Volume)	6.8
☑ 2D Line Distance 4 (Volume)	7.0
☑ 2D Line Distance 5 (Volume)	5.0
☑ 2D Line Distance 6 (Volume)	6.0
☑ <Add New - 2D Line Dist...	---

APPENDIX 4: ST superimposition in Dolphin Imaging Software

Images were superimposed by selecting pre-determined soft tissue landmarks on the face that were not affected by the operation. Some examples include the medial canthi, the philtrum and the junction of the lower lateral cartilage and the nasal sill. Images were cropped prior to superimposition to increase accuracy.

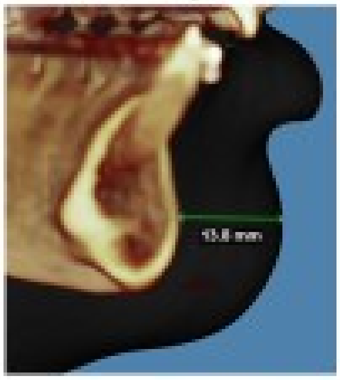



1
2
3
4
1
2
3
4

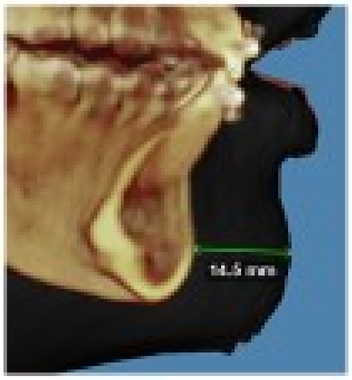


APPENDIX 5: Calculation of the HT: ST ratio

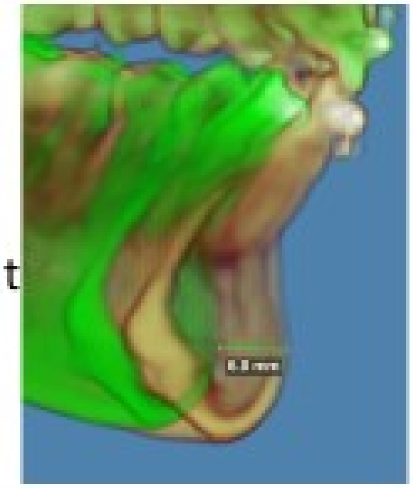
Pre – op ST



Post – op ST



HT Movement



- Change in ST thickness = 0.7mm
    - Post-thickness – pre-thickness
- HT movement = 6.8mm
- ST movement = HT movement + Δ ST Thickness
    - ST movement = 6.8mm + 0.7mm
- 7.5mm / 6.8mm = 1.10
- Therefore, the HT: ST = 1: 1.10

APPENDIX 6: ST analysis calculation example

Digitize/Measurement

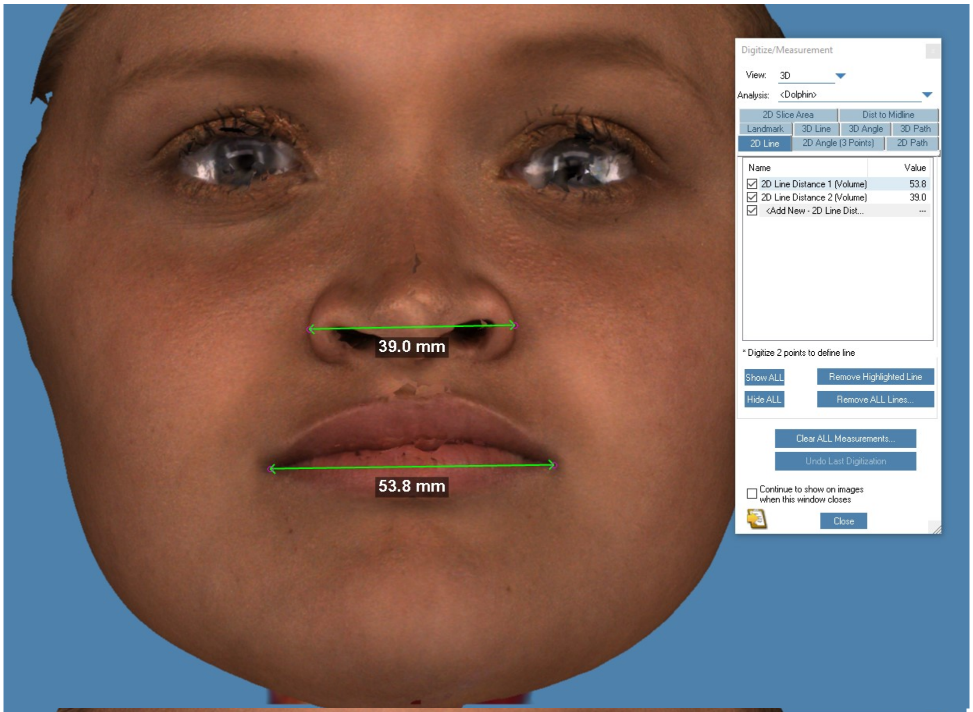
View: 3D

Analysis: <Dolphin>

Name	Value
☑ 2D Angle (3-Point) 1 (Volu...	63.9
☑ 2D Angle (3-Point) 2 (Volu...	99.2
☑ <Add New - 2D Angle (3-...	---

* Digitize 3 points to define angle

☐ Continue to show on images when this window closes



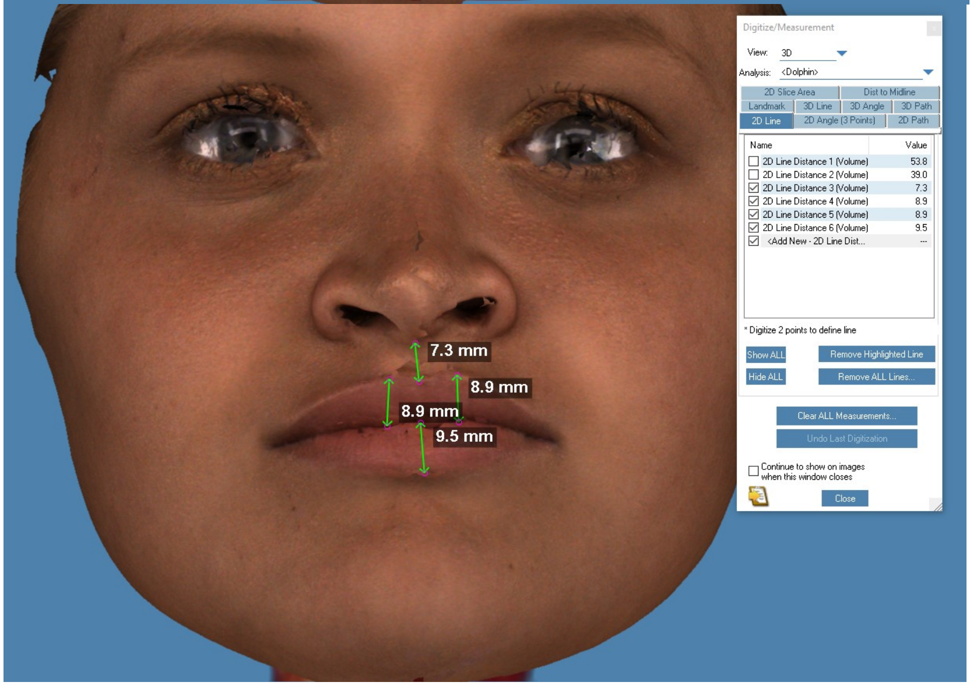
View: 3D

Analysis: <Dolphin>

	Name	Value
☑	2D Line Distance 1 (Volume)	53.8
☑	2D Line Distance 2 (Volume)	39.0
☑	<Add New - 2D Line Dist...	---

* Digitize 2 points to define line

☐ Continue to show on images when this window closes



View: 3D

Analysis: <Dolphin>

	Name	Value
☐	2D Line Distance 1 (Volume)	53.8
☐	2D Line Distance 2 (Volume)	39.0
☑	2D Line Distance 3 (Volume)	7.3
☑	2D Line Distance 4 (Volume)	8.9
☑	2D Line Distance 5 (Volume)	8.9
☑	2D Line Distance 6 (Volume)	9.5
☑	<Add New - 2D Line Dist...	---

