ACCURACY OF CONDYLAR POSITION IN ORTHOGNATHIC SURGERY CASES TREATED WITH VIRTUAL SURGICAL PLANNING: AN EXPLORATORY STUDY

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A thesis submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in the School of Dentistry (Orthodontics).

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ABSTRACT

Ying Wan: Accuracy of condylar position in orthognathic surgery cases treated with virtual surgical planning: an exploratory study
(Under the direction of Tung T. Nguyen)

Objectives: To assess the pre- and short-term post-operative positions of the mandibular condyle in bimaxillary orthognathic surgery cases prepared using Virtual Surgical Planning (VSP). Additional aims are to evaluate the relationship between surgical characteristics and condylar positional changes, as well as to quantify the difference between actual surgical outcome and planned virtual outcome. **Methods**: 15 consecutively operated subjects with Bilateral Sagittal Split Osteotomies (BSSO) prepared with VSP and 10 subjects with conventional surgery planning were selected from a private practice database retrospectively. 3D models generated from CBCT scans obtained pre-surgically (T1), post-surgically (T2), and from the VSP predictions were then oriented to Frankfurt horizontal, superimposed, and registered on the anterior cranial base through a voxel-based method. Anatomic landmarks on the condyles, maxilla, and mandible were manually selected on T1, T2, and VSP models using SlicerCMF (open-source software). Displacement of corresponding landmarks on T1, T2, and VSP models was measured in both 3D distance and in its component vectors in the transverse, vertical, and anteroposterior axes. **Results**: Study groups were well matched for demographic and surgical characteristics except for the type of surgery performed in addition to the BSSO. No significant difference was found between the VSP and conventional group in the magnitude of translation or rotation of the condyles following surgery. Mandibular shape was the only surgical characteristic found to correlate with condylar yaw (P=0.045, $R^z = 0.035$). VSP surgical outcomes differed significantly at all measured landmarks and in all dimensions from predicted outcomes.

Conclusion: Virtual surgical planning does not prevent changes to condylar position as a result of surgery. The magnitude of condylar torque following surgery was largely unexplained by surgical factors such as mandibular shape, mandibular plane, magnitude of mandibular movement, and rotation of mandibular plane. Actual surgical results differed significantly from VSP-predicted outcomes.

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LIST OF ABBREVIATIONS

BSSO	Bilateral Sagittal Split Osteotomy
CAD/CAM	Computer-Aided Design and Computer-Aided Manufacturing
CBCT	Cone-Beam Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
IMF	Inter-maxillary Fixation
ROI	Region of Interest
TMD	Temporomandibular Joint Dysfunction
TMJ	Temporomandibular Joint
VAS	Visual Analog Scale
VSP	Virtual Surgical Planning

LIST OF SYMBOLS

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A REVIEW OF THE LITERATURE

Historical Perspective on the Bilateral Sagittal Split Osteotomy

Orthognathic surgical procedures are designed to correct severe craniofacial anomalies and dentofacial deformities that are outside the scope of treatment by orthodontics and orthopedic growth modification. [1] It is estimated that over 2.5% of the US population has severe dentofacial deformities that would derive esthetic and functional improvements from orthognathic surgery. [2] Left uncorrected, these facial deformities can lead to impaired masticatory, speech, and respiratory function as well as psychosocial distress, ultimately with detriment to the patient's quality of life.

Edward H. Angle, the father of modern orthodontics, was one of the first to acknowledge that jaw discrepancies prevented the achievement of ideal dental relationships in certain individuals. [3] In his lifelong study of occlusion, he came across a number of patients with mandibular prognathism. These cases were of a sufficient severity to convince him that relying solely on tooth movements was not always adequate for establishing the desired occlusion. [4]

The surgeon Vilray Blair, a colleague of Edward Angle, held an interest in the correction of maxillofacial deformities. He was a forerunner in classifying jaw discrepancies into five categories: mandibular prognathism, mandibular retrognathism, alveolar mandibular protrusion, alveolar maxillary protrusion, and open bite. [5] In collaboration with Angle, Blair performed the first documented case of an ostectomy to correct mandibular prognathism in 1897. [4] Blair would later comment: "Treating of skeletal deformities is really surgical work, but the earlier a competent, congenial orthodontist is associated with the case, the better it will be for both the surgeon and the patient."[3] This statement foreshadowed a guiding principle of the consensus sequence for modern orthognathic surgery. [2]

Surgical techniques for correcting the position of the mandible, and later the maxilla, would see many iterations over the next half-century. It was not until 1955 that Austrian surgeon Hugo Obwegeser would publish the earliest version of the 'intraoral sagittal split of the mandible'. [6] Following modifications by Italian surgeon Dal-Pont, this method evolved to become the Bilateral Sagittal Split Osteotomy (BSSO), the most common technique for the advancement and setback of the mandible in use today. [7-11]

<u>Rigid Internal Fixation and the Mandibular Condyles</u>

For many years after its initial introduction, the BSSO relied on wires and intermaxillary fixation (IMF) to stabilize the osteotomy site and achieve union of the bony segments. [8,12] Patients were routinely immobilized in this fashion for six weeks or longer to maximize healing. Complications such as malunion and osteomyelitis were not uncommon because wire fixation, even ideally executed, did not truly hold bony segments in rigid relationships to one another to allow healing to proceed undisrupted. Patients also faced significant postoperative challenges in speech, respiration, nutrient intake, and hygiene from having the jaws secured together. It was with these limitations in mind and a background in orthopedic traumatology that Hans Luhr set out to apply Vitallium screws to secure bony segments in the earliest form of rigid fixation following orthognathic surgery. [3,4] Luhr designed and manufactured Vitallium miniplates to be used in conjunction with the screws; his system of rigid fixation became commercially available in 1969. [13] It is without a doubt that rigid fixation revolutionized orthognathic surgery, granting surgeons the ability to produce a greater range of surgical movements while drastically reducing patient recovery time and the incidence of post-operative complications. [4]

Rigid fixation was not without its drawbacks. Luhr and the surgeons that championed its use quickly recognized that unless the screws for stabilizing the sagittal split sites are carefully placed while the mandibular condyles are centered in their fossae, condylar dislocation and torque would result. [13] Improper positioning of the condyle-ramus segment is possible intraoperatively due to the loss of muscle tonus while a patient is under general anesthesia. Subsequent recovery of function by muscles of mastication results in an effort to return the condyles to the preoperative position. It was believed that the imprecision of wire fixation affords sufficient freedom of movement for the proximal condylar segment to work its way to a physiologic centric position following surgery. [14] By contrast, a screw that is tightened across an osteotomy site forces the bony segments to remain in an artificial position and distorts efforts by the musculature to return the condyle to its centric position. Rigid fixation, thought to be the 'solution' to surgical instability, instead highlighted a new potential cause for relapse. Harris *et al* [15] analyzed surgical factors that affect condylar position following BSSO advancement using 2D image slices selected from 3D computed tomography scans. His findings suggest that the degree of proximal segment rotation and mandibular shape were uncorrelated with the amount of condylar translation and torque. He did, however, detect a statistically significant correlation between mandibular advancement and condylar torque, with the magnitude of advancement explaining 19% of the change in condyle angulation. Mendez-Manjon *et al* [16] completed a similar study in 2016 with data analysis carried out using CBCT-derived 3D models registered on the cranial base. His results showed that the extent of condylar displacement was correlated to amount of mandibular advancement ($P < 0.01$); he did not consider condylar angulation in his study design. Reports of magnitude of angular changes of the condyles following BSSO surgery capture a broad range of values, with one study measuring 1.48° mean rotation in the axial plane and another citing greater than 6° of change. [15,17,18]

Intraoperative Condylar Seating

In a 1986 study, Epker and Wylie [19] proposed 3 reasons to maintain the pre-surgical condylar position:

[1] to ensure the stability of the surgical result;

[2] to reduce the adverse effects on the temporomandibular joint (TMJ);

[3] to improve masticatory function.

