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THE CONCORDANCE OF PREOPERATIVE DIGITAL CEPHALOMETRIC SIMULATION WITH POSTOPERATIVE OUTCOMES IN ORTHOGNATHIC SURGERY PATIENTS

NOURA JAMIL HUSSEIN ODEH

MASTER OF SCIENCE

DEPARTMENT OF ORTHODONTICS

SUPERVISOR
PROF. DR. ZEYNEP AHU ACAR

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STATEMENT

Hereby I declare that this thesis study is my own work, I had no unethical behavior in any stage from planning of the thesis until writing it, I have obtained all the information in this thesis within the academic and ethical rules, I have cited all the information and comments that are not obtained with this thesis study, and these sources are also included in the list of references, I hereby declare that I have no infringement of patents and copyrights during the study and writing of this thesis.

NOURA JAMIL HUSSEIN ODEH

Signature

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II. CONTENTS

IV. PICTURE LIST

V. TABLE LIST

ORTOGNATİK CERRAHİ HASTALARINDA PREOPERATİF DİJİTAL SEFALOMETRİK SİMÜLASYONUN POSTOPERATİF SONUÇLARLA UYUMU

Öğrencinin ismi: Noura Odeh

Danışman: Prof. Dr. Zeynep Ahu Acar

Bölüm: Ortodonti Anabilim Dalı, Marmara Üniversitesi

1. ÖZET

AMAÇ: NemoCeph ortodontik yazılımı tarafından üretilen bilgisayarlı ortognatik tahminleri cerrahi olarak tedavi edilen ortodontik hastalarda gerçek tedavi sonuçlarıyla karşılaştırmaktır.

GEREÇ VE YÖNTEMLER: 30 ortognatik cerrahi hastasının ameliyattan 1-4 ay sonra elde edilen postoperatif sefalometrik radyografileri NemoCeph ortodontik yazılımı kullanılarak çizilmiş ve preoperatif olarak üretilen simülasyon ölçümleriyle karşılaştırılmıştır. Kullanılan parametreler SNA açısı, SNB açısı, SN-Go-Me açısı, SN-PP açısı, ANS-Me / N-Me oranı ve Ar-Go / N-Me oranıydı. Tahmin edilen ölçümler ile gerçek postoperatif ölçümler arasındaki uyumu değerlendirmek için Bland & Altman plot analizi yapılmıştır.

BULGULAR: Tahmini ve gerçek ölçümler arasındaki ortalama farklar (x) ve bunların standart sapmaları (SD) aşağıdaki gibidir: SNA: x= 0.766 , SD=3.6, SNB: x=0.6667, SD=2.22, SN-Go-Me: x =0.9333, SD=3.96, Sn-PP: x=1.267, SD=2.74, ANS-Me/N-Me: x=0.3733 SD=2.21, Ar-Go/N-Me: x=0.89, SD=3.92. Ar-Go/N-Me oranı ve Sn-PP hariç, tüm parametrelerde iki ölçüm arasındaki farklar, SNA, Ar-Go/N-Me ve ANS-Me içi ortalamanın altında ve üstünde iki standart sapma içinde dağımıştır. SNA, Ar-Go/N-Me , ve ANS-Me/N-Me her birinin bir aykırı değeri, SN-Go-Me'nin üç aykırı değeri ve SN-PP'nin üç aykırı değeri varder, SNB'nin hiç değeri yoktu.

SONUÇ: NemoCeph ortodontik yazılımı kullanılarak oluşturulan tahmini preoperatif sefalometrik ölçümler, cerrahi olarak tedavi edilen ortognatik hastalarda gerçek postoperatif sonuçlarla kabul edilebilir bir uyum göstermiştır. Sagital ölçümlerde uyum dikey olanlara göre daha yüksektir.

Anahtar Kelimeler: Ortognatik Cerrahi, Sefalometrik Simülasyon**,** Dijital ortodonti

THE CONCORDANCE OF PREOPERATIVE DIGITAL CEPHALOMETRIC SIMULATION WITH POSTOPERATIVE OUTCOMES IN ORTHOGNATHIC SURGERY PATIENTS.

Name of the student: Noura Odeh

Supervisor: Prof. Dr. Zeynep Ahu Acar

Department: Department of Orthodontics, Faculty of Dentistry, Marmara University

2. SUMMARY

AIM: To compare computerized orthognathic predictions produced by NemoCeph software with the actual outcomes in orthognathic surgery patients.

MATERIAL and METHOD: We used postoperative cephalometric radiographs of 30 orthognathic surgery patients, obtained 1-4 months after surgery, that were traced using NemoCeph orthodontic software, the measurements were compared to the predicted measurements preoperative measures. The parameters used were SNA angle, SNB angle, SN-Go-Me angle, SN-PP angle, ANS-Me/N-Me ratio and Ar-Go/N-Me ratio. Bland & Altman test was used to evaluate the agreement between the simulated measurements and the actual postoperative measurements .

RESULTS: The mean differences (x) and their standard deviations(SD) between the predicted and actual measurements were as follows: SNA: x= 0.766 , SD=3.6, SNB: x=0.6667, SD=2.22, SN-Go-Me: x=0.9333, SD=3.96, Sn-PP: x=1.267, SD=2.74, ANS-Me/N-Me: x=0.3733 SD=2.21, Ar-Go/N-Me: x=0.89, SD=3.92 . Except for Ar-Go/N-Me ratio and Sn-PP, the differences between the two measurements in all parameters were distributed within two standard deviations below and above the mean with SNA , Ar-Go/N-Me , and ANS-Me/N-Me each had one outlier, SNB had no outlier, SN-Go-Me and SN-PP each had three outliers .