* Digitize 2 points to define line

☐ Continue to show on images when this window closes

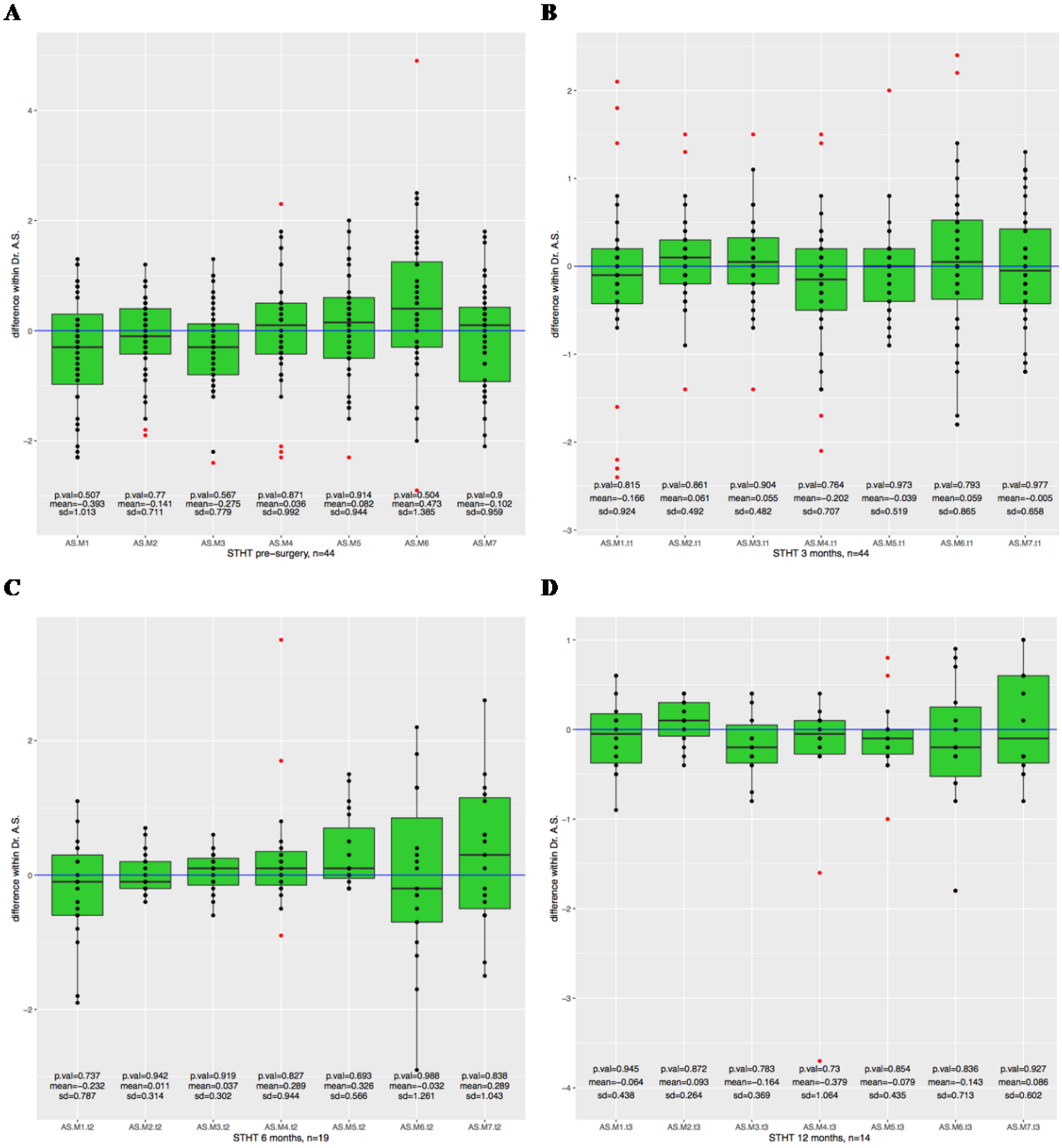
APPENDIX 7: Patient information summary

Patient ID	Procedure	Age	Sex	Height (cm)	Weight (kg)	BMI	ASA
OMFS201801	BSSO	14	F	156	59	24.2	2
OMFS201802	BSSO	16	F	162	70.5	26.9	1
OMFS201803	LeFort I, BSSO	26	F	158	58	23.2	1
OMFS201804	LeFort I	29	M	180	114	35.2	1
OMFS201805	LeFort I, BSSO	37	F	150	142	63.1	2
OMFS201806	LeFort I, BSSO	36	M	178	98	30.9	1
OMFS201807	LeFort I, BSSO, FG	58	F	161	92	35.5	2
OMFS201808	BSSO	15	M	177	70	22.3	1
OMFS201809	LeFort I, BSSO	26	M	189	86	24.1	1
OMFS201810	BSSO	20	M	169	67	23.5	1
OMFS201811	LeFort I, BSSO	39	M	178	78	24.6	2
OMFS201812	LeFort I, BSSO	17	F	159	60	23.7	1
OMFS201813	LeFort I	21	M	175	97	31.7	1
OMFS201814	LeFort I, BSSO	29	F	163	55	20.7	1
OMFS201815	LeFort I, BSSO	39	M	180	87.5	27	2
OMFS201816	BSSO	20	M	176	53.3	17.3	1
OMFS201817	LeFort I, BSSO	27	F	157	88	35.7	1
OMFS201818	LeFort I, BSSO, FG	33	F	159	95.7	37.9	2
OMFS201819	LeFort I, BSSO	16	F	172	62	21	1
OMFS201820	LeFort I	47	M	177.8	90	28.47	1
OMFS201821	BSSO	17	F	164	57.5	21.4	1
OMFS201822	LeFort I, BSSO	53	M	190.5	87	24	2
OMFS201823	LeFort I, BSSO	16	F	168	58	20.5	1
OMFS201824	LeFort I	38	F	169	104.5	36.6	2
OMFS201825	BSSO	52	M	175	93.6	30.6	1

Patient ID	Procedure	Age	Sex	Height (cm)	Weight (kg)	BMI	ASA
OMFS201826	LeFort I	17	F	166	65.1	23.6	1
OMFS201827	BSSO	16	F	162	83	31.6	2
OMFS201828	LeFort I, BSSO	34	F	152.4	47.5	20.5	2
OMFS201829	BSSO	17	F	173	65	21.7	1
OMFS201830	LeFort I, BSSO	31	F	156	46	18.9	1
OMFS201831	LeFort I	47	M	177.8	90	28.47	2
OMFS201832	LeFort I, BSSO, FG	20	M	172	72	24.3	2
OMFS201833	LeFort 1, BSSO, FG	17	F	153	48	20.5	3
OMFS201834	LeFort I, BSSO	16	F	161	64	24.7	1
OMFS201835	LeFort I, BSSO	20	F	170	66.5	23	1
OMFS201836	LeFort I	32	F	166	125	45.4	2
OMFS201837	LeFort , BSSO	34	F	169	64	22.4	1
OMFS201838	BSSO, FG	42	F	154.5	68.7	28.8	2
OMFS201839	LeFort I, BSSO	28	F	156.5	72.6	29.6	1
OMFS201840	LeFort I, BSSO	26	F	156	65	26.7	2
OMFS201841	LeFort I, BSSO	19	M	190.5	99	27.3	1
OMFS201842	LeFort I, BSSO	21	M	173	93	31.1	1
OMFS201843	BSSO, FG	39	M	190.5	130	35.8	2
OMFS201844	LeFort I, BSSO	30	F	174	93	30.7	1

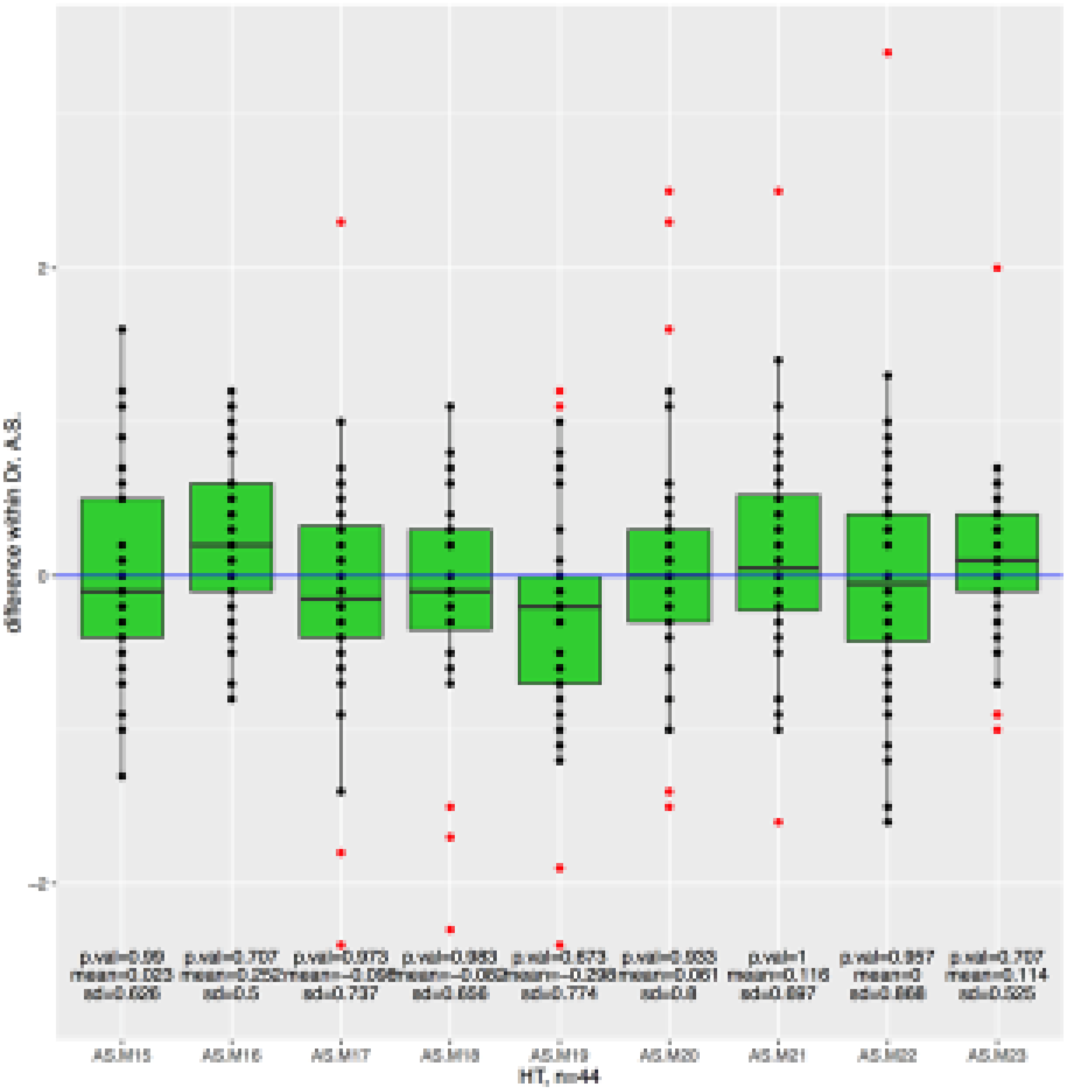
APPENDIX 8: Intra-observer reliability testing for the soft tissue thickness measured by observer 1.