Since then, a number of investigations have examined the consequences of imprecise condylar seating, also termed condylar 'sag' by some authors. [19-21] Among the most commonly reported findings are increased symptoms of temporomandibular joint dysfunction (TMD) and post-surgical relapse [20]. Will *et al* reported development of TMD in 18 out of a sample of 41 patients that underwent mandibular advancement surgery. [21] Joss and Vassalli, in their systematic review of BSSO stability with rigid internal fixation, found 2.0 to 50.3 percent of patients experience relapse with bicortical screw fixation and 1.5 to 8.9 percent with miniplates. [8] Relapse can be characterized as early versus late phase and is distinguished by the presence or absence of morphologic changes in the condyles. [22,23] Studies have defined early postoperative relapse as occurring within 6 months of the surgery, resulting from the malpositioned condyle(s) being pulled into an unfavorable site by musculature. [8] It is important to note that with early relapse, the condyles themselves do not change in size or in form, only in position. By contrast, late postoperative relapse takes place 12 months or later following surgery and is often secondary to resorptive changes in the condylar head. [12] Over time, displacement and torque of the condyles alters their mechanical loading during function and gives rise to adaptive changes in their morphology. [8,12] Xi *et al* [22] followed 56 patients with BSSO advancement surgery for one year postoperatively and reported an average reduction in condylar volume of 6.1%. Condylar remodeling was also found to correlate strongly with surgical relapse ($p = 0.003$).[22]

Various appliances were devised to assist the surgeon in accurate intraoperative placement of the condyle-ramus segment to preoperative positions. Assessment and comparison of treatment outcomes with and without the use of condylar positioning devices has produced inconclusive evidence.[24,25] Gerressen *et al*[11] argued that manual approximation of condyles in experienced hands produced outcomes at least as good as those of condylar positioning devices and that the additional preparatory time before and during surgery made these devices impractical to use. Perhaps for these reasons, manual seating of the condyles in their centric position remains the preferred technique today despite the acknowledged consequences of condylar dislocation.

Virtual Surgical Planning

In the 'classic' approach for orthognathic surgical planning, 2D cephalometry and articulator-mounted dental casts are employed in a mock surgical procedure. The surgeon derives measurements for the maxillary and/or mandibular movements in all three planes of space by moving the dental models relative to one another and to the mounting platform. The amount of movement required is dictated by analysis of the lateral and frontal cephalograms as well as of the patient's facial photos. Once the surgical movements are finalized, an interocclusal acrylic splint is fabricated to assist the surgeon intraoperatively in achieving the planned movements. This multi-step process demands precision at each stage from diagnosis to surgical execution and comes with a number of practical challenges. From a diagnostic standpoint, the reliance upon 2D imaging for visualizing complex shapes and movements in 3D space yields significant incongruities at best and omits information altogether at worst.[25-27] For instance, asymmetries of the craniofacial skeleton are often present in all three planes and cannot be fully defined with any single 2D image. Inconsistencies in patient head position and image acquisition protocol can generate magnification and distortions that ultimately produce erroneous diagnoses. Intraoperatively, 2D radiographs offer very limited information for the surgeon to consistently make the optimal decision on placement of osteotomy cuts, adequate reduction of bony interferences, and centric seating of the mandibular condyles. In short, the quality of surgical outcomes in a case planned in the traditional method depends heavily on a surgeon's spatial perception, tactile awareness, and surgical experience.

A more recent paradigm shift came with the introduction of Cone Beam Computed Tomography (CBCT). This 3D imaging modality heralded significant improvements in diagnosis, treatment planning, patient education, and outcomes assessment. The considerable reduction in radiation for CBCT imaging as compared to conventional medical CT and the ease of in-house image acquisition also played a role in its widespread implementation in dentistry and orthognathic surgery. Virtual Surgical Planning (VSP) was later developed as an adjunctive technology to 3D imaging.[25] VSP was, broadly speaking, an effort to bridge the information vacuum between diagnostic imaging and surgical execution. Using this planning technique, a 3D virtual model of the patient's maxillofacial skeleton is generated from a CBCT scan and merged with digital scans of the patient's dentition. The surgeon can then perform a number of osteotomy cuts on the virtual model with sufficient sophistication to mimic real-life procedures. Surgical movements are quantified in 3D space and surgeons are able to experiment with multiple approaches. These mock procedures can be revised as needed until the optimal outcomes are achieved. With anticipation of bony segment placement in 3D space, as well as foresight into potential areas of bony interferences or osteotomy gaps, it was rationalized that

VSP should significantly improve the efficiency and outcome of orthognathic surgery.[25-32]

A number of clinical studies have sought to document whether surgeries performed with VSP yield outcomes better than those with traditional planning methods. Authors assessing this topic have approached from multiple vantage points including efficiency, cost-effectiveness, craniomaxillofacial harmony of planned results, and accuracy of surgical outcome. Schwartz, Wrzosek, and Xia all independently compared the average time required for traditional versus virtual surgical preparation, and all three groups individually concluded that VSP offered significant time-savings in the planning stages, from 1 to nearly 4.5-hours difference, respectively.[28,31,33] Schwartz also examined the surgical times for the two groups but found no difference in total time between first incision and wound closure.[31]

In a separate investigation, Xia *et al* addressed the question of whether VSP yielded surgical plans with improved craniomaxillofacial harmony over traditional methods.[30] To accomplish this aim, 12 patients undergoing bimaxillary surgery had surgical planning completed using both VSP and traditional techniques. A virtual simulation of the surgical outcomes from each option was presented side-by-side to two blinded observers who were instructed to evaluate the simulations using a visual analog scale (VAS) on criteria including midline correction, cant correction, and yaw correction. The VSP simulation was given a higher VAS score in all measured outcomes, with mandibular proximal/distal segment placement receiving the largest difference in scores, and maxillary midline correction showing the least difference in VAS score between the two groups. Xia concluded that these results were unsurprising because while traditional cast surgery could achieve satisfactory results by dentally-defined metrics, it was inadequate for planning skeletal movements, such as mandibular proximal/distal segment placement.

Surgical success depends on both the accuracy of surgical planning and clinician technique. Although these studies served as proof-of-concept for demonstrating that VSP could potentially improve orthognathic surgical planning and outcomes, it remains to be seen whether VSP can actually produce predictably better outcomes over traditional planning. In other words, while VSP may offer new possibilities in surgical planning, its capacity to supplant a surgeon's experience and technique is still unclear. At this time, no studies exist that directly compare surgical outcomes from VSP cases and with cases planned using conventional 2D methods. However, a number of clinical trials have been published comparing 3D virtual plans to their corresponding surgical outcomes to evaluate surgical accuracy. [29,32] In all of these studies, the transfer of virtual plans to surgical execution occurred by means of computer-aided design and computer-aided manufacturing (CAD/CAM) fabrication of surgical splints.