Box plots represent the difference in the repeated measurements by observer 1 (Dr. A.S) from the hard to the soft tissue landmarks across the four times points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p-value greater than 0.1. No statistically significant difference was found within the two analyses performed by observer 1.



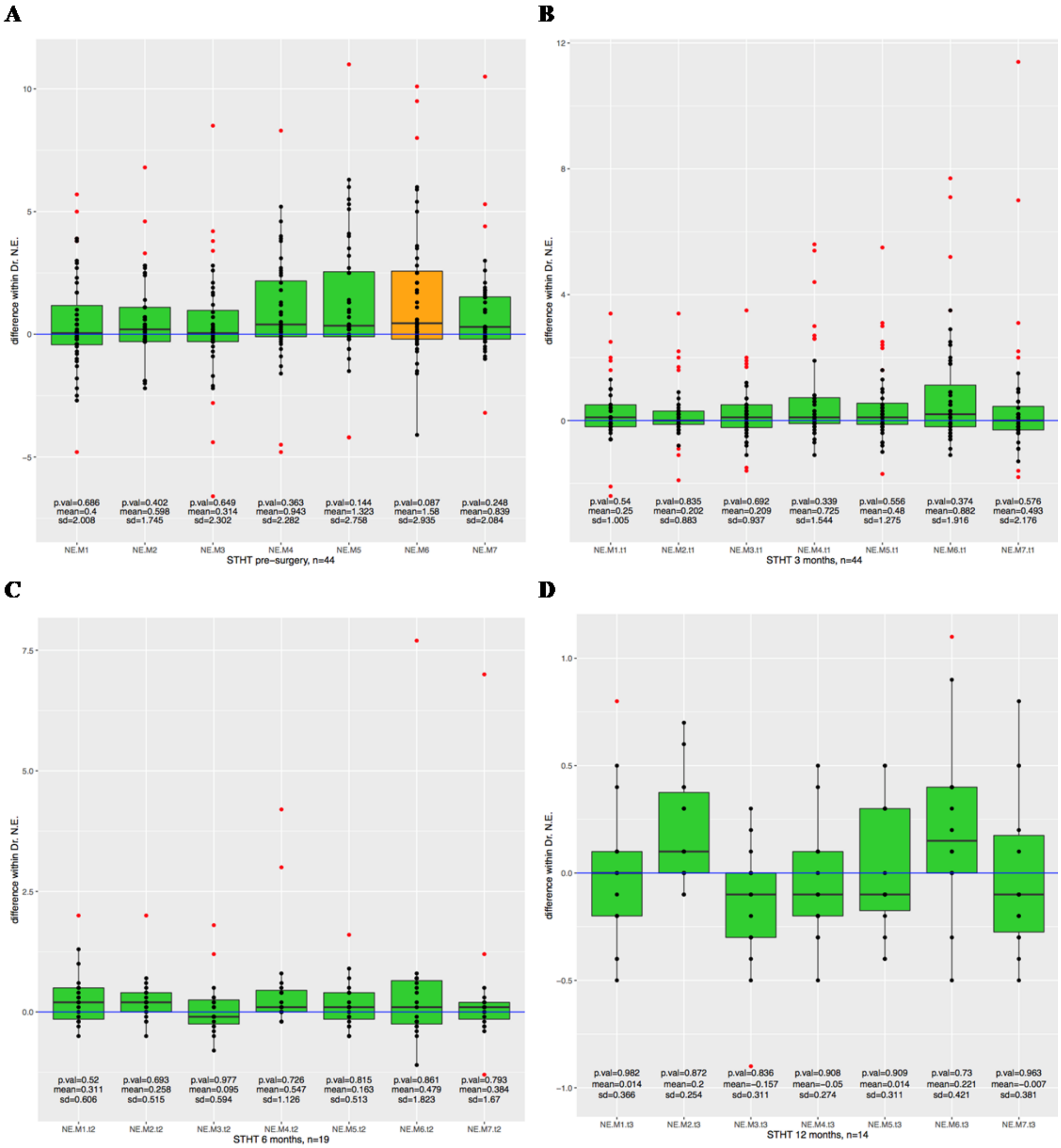
APPENDIX 9: Intra-operator reliability testing for hard tissue measurements performed by observer 1.

Box plots represent the repeated measurements by observer 1 (Dr. A.S) from the hard tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p- value greater than 0.1. No statistically significant difference was found within the two analyses performed by observer 1.



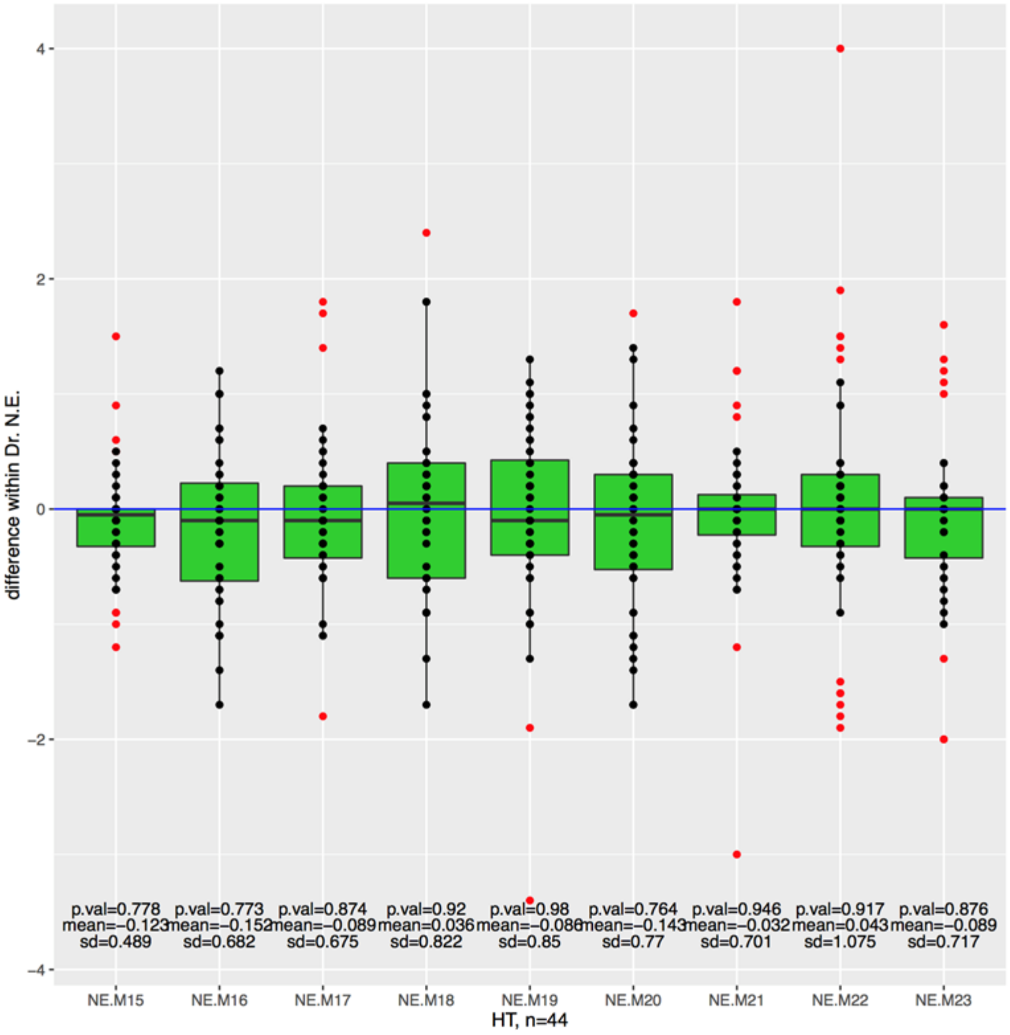
APPENDIX 10: Intra-observer reliability testing for the soft tissue thickness measured by observer 2.

Box plots represent the repeated measurements by observer 2 (Dr. N.E) from the hard to soft tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p-value greater than 0.1. The orange color represents a p-value between 0.05 and 0.1. No statistically significant difference was found within the two analyses performed by observer 2.



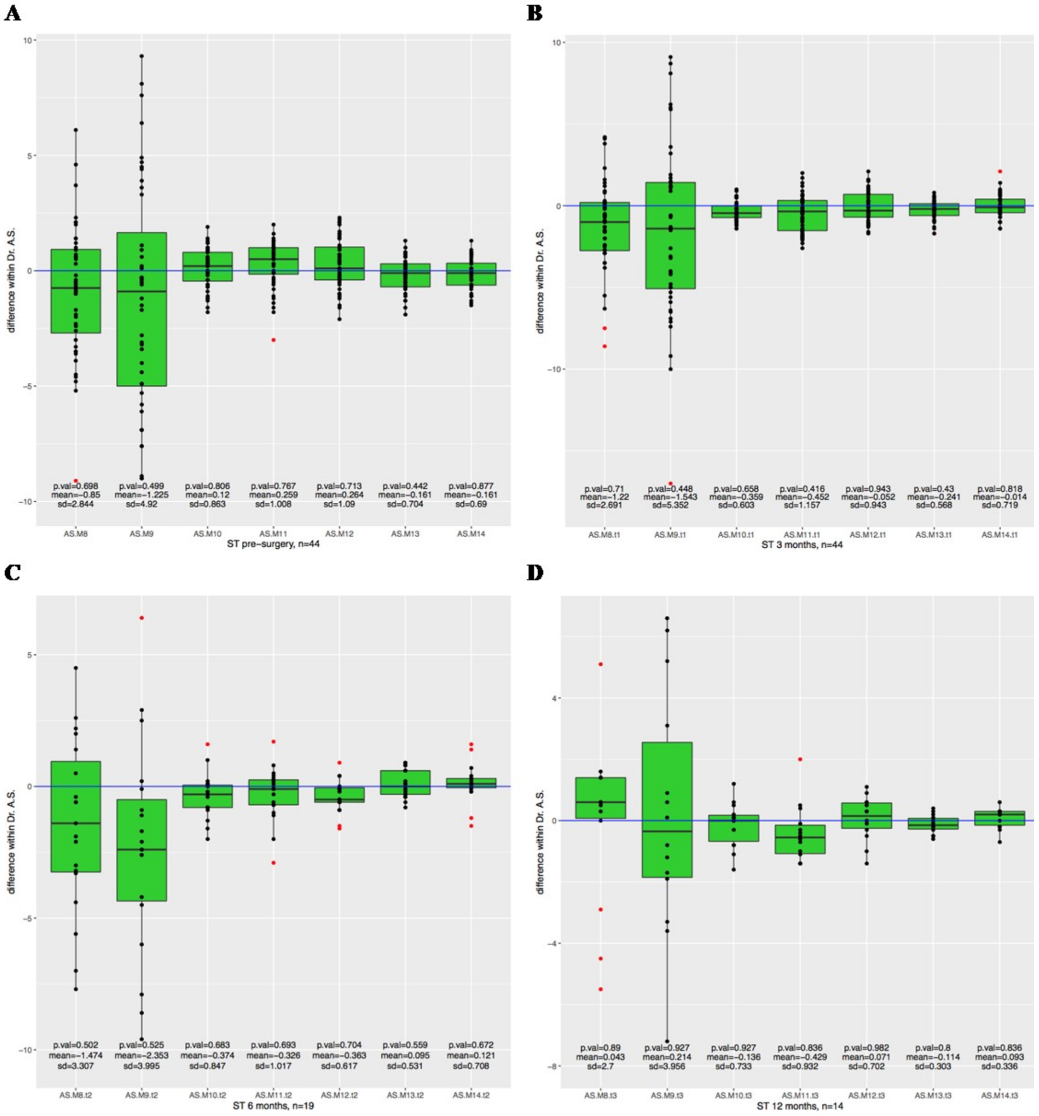
APPENDIX 11: Intra-operator reliability testing for hard tissue measurements performed by observer 1.

Box plots represent the repeated measurements by observer 2 (Dr. N.E) from the hard tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p- value greater than 0.1. No statistically significant difference was found within the two analyses performed by observer 2.



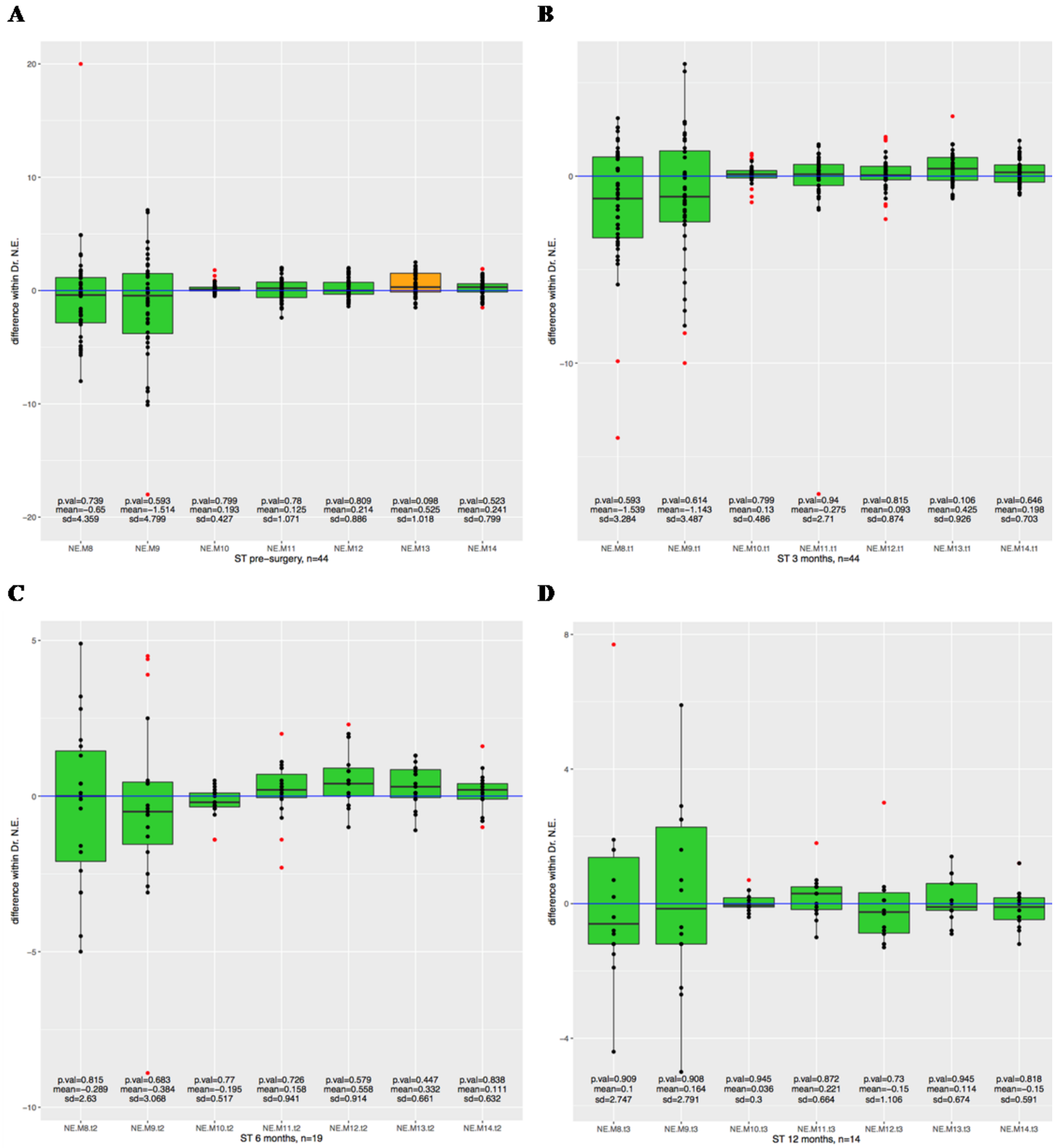
APPENDIX 12: Intra-observer reliability testing for soft tissue measurements performed by observer 1.