In a pilot study consisting of five prospectively enrolled patients undergoing double jaw surgery, Xia *et al*[29] measured the difference between planned and actual outcomes at nine manually-selected anatomic landmarks in the maxilla, mandible, and chin. 3D virtual models from surgical planning and from post-operative CBCT were superimposed on unoperated portions of the craniofacial skeleton using a surface-best-fit method. The differences between x-, y-, and z-coordinates of each pair of landmarks from planned and actual outcomes were calculated to generate descriptive statistics including mean, median, standard deviation, and range. Xia reported difference in translation between planned and actual outcomes to be 0.9 mm and 1.7° for angular (pitch, roll, yaw) measurements. Hsu *et al*[32] employed the same methodology in his prospective, multicenter study of 65 consecutively operated double-jaw patients but constructed an average "centroid" coordinate to condense positional information from each set of three landmarks selected in the maxilla, mandible, and chin. When comparing the virtually-planned and actual surgical outcomes, his results showed the maxilla and mandible to have linear differences of 1.1 mm and 1.0 mm, respectively; angular differences were 1.5° and 1.8°, respectively. It was unclear from either study whether mean values were calculated using the absolute values of measurements (without positive or negative signs). Failure to do so would have resulted in underestimation of differences between planned and actual outcomes simply as a property of arithmetic means.

Both authors adhered to definitions of clinical success that were defined by historic cephalometric studies: less than 2 mm or 4° of difference from planned to actual post-surgical lanmarks [34]. Marchetti *et al* [35] and Mazzoni *et al* [36] conformed to the same guidelines in their studies of VSP surgical accuracy. Rather than measuring differences between reference points, Marchetti and Mazzoni relied on surface-to-surface distance calculations for their analysis. This technique considers the minimum Euclidean distance between the surfaces of two superimposed virtual models from planned and actual outcomes. Marchetti and Mazzoni found the two models to be within 2 mm of one another in over 80% of the surfaces and concluded that virtual surgical plans were accurately executed. In a validation study conducted by Jabar *et al* [37], the surface-to-surface method of assessing positional changes was found to grossly underestimate the actual surgical changes because measurements are made by selecting the closest points on two surfaces rather than the corresponding anatomic points. The resulting measurements are approximately one-third to one-half that of true movement, and Jabar urged caution when interpreting data gathered using this technique [37].

Despite the number of publications assessing the accuracy of VSP surgeries, these authors have largely focused on the position of the maxilla and distal segment of the mandible. No studies to date have identified the impact of virtual planning on accuracy of condylar positioning. In particular, there have been no reports quantifying changes to condylar position using superimposed pre- and post-surgical 3D images, an approach that overcomes many of the limitations of measuring skeletal changes using 2D images. Given the implications of inaccurate condylar seating on the quality and stability of surgical outcomes, there is a need to understand whether virtual planning can offer advantages over conventional planning methods in these regards. A more nuanced comprehension of this topic will be an important step towards achieving consistent surgical outcomes in a real-world setting of variable clinician experience.

Conclusion

Surgical techniques have seen continued improvements over the past 50 years with advances in diagnostic imaging and rigid internal fixation, reducing recovery time and post-surgical complications. More recently, 3D virtual surgical planning (VSP) was made possible through the widespread adoption of Cone Beam Computed Tomography (CBCT) in dental imaging. This technology was introduced as a planning tool for the surgeon to visualize spatial relationships of bony segments and optimize the surgical procedure. This imaging stands in contrast to traditional methods of surgical work-up using 2D radiographs and dental models, which provided very limited spatial information to guide skeletal movements. While VSP appears to be effective at improving the efficiency of surgical planning and skeletal harmony of outcomes, existing studies do not evaluate its effect on condylar position, an important element in surgical stability [38-43]. Improper positioning of the condyle-ramus segment during mandibular surgery may provoke post-surgical condylar remodeling, resorption, and potential long-term instability of the surgical correction. [38,39,41,42,44]

This project seeks to expand our understanding of virtual surgical planning and its potential to improve orthognathic surgical outcomes. The aims are as follows:

1. To assess the pre-operative and short-term post-operative positions of the mandibular condyle in bimaxillary orthognathic surgery cases prepared using Virtual Surgical Planning (VSP);
2. To evaluate the relationship between surgical characteristics and condylar positional changes in 3D;
3. To quantify the difference between actual surgical outcomes and planned virtual outcomes at the maxilla and mandible.

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Background and Introduction

Orthognathic surgical procedures are designed to correct severe craniofacial anomalies and dentofacial deformities that are outside the scope of treatment by orthodontics and orthopedic growth modification. [1] It is estimated that over 2.5% of the US population has severe dentofacial deformities that would derive esthetic and functional improvements from orthognathic surgery. [2] Left uncorrected, these facial deformities can lead to impaired masticatory, speech, and respiratory function as well as psychosocial distress, ultimately with consequences on the patient's quality of life.

Surgical techniques have seen continued improvements over the past 50 years with advances in diagnostic imaging and rigid internal fixation, reducing recovery time and post-surgical complications. [3-5] More recently, Virtual Surgical Planning (VSP) was made possible through widespread acceptance of Cone Beam Computed Tomography (CBCT) in dental imaging. These technologies were introduced as planning tools for the surgeon to visualize spatial relationships of bony segments and more precisely quantify skeletal movements as a result of surgery. [5-8] This is in contrast to the traditional method of surgical work-ups using 2D radiographs and dental models, which provide more limited information to guide the surgical procedure. While VSP has been shown to be effective in improving the efficiency and esthetic outcomes of surgery, existing studies do not address whether use of VSP has an effect on the accurate positioning of the proximal segment. [9-12] A factor that contributes to surgical relapse is the challenge of maintaining the condyle-ramus segment position while performing mandibular surgical manipulations.[13-19] Improper positioning of the condyle-ramus segment is possible due to the loss of muscle tonus while patient is under anesthesia, but recovery of function by muscles of mastication results in potentially unfavorable displacement to the preoperative position. A number of studies using 2D and/or 3D imaging have attempted to quantify condylar displacement following mandibular surgery. Due to differences in study methodologies, however, a wide range of values have been reported.[14,17,20] Furthermore, torsion of the condyle-ramus segment during fixation of proximal and distal bony segments in mandibular surgery may provoke post-surgical condylar remodeling, resorption, and potential long-term instability of surgical correction.[21-25]

While studies have examined the accuracy of VSP-guided surgeries through the measurement of distal segment landmarks, no studies have quantified post-surgical condylar position changes in cases planned using VSP versus conventional methods. In particular, there have been no reports on condylar positional changes identified using superimposed pre- and post-surgical 3D images, which overcomes many of the limitations and inaccuracies of measuring skeletal changes in 2D images. Through this exploratory study, we hope to evaluate the potential for VSP to prevent unfavorable condylar seating. Secondary aims are to assess how closely the actual surgical results approximate predicted outcomes and whether various surgical characteristics are associated with condylar torque. Addressing these questions will be an important step towards achieving consistent surgical outcomes in a real-world setting of variable clinician experience.