Box plots represent the repeated measurements by observer 1 (Dr. A.S) from the soft tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p- value greater than 0.1. No statistically significant difference was found within the two analyses performed by observer 1.



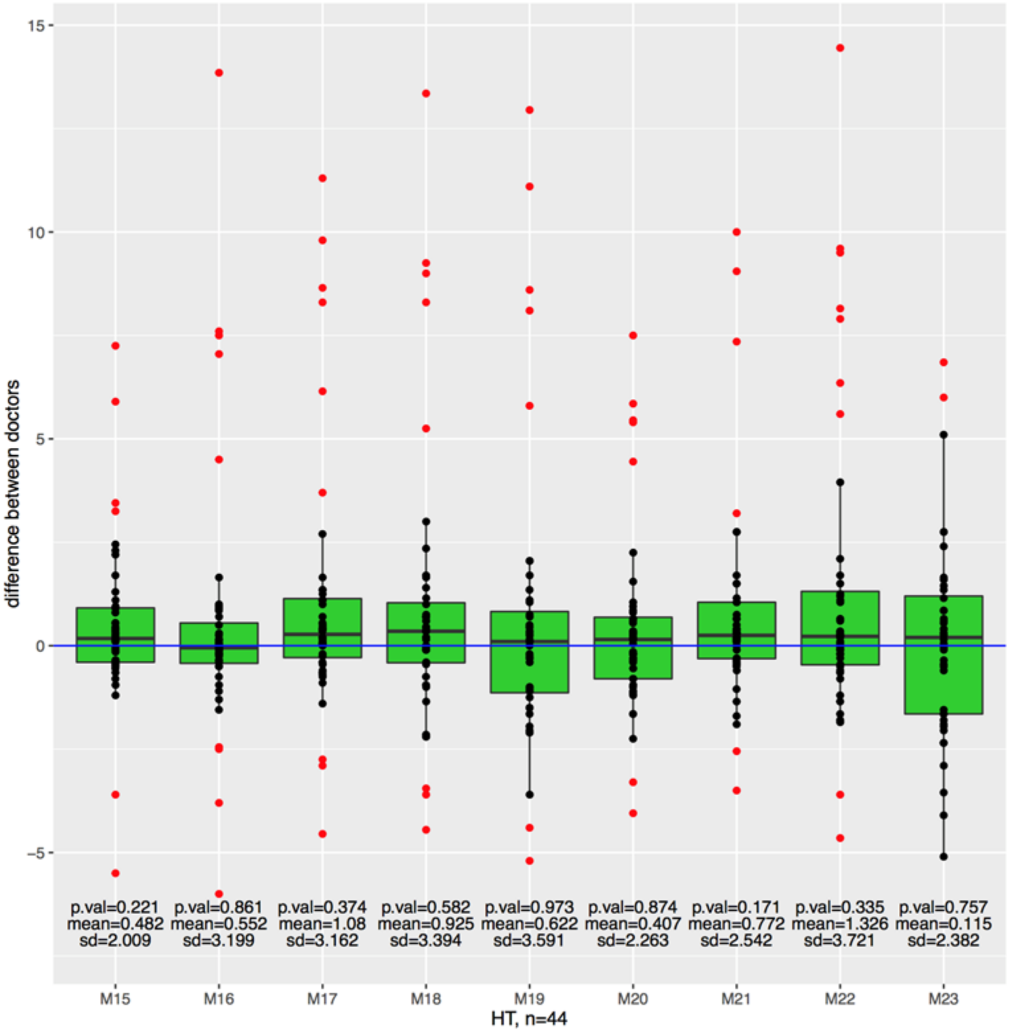
APPENDIX 13: Intra-operator reliability testing for soft tissue measurements performed by observer 2.

Box plots represent the repeated measurements by observer 2 (Dr. N.E) from the soft tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p- value greater than 0.1. The orange color represents a p- value between 0.05 and 0.1. No statistically significant difference was found within the two analyses performed by observer 2.



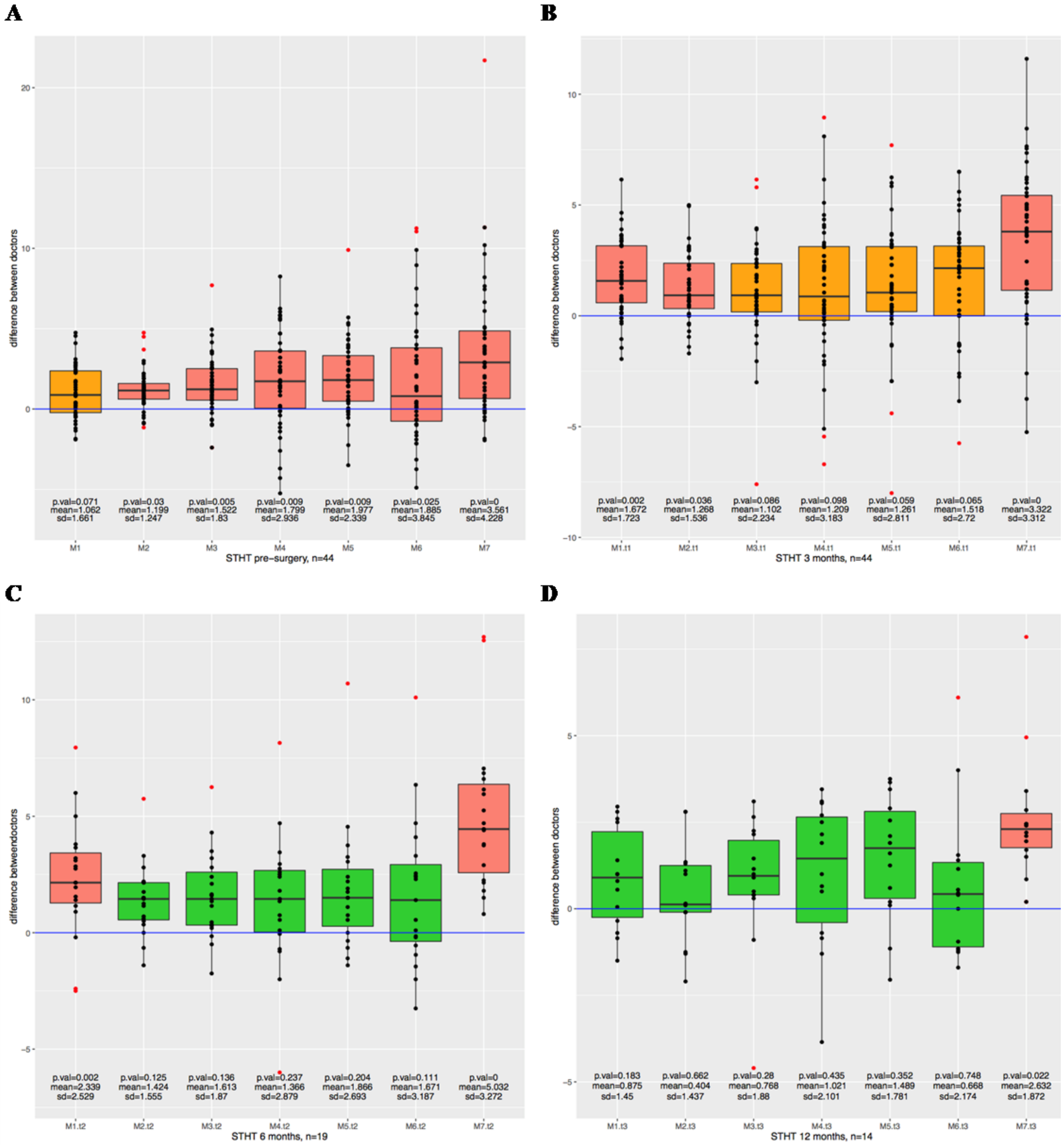
APPENDIX 14: Inter-observer reliability testing for hard tissue measurements performed by both observers.

Box plots represent the repeated measurements by both observers (Dr. N.E and A.S) from the hard tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p- value greater than 0.1. No statistically significant difference was found within the hard tissue analyses performed by the two observers.



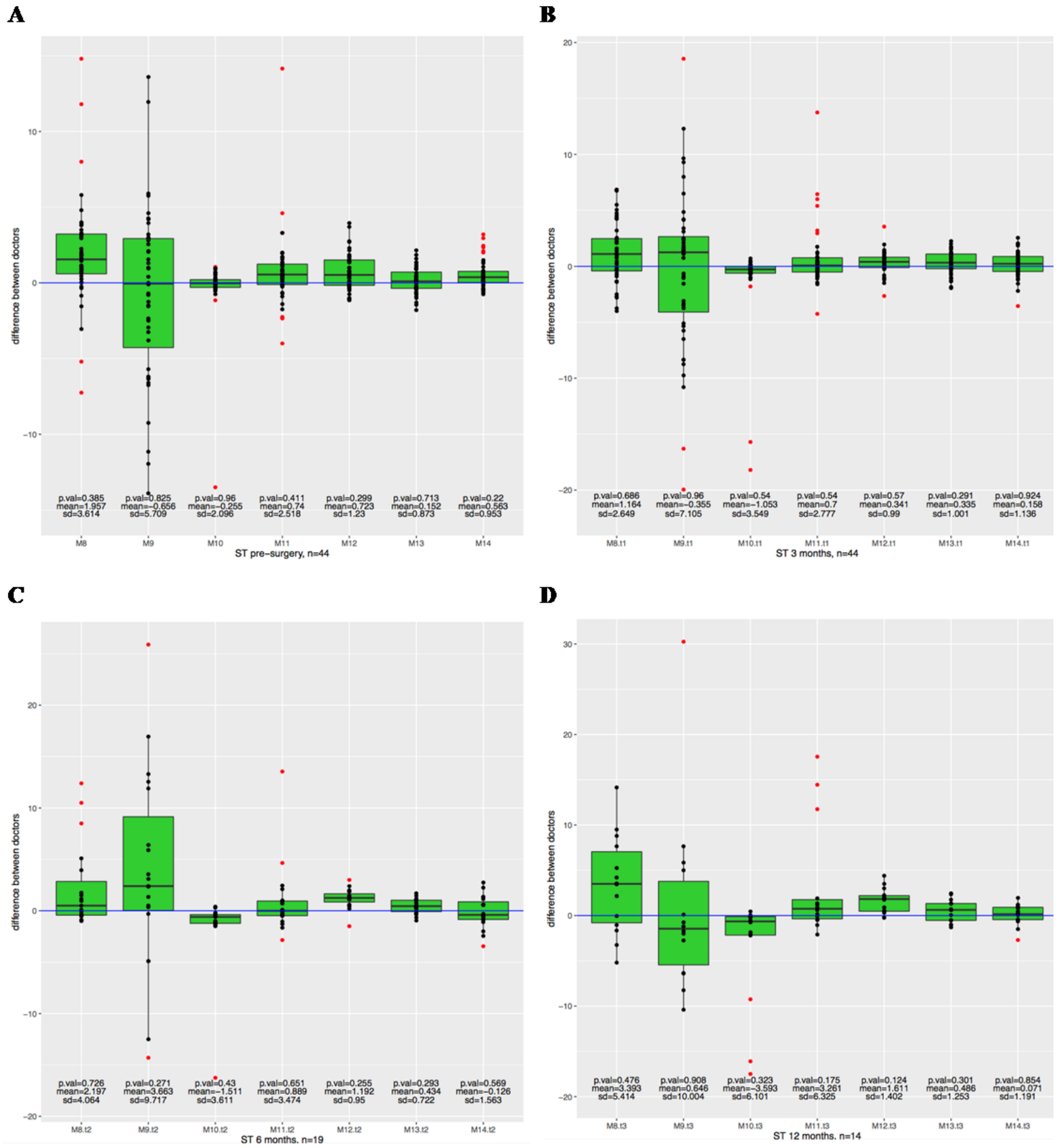
APPENDIX 15: Inter-observer reliability testing for hard to soft tissue measurements performed by both observers.

Box plots represent the repeated measurements by both observers (Dr. N.E and A.S) from the hard to soft tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p- value greater than 0.1. The orange color represents a p-value between 0.05 and 0.1. The red color represents a p- value of less than 0.05. A statistically significant difference was identified between the soft to hard tissue analyses performed by the two observers.



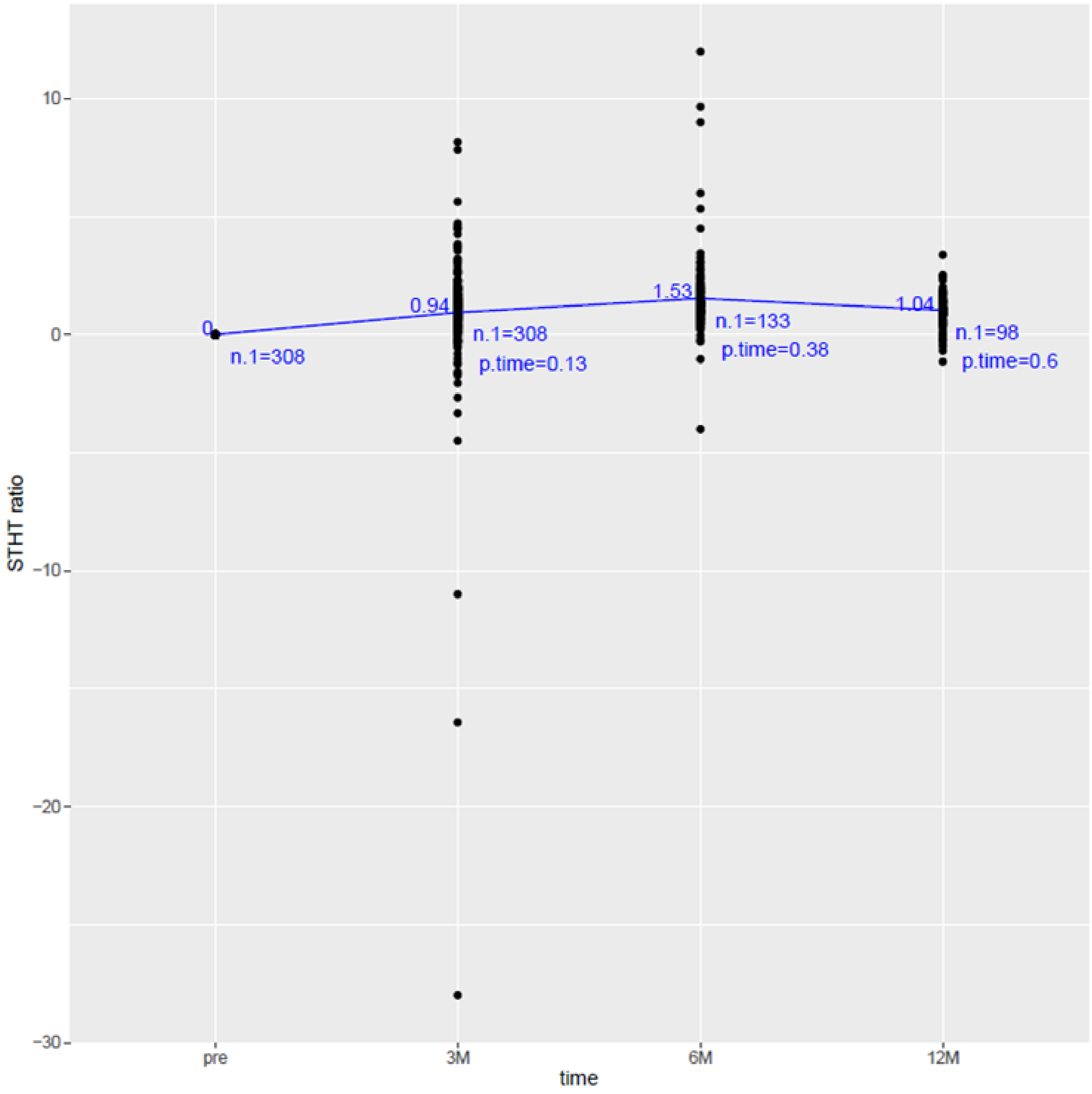
APPENDIX 16: Inter-operator reliability testing for soft tissue measurements performed by both operators.

Box plots represent the repeated measurements by both observers (Dr. N.E and A.S) from the soft tissue landmarks across the four time points: A) pre-operative, B) 3 months (T1), C) 6 months (T2) and D) 12 months (T3). Outliers are depicted as red dots. The green color represents a p- value greater than 0.1. No statistically significant difference was found within the two soft tissue analyses performed by the two observers.