Materials and Methods

Study design and sample

This is a retrospective study of condylar positional changes following orthognathic surgery cases involving the Bilateral Sagittal Split Osteotomy (BSSO) technique. All surgeries were performed by one of two oral surgeons at a private practice in Charlotte, NC between December 2012 and December 2015. We searched the practice data archives to identify all subjects who met the following study criteria (Figure 1) during this time interval:

1. Surgery was prepared using Virtual Surgical Planning (3D Systems, Littleton, CO) with STL files of simulated surgical movements;
2. CBCT scans were taken within 2 weeks prior to surgery (T1) and within 6 weeks following surgical splint removal (T2).

The exclusion criteria were the following:

1. Cases with incomplete CBCT records, i.e. missing T1 or T2 CBCT, missing critical anatomic structures in the CBCT image;
2. T2 CBCT taken without surgical splint removal;
3. Non-BSSO mandibular procedures such as genioplasty or inverted-L osteotomies;
4. Previous orthognathic surgery;
5. Craniofacial syndromes of any type.

A second group of consecutively-operated subjects were identified for the control group in this study. The control group follows all inclusion and exclusion criteria with the exception that these orthognathic surgeries were planned using traditional methods without employing VSP.

Demographic data including patient gender and age at time of surgery was gathered from the data archives. 15 participants met the inclusion criteria for the experimental (VSP) group and 10 participants for the control group.

The University of North Carolina Office of Human Research Ethics found this study to be exempt from IRB approval.

The sample size calculation was based on preliminary data collected from a 10-patient sample from the same source. Detection of a 2-mm or 4-degree intergroup difference at 80% statistical power and alpha = 0.05 requires a sample of 10 patients.

Data collection

Aim 1: Condylar translation and torque following VSP surgery:

1. Image de-identification: Using ITK-SNAP 2.4.0 (open-source software, www.itksnap.org), all DICOM files were converted to NRRD format to remove patient identifiers.
2. File down-sizing: Using 3D Slicer 4.4 (open-source software, www.slicer.org), image resolution was reduced from 0.25mm to 0.5mm voxel size.
3. Generate volumetric label map: the cranial base, maxilla, and mandible were segmented for T1 and T2 CBCT scans using ITK-SNAP 2.4.0. Manual
4. Generate virtual 3D surface model: Virtual 3D surface models were rendered from the segmented volumetric label maps in Slicer.
5. T1 model reorientation: All T1 3D surface models were reoriented to coincide with the 3D Cartesian coordinate system in Slicer as follows:
    a. Axial: parallel to Frankfurt horizontal (Porion – Orbitale);

    b. Coronal: parallel to infraorbitale line connecting most inferior point of the left and right orbita;
    c. Sagittal: coincident with midsagittal plane of the skull as defined by nasion and crista galli.
6. 3D cranial base superimposition: T1 and T2 scans were superimposed in three steps using 3D Slicer 4.4
    a. T2 scans were manually approximated to the oriented T1 scan
    b. Fully-automated voxel-based registration was executed in Slicer using the anterior cranial fossa from T1 scan as the best fit reference to achieve the final superimposition.
    c. Transformation matrix recording movements of T2 scan for superimposition to T1 scan was applied to T2 3D surface model.
7. Landmark identification: Anatomic landmarks of the left and right condyles were selected in registered T1 and T2 surface models using the Q3DC module in Slicer as displayed in Table 1 and Figure 1.
8. Quantitative measurements: All quantitative measurements were obtained using Slicer. Linear translation of corresponding landmarks from T1 and T2 registered models was measured in total 3D distance and in its component x-, y-, and z-axis vectors. Angular changes of left and right condyles in pitch, roll, and yaw were also recorded.

Aim 2: Comparison of VSP predicted and actual surgical outcome

1. 3D Region of Interest (ROI) superimposition: 3D virtual surface models of surgical predictions were procured from Medical Modeling (3D Systems Healthcare, Littleton,

CO). VSP and T2 surface models were superimposed on the entire cranial base using the ROI superimposition function in Slicer.

2. Landmark identification: Anatomic landmarks of maxilla and mandible were selected in registered VSP and T2 surface models using the Q3DC module in Slicer as displayed in Table 1.
3. Quantitative measurements: Linear translation of corresponding landmarks from VSP and T2 registered models were measured in total 3D distance and in its component x-, y-, and z-axis vectors. Measurements are assigned a positive or negative value as previously defined.

Aim 3: Association between condyle torque and surgical characteristics

1. Landmark identification: Anatomic landmarks of the maxilla and mandible were selected in registered T1 and T2 surface models using the Q3DC module in Slicer as displayed in Table 1.
2. Quantitative measurements:
    a. Frankfort-Mandibular Plane:
        i. Pre-surgical mandibular plane: Measured as the pitch component of angle between lines right Porion – right Orbitale and right Gonion – Menton.
        ii. Change in mandibular plane due to surgery: Measured as pitch component of angle between planes defined in T1 and T2 models by three mandibular points (Pogonion and lower second molars).
    b. Mandibular advancement: Measured as the antero-posterior component of B-point linear translation.

c. Mandibular shape: Measured as yaw component of angle between lines connecting Menton to left and right Gonion.

Statistical analysis

Statistical analysis was executed in R: A Language and Environment for Statistical Computing (Version 3.3.2; R Foundation for Statistical Computing, Vienna, Austria). Condyle landmarks were re-identified for ten randomly selected subjects after a 2-week washout period to determine operator error using Bland and Altman's method at ±2 standard deviations. [26,27] The Shapiro-Wilk test determined our data sample to be non-parametric. Wilcoxon rank-sum test was used to compare data from the left versus right condyles and found no significant difference between the two condyles. Hence, all statistical analyses were performed with data from the left and right condyles combined. Raw linear and angular measurements took positive or negative values depending on the direction of movement in each dimension (i.e. superior = positive, inferior = negative). To prevent mathematic operations in our statistical analysis from under-reporting outputs as a result of summing positive and negative values, absolute values of all data was used for analysis.

The Wilcoxon rank-sum test was again performed to assess difference in condylar changes following surgery in the control and the VSP subject groups for Aim 1. For Aim 2, a mixture of zero and chi-square distribution was used to test the null hypothesis that the difference between planned and actual surgical movements at the selected landmarks was zero. For Aim 3, univariate and multivariate regression analysis were applied to identify associations between the response variables of condylar yaw and roll and predictor variables of pre-surgical mandibular plane angle, mandibular shape, surgical change to mandibular plane angle, and magnitude of sagittal mandibular movement.

All statistical analyses were set to a significance level of $P<0.05$.

Results

Sample

Demographic and surgical characteristics of control and experimental groups are found in Table 2. Groups were well-matched for gender (P = 0.211), age at time of surgery (P = 0.331), and for all surgical characteristics. Pre-surgery mandibular plane (P = 0.935), mandibular shape (P = 0.238), change in mandibular plane following surgery (P = 0.375), and A-P component of change in B-point (P = 0.446) were each comparable between the two groups.

Method error

Observer consistency for landmark selection in three dimensions (anteroposterior, transverse, superior-inferior) was evaluated through Bland-Altman plots (Figure 2). Observer bias was very low and observer consistency was good in all three dimensions, with the highest bias found in the superior-inferior orientation at -0.14mm.