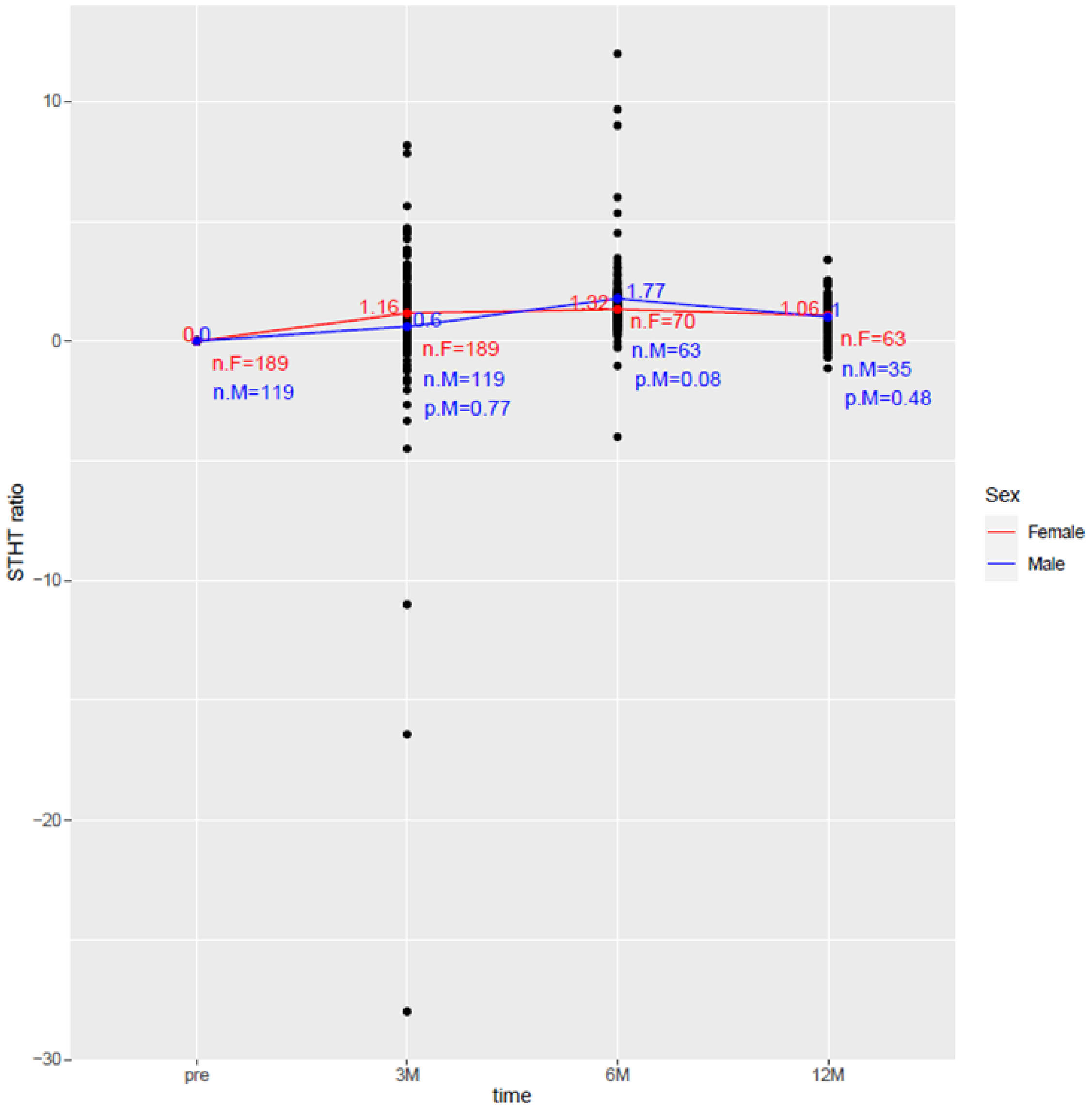
APPENDIX 17(A): The HT: ST ratio following orthognathic surgery.

Graphical representation of the hard to soft tissue ratio of movement across four time points: pre-operative, 3, 6 and 12 months post-surgery. The n.1 represents the number of values included within each group analyzed while the p-value was denominated as p.time in this instance. The ratio of movement between the two tissue types was found to be 1:1 with the soft tissues moving 1mm for each 1mm of hard tissue movement post-orthognathic surgery.



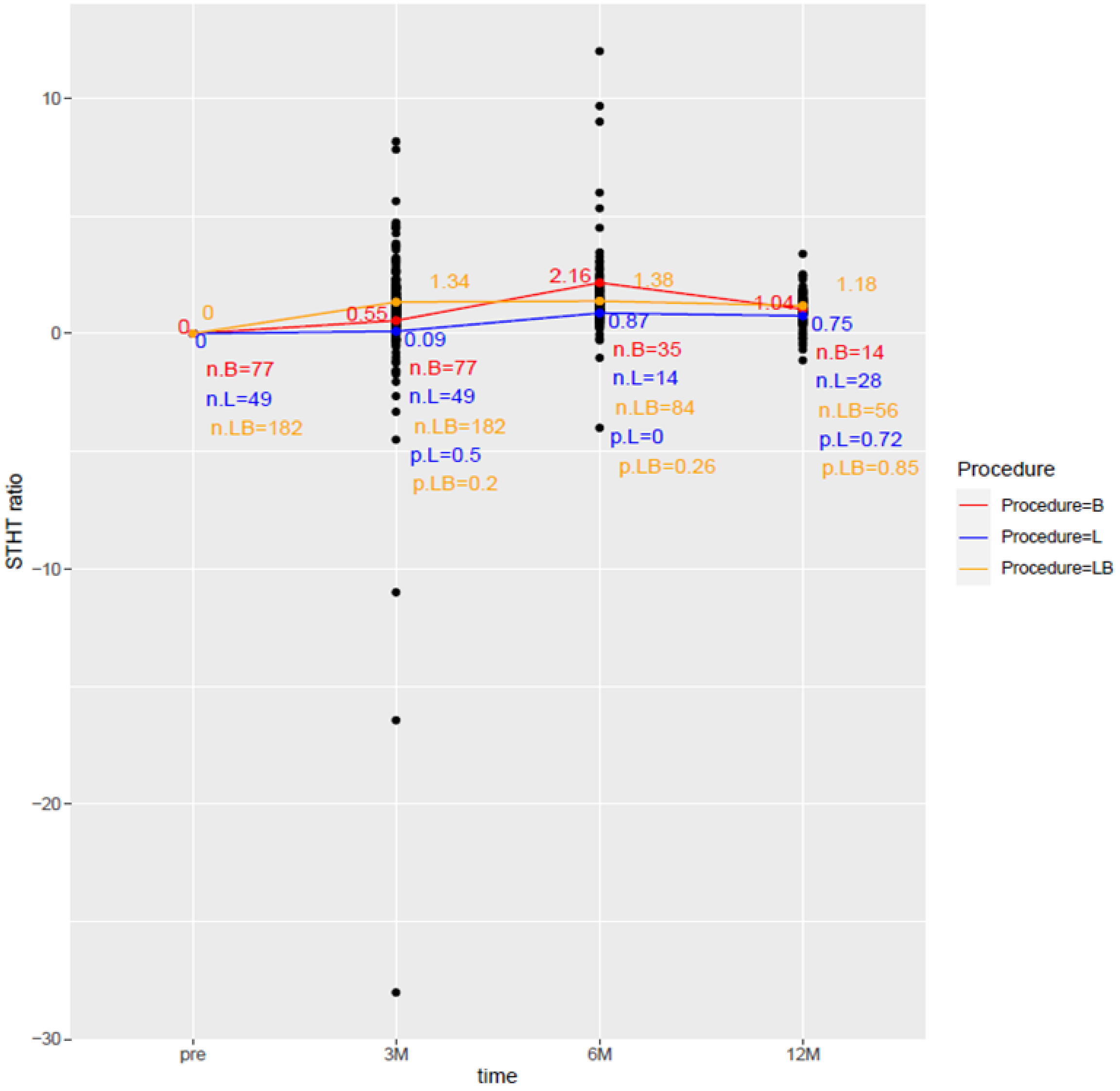
APPENDIX 17(B): The HT: ST ratio by sex.

This graph represents the change in soft tissues following orthognathic surgery and data segregation based on sex. The red line depicts the female patients included in this analysis while the blue line shows the male group. The n.F and n.M indicates the number of values included in the female and male groups, respectively. Sex was not found to affect the hard to soft tissue ratio of movement.