Aim 1: Condylar translation and torque

Descriptive statistics for changes in condylar translation and torque for both the VSP and conventional groups are presented in Table 3 and Figures 3A-3D. No statistically significant differences for translation were found between the two groups at any landmark in any dimension. In comparing the angular changes between the two groups, only yaw was found to be significantly different with the VSP group showing a greater change (P = 0.034).

Aim 2: Factors influencing condylar yaw and roll

Multivariate linear regression analysis was performed to evaluate possible associations between condylar yaw and roll and T1 mandibular plane (T1 MPA), T1-T2 change in mandibular plane (T1-T2 MPA), mandibular shape, and AP component of B-point change. Individual multivariate linear regression models for each of the predictors are depicted in Figures 4A-4H and the associated R^2 and P-values are listed in Table 4. Mandibular shape was the only predictor found to be significantly associated to condylar rotation, specifically to yaw (P = 0.045). The R^2 values for all models are low, reflecting that all of our predictors are poor prognostic factors and that most of the variations among the observations remain unexplained.

Aim 3: Accuracy of VSP surgery

Descriptive statistics for positional differences between predicted (VSP) and actual (T2) surgical movements (Table 5 and Figure 5) reveal a significant difference for all outcomes in every dimension. An irregularity percentage was calculated for each outcome in each dimension to detect the percentage of subjects with a measured discrepancy of greater than 2mm or 4 degrees between VSP-prediction and actual surgery. The irregularity percentage was found to be greatest in the anteroposterior dimension and least in the transverse dimension for all landmarks (Table 5 and Figure 6).

Discussion

A major strength of the current study is the direct measurement of anatomic differences on 3D images without the reliance upon reference planes seen in previous studies. Reference plane-based measurements require additional steps that are inherently subjective and can compound measurement errors. The workflow of voxel-based registration streamlines the measurement process and reduces subjectivity to a single step in landmark selection. While manual landmark placement does involve operator bias and error, our observer showed good consistency and 95% of measurement errors were no greater than 1mm. This is well within the 2mm threshold for clinical significance that we established.

Aim 1: Condylar translation and torque

Virtual planning did not produce a detectable difference in the magnitude of condylar translation following surgery as compared to conventional planning, suggesting that VSP is no better at assisting surgeons with condylar seating. While VSP facilitates the visualization of craniofacial skeleton and surgical osteotomies, the transfer of this information from planning to execution occurs through surgical splints. Aside from a difference in the method of fabrication, VSP surgical splints are no different from their counterparts in conventional planning; both splints function to guide the surgeon in achieving a precise relationship of the maxilla and mandibular distal segment through occlusion. There is no intraoperative guide for positioning the proximal segment and proper seating remains a technique-sensitive aspect of the surgery that requires a high level of spatial awareness, proprioception, and experience.

One could still argue that the ability to visualize osteotomies and potential sites for bony interferences or gaps through VSP should confer an advantage to the surgeon. If so, we would expect to observe a smaller change to condylar position following a VSP surgery. We suspect that the absence of such a finding may be attributable to our clinicians' level of expertise. The surgeons in our study were trained at the same institution and each has over 10 years of operating experience. It is possible that with their surgical aptitude, the additional spatial information provided by VSP is redundant and adds no value to the surgery process. On the other hand, a more novice clinician may benefit from this planning adjunct. VSP could also be very helpful in cases

Condylar yaw was the only outcome that differed significantly between our VSP and control groups, with VSP group showing an unexpectedly greater degree of yaw (median=7.23°, range=0.71-14.27°) than conventional group (median=3.97°, range=0.05-5.54°). This result may be explained by the difference in surgical procedures performed on our subjects in each group. Due to the retrospective nature of this study, we were unable to randomize the cases that received virtual planning. As a result of clinician preference, all double-jaw cases were planned virtually and isolated mandibular operations were planned using conventional methods. Nearly all control subjects (93.3%) received BSSO advancement for Class II correction and the majority of VSP subjects (80.0%) received BSSO setback as part of Class III correction (Table 1). The magnitude of mandibular movement in the sagittal plane did not differ significantly between the two groups ($P = 0.461$), but an argument could be made that the direction of mandibular movement influences the severity of condylar yaw. Our measurements for condylar yaw in the VSP group is in accordance with values from a study by Kim *et al* [28] on condylar changes following two-jaw surgery involving mandibular setback. Our values for condylar yaw in the control group follows closely the values reported by Alder *et al* [13] in their sample of sagittal split advancements. No single study to date has examined the effect of AP direction of mandibular correction on condylar torque.

It is also possible that the additional challenges of a double-jaw surgery masked the positive effects that VSP may have had on proper condylar seating. Kim *et al* [20] evaluated condylar position changes following single-jaw versus double-jaw correction of skeletal Class III discrepancies and found the double-jaw cohort to exhibit significant angular changes to the condyles following surgery. They speculated that surgical technique likely plays a major role in passive condylar seating. Indeed, the additional stage in double-jaw surgery requiring the use of an intermediate splint could magnify errors in condylar positioning, offering an explanation for the greater condylar yaw observed in our VSP group.

Aim 2: Factors correlated with condylar yaw and roll

We selected various surgical and patient characteristics to test as factors putatively correlated to condylar yaw and roll based on reports from previous literature. [13,17,18,29] Out of the 4 factors that we included in our multivariate linear regression analysis, only mandibular shape was found to be significantly associated with condylar yaw and shows a negative correlation. As the mandible becomes narrower or more acutely shaped from an axial perspective, condylar yaw increases holding all else constant, albeit this relationship explains only 3.5% of the variation in yaw. Despite our inconclusive results on the remaining factors, we can agree with other authors that changes to condyle angulation following surgery may be more a function of patient soft-tissue factors and surgeon technique. [17,30]

Aim 3: Accuracy of VSP surgery

When comparing VSP-predicted surgical changes to our actual surgical outcomes, we discovered that the discrepancy was significant at all landmarks assessed. Mean values for the discrepancy were as large as 3.74mm, which is undeniably clinically significant. The greatest error in execution occurred in the anteroposterior direction, which is often the emphasis in diagnosis and treatment planning for most of orthodontics and orthognathic surgery. Errors were least in the transverse dimension, perhaps because symmetry and midline coincidence are the most straightforward to detect clinically. The irregularity percentage for discrepancies greater than 2mm was consistently highest in the anteroposterior direction at all landmarks, followed by superior-inferior, and least in the transverse (left-right). Over 40% of subjects in the VSP sample had a surgical outcome that deviated more than 2mm from the planned result in the AP direction, along with over 20% of subjects in the vertical, and 6% in the transverse. These values differ dramatically from previously reported VSP accuracy data that found surgical results to be within

1mm of predictions.[8,31,32] The results imply that virtual surgery could very well design the most ideal outcome but only partially achieve its plan. This shortfall is likely due to information loss at the surgical splint, which is effective at controlling the AP and transverse positions of the mobilized maxilla and mandibular distal segment relative to one another but not to the cranial base. For this reason, a surgery could yield a perfect match of the occlusion to the planned outcome, and still result in a non-ideal relationship of the skeletal segments.

Conclusions

In a retrospective study of consecutively-treated orthognathic surgery cases involving BSSO, planned either with VSP or conventional methods,

- Virtual surgical planning did not reduce the changes to condylar position and angulation that resulted from conventionally-planned orthognathic surgery.
- The magnitude of condylar torque following surgery, whether planned using VSP or conventional techniques, was largely unexplained by surgical factors such as mandibular shape, mandibular plane, magnitude of mandibular movement, and rotation of the mandibular plane.
- Actual surgical results differed significantly from VSP-predicted outcomes, contradicting claims made by previous studies on VSP surgeries being highly accurate.

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APPENDIX

Table 1: Definition of 3D cephalometric landmarks and measurements

Landmarks	Definition	Bilateral structure
A-point	The point of maximum concavity in the midline of the alveolar process of the maxilla	
B-point	The point of maximum concavity in the midline of the alveolar process of the mandible	
Condyle		
Medial pole	The most medial point of condyle	X
Superior pole	The most superior and central point of condyle	X
Lateral pole	The most lateral point of condyle	X
Gonion	Projection of a visual bisector of a line tangent to mandibular base and posterior border of mandible	X
Menton	The most inferior midpoint of the chin on the outline of the mandibular symphysis	
Orbitale	The most inferior point of the infraorbital margin	X
Pogonion	The most anterior midpoint of the chin	
Porion	The most superior point of the bony external auditory meatus	X

Measurements	Definition
Frankfort mandibular angle (FMA)	The pitch component of the angle between Frankfort horizontal and the mandibular plane
Frankfort horizontal plane	The plane defined by points Porion and both left and right Orbitale
Mandibular shape	The angle defined by points Menton and both left and right Gonion

Table 2: Descriptive statistics and p-values for demographic and surgical characteristics between VSP and control groups

	VSP (N=15)		Control (N=10)		
	Mean	SD	Mean	SD	*p*-value
Age at surgery (years)	20.93	6.54	19.23	4.846	0.331
Females (%)	46.7	--	80.0	--	0.211
Mandibular shape (°)	66.45	4.75	71.30	6.42	0.238
Pre-surgical Frankfort mandibular plane (°)	26.09	5.66	25.66	9.40	0.935
AP component post-surgical change in B-point (mm)	4.35	2.78	4.79	2.26	0.461
Post-surgical change in Frankfort mandibular plane (°)	3.14	2.93	1.76	0.75	0.375
Bimaxillary surgery (%)	100.0	--	0.0	--	1.000
BSSO only (%)	0.0	--	100.0	--	1.000

Table 3. Condylar displacement and torsion following surgery in VSP and control groups

			VSP						Control						
			Min	Q1	Q2	Q3	Max	% irr	Min	Q1	Q2	Q3	Max	% irr	p-value
Linear displacement (mm)	Lateral pole	R-L	0.15	0.56	0.87	1.31	2.24	3.3	0.03	0.34	0.90	1.35	2.21	10.0	0.621
		A-P	0.01	0.27	0.91	1.30	2.51	6.7	0.01	0.51	0.91	1.50	3.72	20.0	0.400
		S-I	0.10	0.52	0.83	1.22	4.54	6.7	0.19	0.65	1.36	1.94	3.56	25.0	0.099
		3D	0.72	1.40	1.74	2.29	5.19	40.0	0.80	1.53	2.20	3.08	4.28	55.0	0.181
	Superior pole	R-L	0.00	0.49	1.06	1.73	3.79	16.7	0.00	0.43	1.03	1.45	2.48	5.0	0.782
		A-P	0.00	0.29	1.02	1.71	3.48	13.3	0.24	0.80	1.20	1.69	2.70	10.0	0.285
		S-I	0.05	0.63	0.84	1.27	2.79	10.0	0.01	0.53	0.87	1.38	3.31	10.0	0.914
		3D	0.05	1.04	2.45	2.89	3.96	56.7	0.93	1.78	2.21	2.38	4.28	65.0	0.905
	Medial pole	R-L	0.05	0.33	0.76	1.13	1.88	0.0	0.04	0.25	0.64	1.13	3.07	10.0	0.736
		A-P	0.11	0.70	1.16	1.70	4.03	16.7	0.01	0.37	1.14	2.24	3.66	30.0	0.789
		S-I	0.04	0.55	1.54	2.48	5.00	33.3	0.07	0.30	0.76	2.14	3.10	25.0	0.257
		3D	1.05	1.79	2.41	3.06	5.30	70.0	0.60	1.59	2.75	3.03	4.17	60.0	0.670
Angular changes (°)	Yaw		0.71	4.00	7.29	8.47	14.27	73.3	0.05	2.75	3.97	5.54	11.03	45.0	**0.034**
	Roll		0.75	2.64	4.94	9.40	19.82	63.3	0.20	2.40	5.55	7.85	15.68	55.0	0.589

Data from left and right condyles are combined to generate descriptive statistics
%irr = percentage of irregular observations, defined as displacement greater than 2mm or 4° in yaw/roll.

Table 4. Prognostic value of surgical variables in predicting condylar yaw and roll using multivariate linear regression

		Surgical variables											
		A-P change of B-point			Pre-surgical FMA			Mandibular shape			Post-surgical FMA change		
		Est	SE	p-value	Est	SE	p-value	Est	SE	p-value	Est	SE	p-value
Condyle	Yaw	0.017	0.179	0.924	-0.164	0.090	0.070	-0.237	0.118	**0.045**	0.214	0.156	0.169
	Roll	-0.238	0.232	0.306	-0.018	0.160	0.912	0.102	0.166	0.537	0.510	0.329	0.121
R-square			0.016			0.011			0.035			0.059	

Table 5. Positional difference between VSP-predicted and actual surgical outcome

	Positional difference (mm)											
	Right-Left				Anterior-Posterior				Superior-Inferior			
Landmarks	**Mean**	**SD**	**p-value**	**%irr**	**Mean**	**SD**	**p-value**	**%irr**	**Mean**	**SD**	**p-value**	**%irr**
A-point	1.00	1.41	**0.044**	13.3	2.81	2.00	**<0.0001**	60.0	2.59	2.32	**0.002**	53.3
B-point	1.23	1.46	**0.019**	6.7	2.54	2.84	**0.013**	40.0	2.39	2.80	**0.018**	33.3
Pogonion	1.73	1.62	**0.003**	26.7	2.85	3.48	**0.022**	46.7	2.30	2.93	**0.028**	33.3
Lower-left second molar	1.05	0.93	**0.001**	20.0	3.64	2.67	**0.0001**	66.7	1.39	1.45	**0.007**	20.0
Lower-right second molar	1.31	1.04	**0.0003**	20.0	3.74	3.17	**0.001**	53.3	1.41	1.66	**0.018**	33.3

%irr = percentage of irregular observations, defined as displacement greater than 2mm or 4° in yaw/roll.