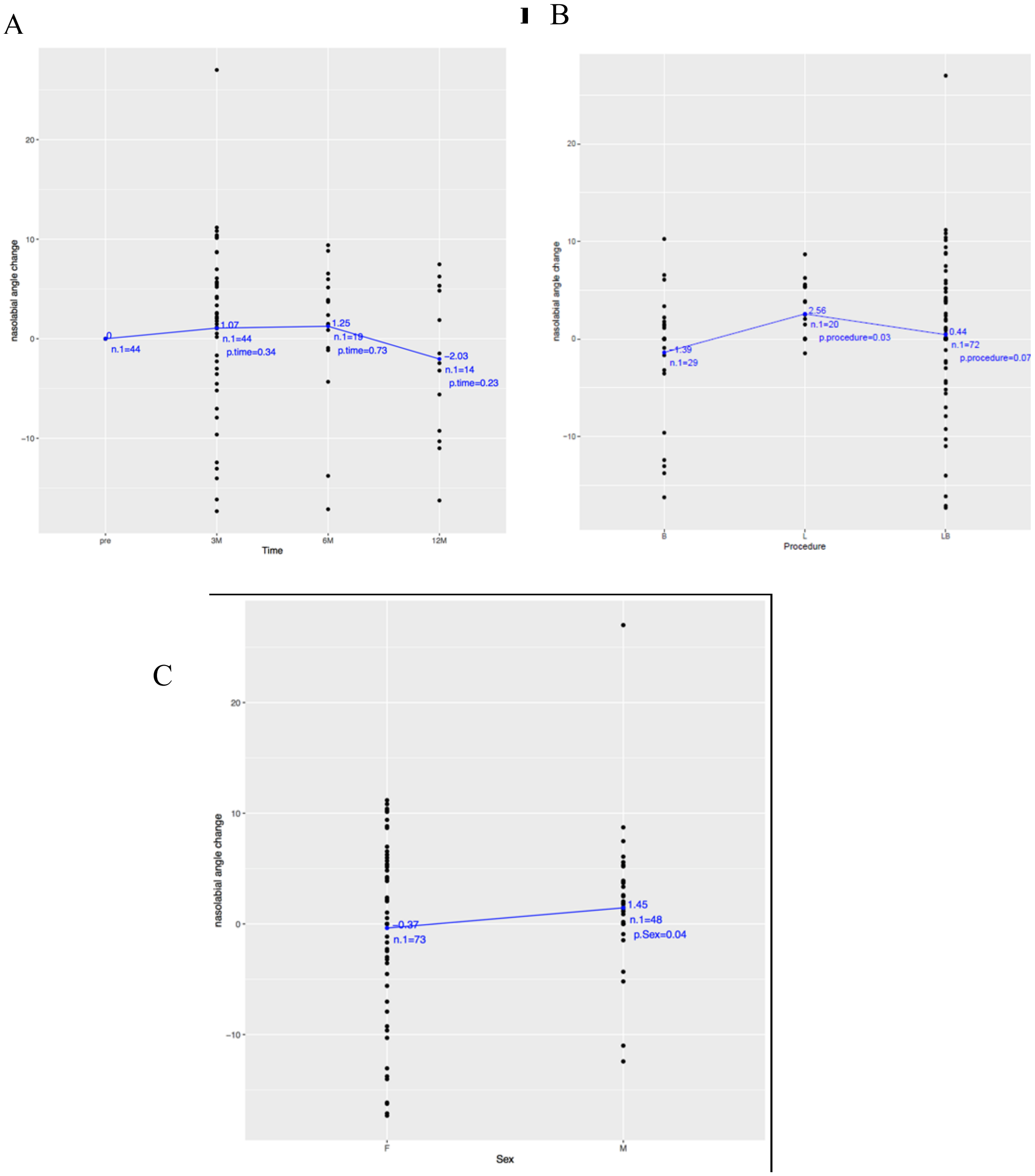
APPENDIX 17(C): The HT: ST ratio by procedure type.

This graph represents the ratio of hard to soft tissue movement as determined by the surgical procedure performed: B= BSSO (red), L= LF (blue) and LB= LF and BSSO (orange) at the four time points: pre-operatively, 3, 6 and 12 months post-operatively. The number of values included in each group is represented by n.B, n.L and n.LB. Data segregation based on procedure type did not reveal a statistically significant change in the ratio of hard to soft tissue movement with the ratio remaining at close to 1:1 regardless of the patient receiving single or double jaw surgery.



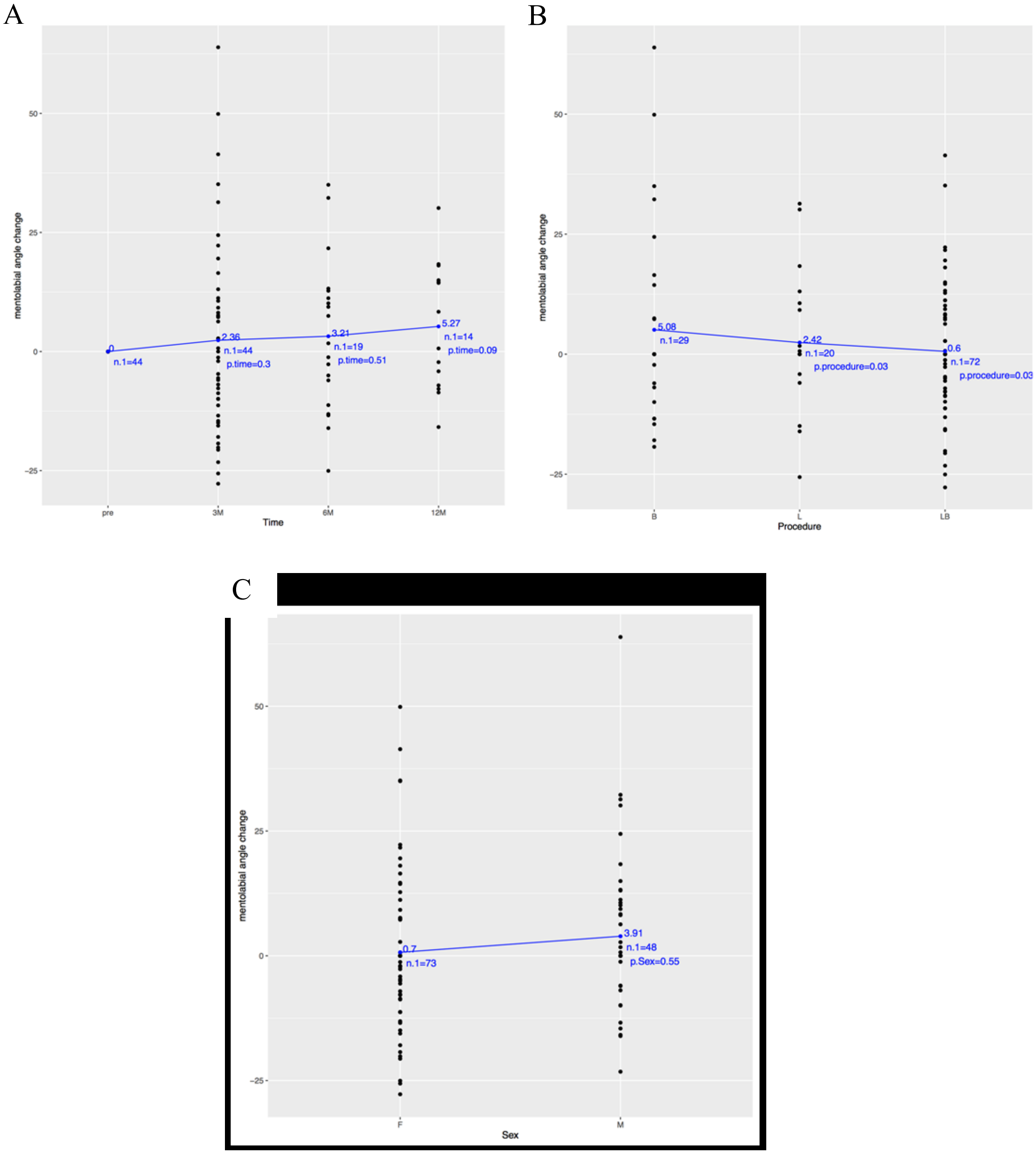
APPENDIX 18: The change in nasolabial angle following orthognathic surgery.

A) Although the change in the nasolabial angle across patients is not statistically significant, our analysis revealed a trend emerging at 3 months with a slight increase in the nasolabial angle followed by a decrease at 12 months post-surgery. B) Further analysis of the change in nasolabial angle based on procedure type identified a statistically significant increase in the nasolabial angle in the LF only (L) group as compared to the groups receiving BSSO (B) only or LF and BSSO (LB) surgeries. The n.1 represents the number of values analyzed in each group.



APPENDIX 19: The change in mentolabial angle following orthognathic surgery.

A) No statistically significant change in the mentolabial angle was observed across the four timepoints: pre-operative, 3, 6 and 12 months post-operatively. Although an upward trend was noted, given the non-significant p- value and small sample size at the 12 month timepoint, it is reasonable to conclude that the mentolabial angle does not change after orthognathic surgery. B) Despite a statistically significant decrease in the mentolabial angle in the LF only (L) and LF & BSSO (LB) group, this change is not clinically significant as the decrease observed accounts for approximately 6 degrees. The number of values included in the analyses is represented by n.1. C) Changes in the Mentolabial angle stratified by sex.



APPENDIX 20: The change in alar width following orthognathic surgery.

A) A statistically significant increase in alar width was identified within the data set analyzed with the greatest increase occurring at 12 months post-operatively. However, given the small sample size at the 12-month time point and the increase in alar width of less than 3mm, we can conclude that the change in alar width is clinically negligible. B) Patient receiving a LF only (L) surgery experienced the greatest increase in alar width while patients undergoing double jaw surgery had a smaller increase. The number of values assessed in each group is indicated by n.1. C) Changes in the alar width stratified by sex.