Figure 1. Flow diagram of sample selection process

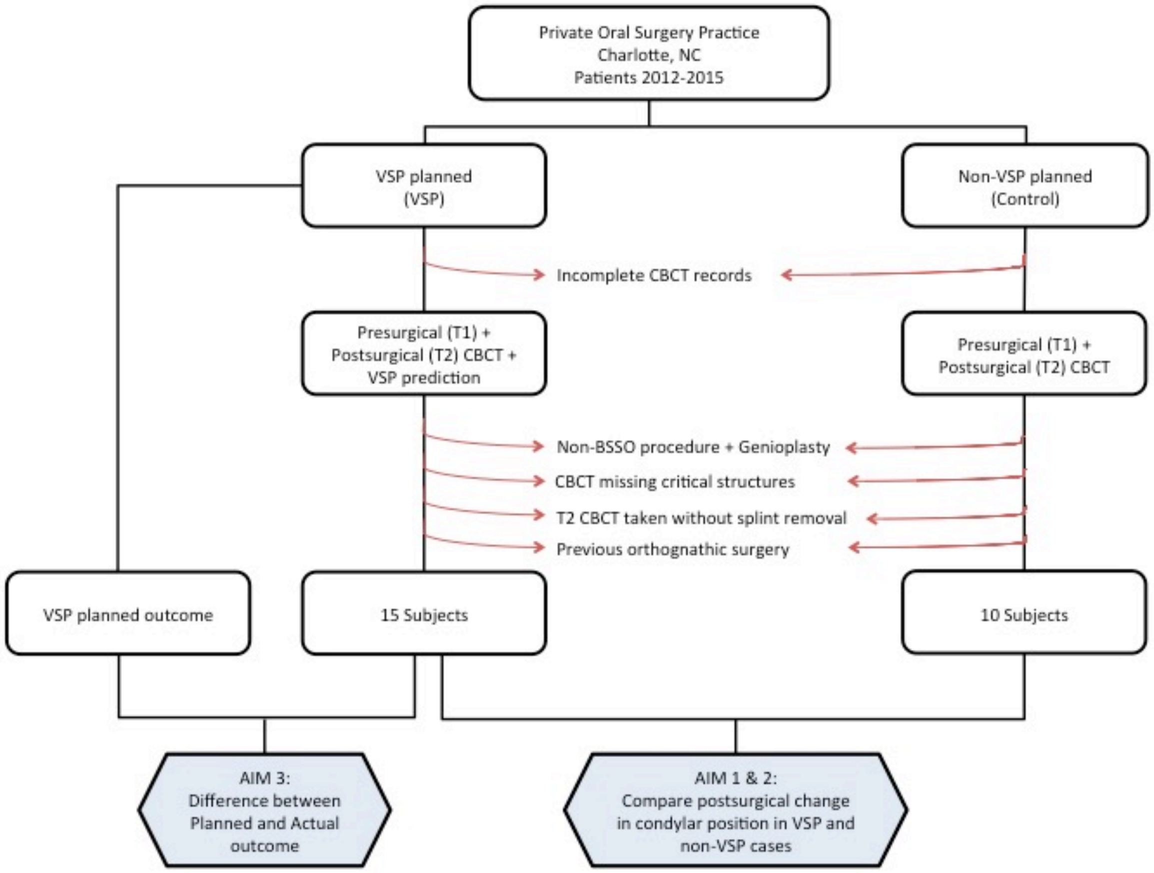

Figure 2. Bland-Altman plots of difference between repeated measurements

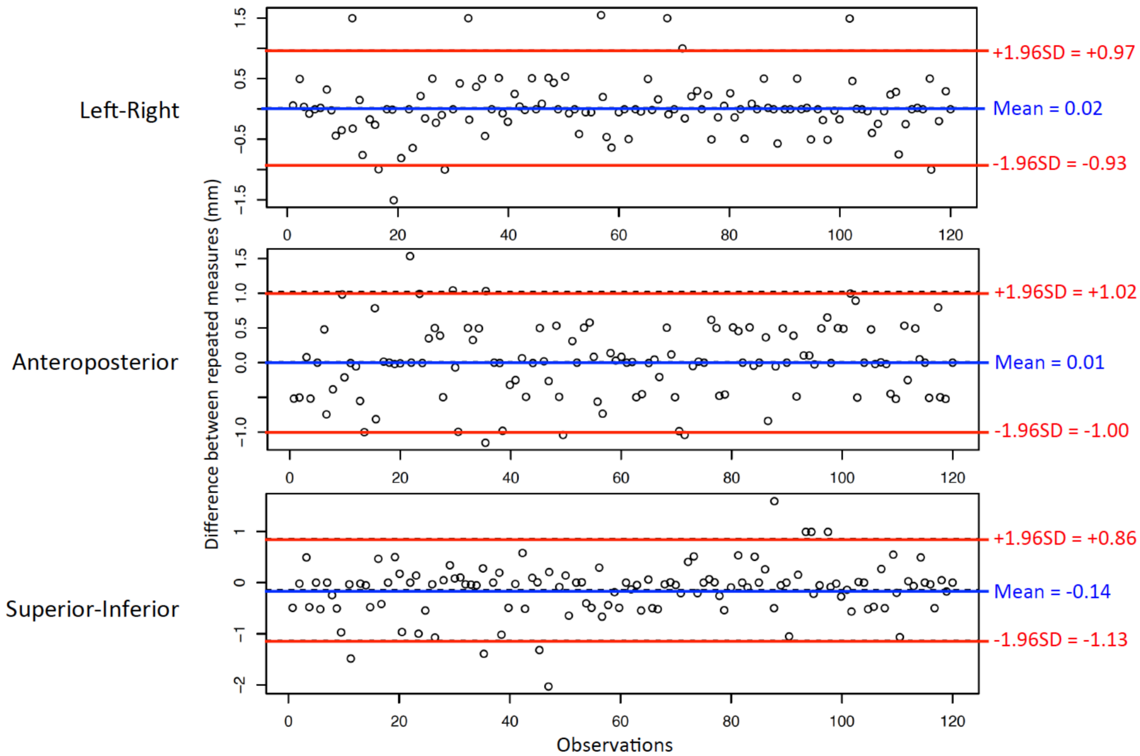

Figure 3A-D. Condylar translation and torque for VSP and control groups

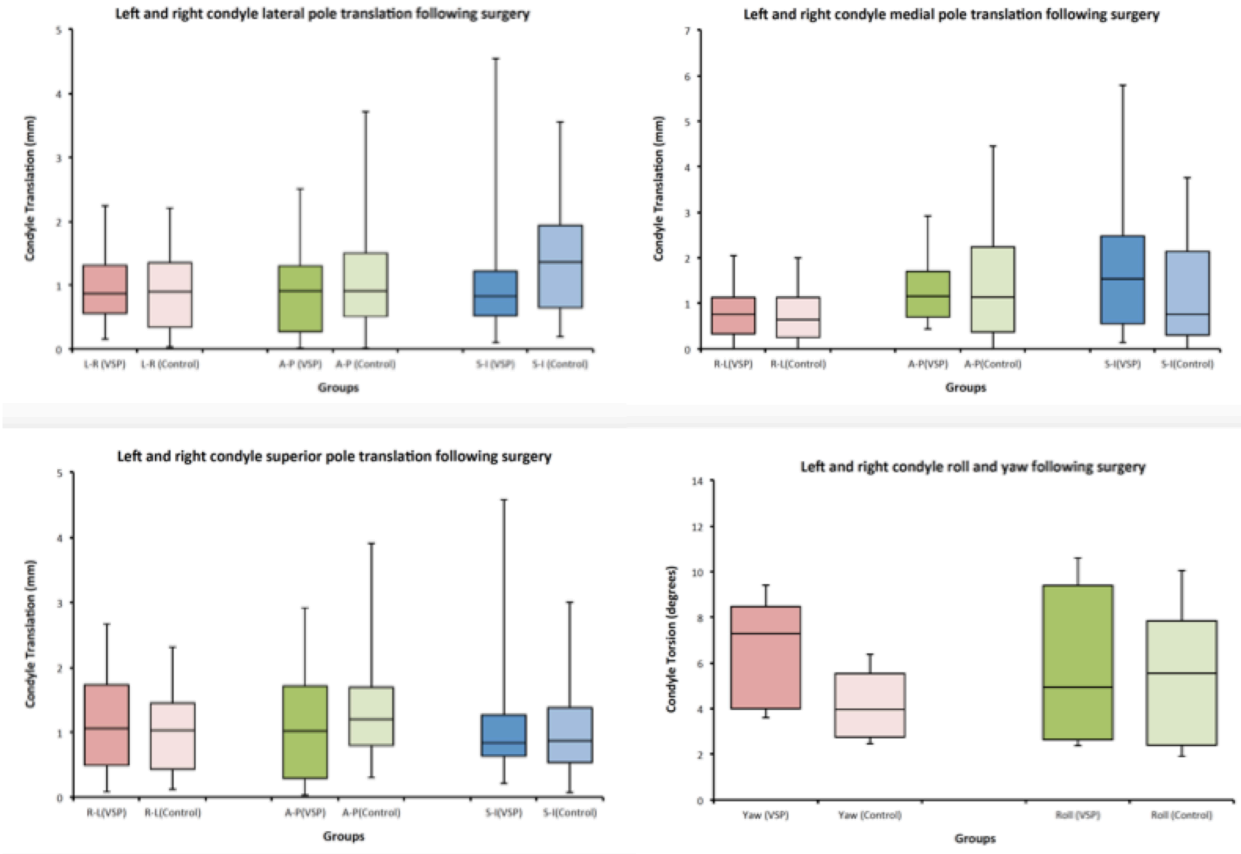

Figure 4A-H. Multivariate linear regressions for predictors and condylar yaw and roll

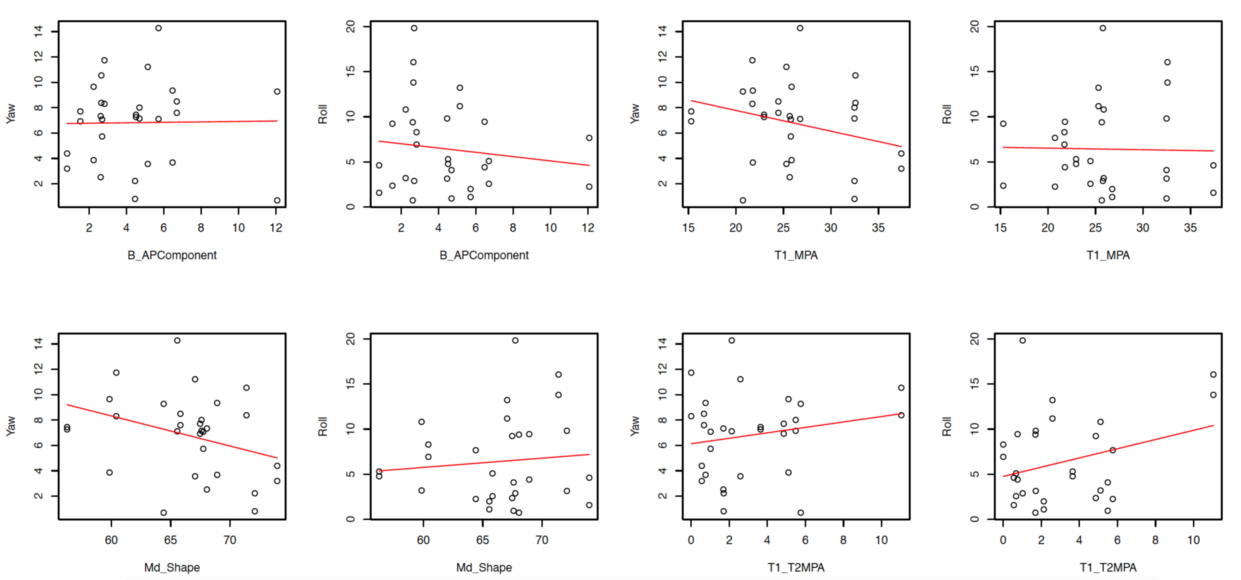

Figure 5. Positional differences between VSP-predicted and actual surgical movement

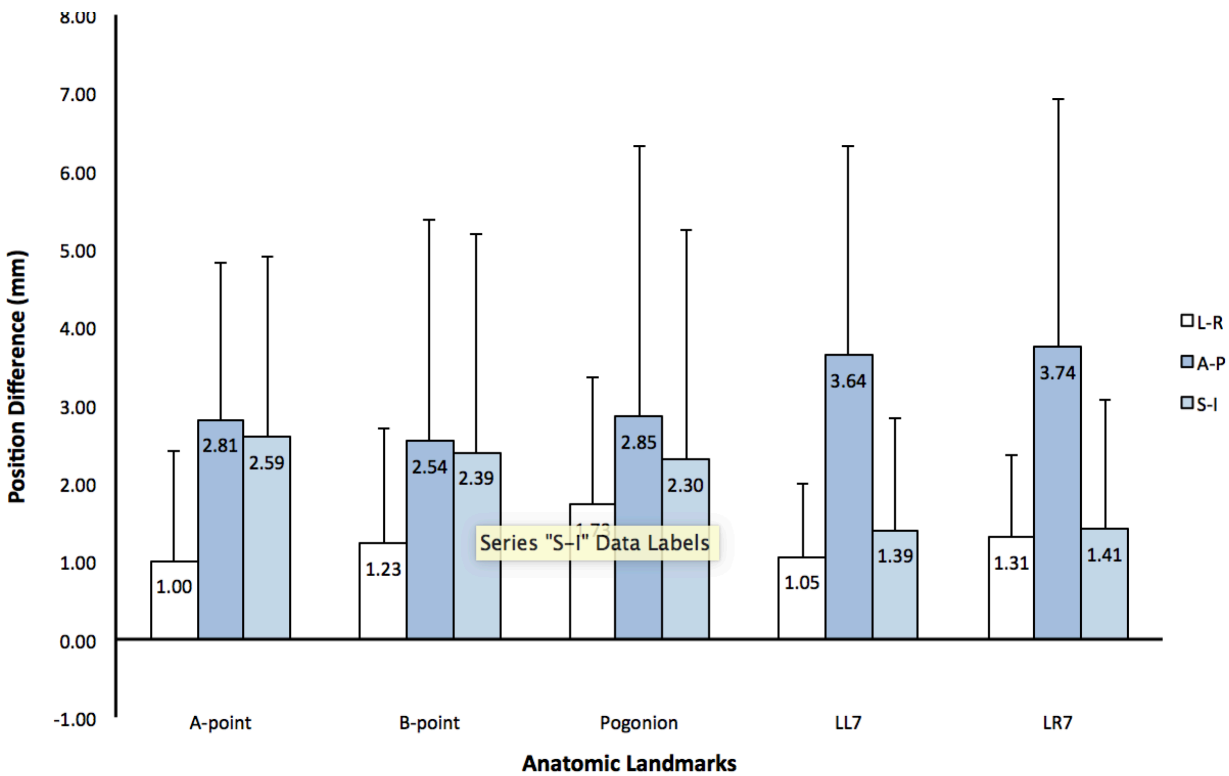

Figure 6. Percentage of cases with discrepancy between planned and surgical position greater than 2mm