CONCLUSION: The predicted preoperative cephalometric measurements generated using NemoCeph orthodontic software showed acceptable concordance with the actual postoperative outcomes in surgically treated orthognathic patients. Concordance in sagittal measurements was higher compared to vertical ones.

Key Words: Orthognathic surgery, Cephalometric Simulation, Digital orthodontic

3. INTRODUCTION and AIM

One of the greatest challenges in orthodontics is the treatment planning and management of orthognathic surgical cases. A surgical orthodontic treatment approach is carried out in patients with severe malocclusions that require close collaboration between orthodontists and surgeons to establish the final desired treatment results. During recent decades, orthognathic surgery has become widely accepted as the preferred method of correcting moderate-to-severe skeletal deformities including facial esthetics. Recognition of esthetic factors and prediction of the final facial profile play an increasingly important role in orthognathic treatment planning (Klein et al., 2019). For routine orthognathic surgery cases, cephalometry and two dimensional photogrammetry are common and less expensive tools that may have the potential to analyze and predict the resulting profile (Ferguson and Luyk, 1992). As part of the daily clinical routine in the orthodontic practice nowadays, computer programs that perform orthognathic surgery simulations on cephalometric radiographs are extensively used. Although provided by different companies these programs encompass almost the same principle of Virtual Treatment Objectives (VTO). The simulations produced by these programs help the orthodontist to predict hard and soft tissue changes expected after surgery, and can be utilized to plan treatment of orthognathic cases and to aid in communication between the orthodontist, surgeon, and patients. Accuracy of the simulations produced by the currently available programs is variable, thus the aim of the present study is to measure the agreement between the values predicted by two dimensional (2D) simulations and postoperative cephalometric radiographs.

A proper understanding of the predicted results by the patients is a key for the success of the treatment. Visualized treatment objectives are important predictive tools to give a detailed preview of the final results for the patients (Özgür et al., 1998). Orthognathic surgery patients seek such a complicated long treatment to correct their disfigured profiles, their expectations vary according to the extent of disfigurement and the psychological impact of it, making it extremely important to give the patient a preview of the final result and make sure the patient does have realistic expectations. Skeletal disfigurement has a negative impact on a patient’s social life because patients with malocclusion, especially those in need of surgical correction, have lower health related quality of life (HRQOL) and higher anxiety (Azuma et al., 2008). Quality of life is defined as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

This highlights the importance of the predictions produced by the computerized softwares. Evaluating the accuracy of these simulations will enable the orthodontist and the surgeon to optimize treatment planning and communication for better treatment outcomes and increased patient satisfaction after the treatment, it also evaluates the extent to which the orthodontist can rely on those simulations. Although many studies in the field of orthognathic surgery were performed only a few have attempted to evaluate orthognathic precision by comparing preoperative prediction with postoperative outcome.

4. GENERAL INFORMATION

4.1. Orthognathic Surgery

4.1.1 What is orthognathic surgery

Orthognathic surgery is the surgical correction of dentofacial deformities. It involves a combination of orthodontic and maxillofacial treatment. The origin of the word “orthognathic” comes from the Greek words “ortho” and “gnathos”, which means “straighten” and “jaw” respectively. This rearrangement of the facial skeleton components aims to restore the appropriate anatomic and functional relationships of the skeleton and the soft tissue of the face. Currently in the dental practice, combined orthodontic surgical treatment includes two modalities: the first is a conventional combined orthodontic surgical treatment, and the second is a surgery first approach.

The conventional approach consists of three phases of varying durations: a presurgical orthodontic treatment, orthognathic surgery , and a postsurgical orthodontic treatment. The aim of orthognathic surgical correction is to restore good function as well as improve facial symmetry and esthetics. Orthognathic surgery has improved the correction of maxillomandibular malformations (Lira et al.,2012). The high expenses of the combined orthodontic surgery treatment and its long duration, in addition to the trauma and interference to routine daily life caused by the surgical phase of the treatment, might cause uncertainty and confusion for the patients, patients might reconsider receiving this combined long treatment and might even change their mind and choose a less invasive treatment approach.

4.1.2 Types of orthognathic surgery

4.1.2.1 Maxillary area orthognathic surgery

The main type of surgery for the maxillary area is the Le Fort, in this surgery the surgeon can relocate the maxilla in any direction. Maxillary surgery is typically performed in conjunction with mandibular setback surgery, resulting in optimal and stable results.

4.1.2.2 Mandibular area orthognathic surgery

The main debate on orthognathic surgery in the mandibular area is the type of osteotomy that will be used for the mandibular setback. Intraoral vertical ramus osteotomy (IVRO) can be the option in some cases, bilateral sagittal split osteotomy (BSSO) is the most common osteotomy type (Monson, 2013).

4.1.3 Indications for orthognathic surgery

Orthognathic surgery approach is the treatment of choice in severe skeletal jaw discrepancy and asymmetrical facial skeleton in which orthodontic camouflage treatment won’t solve the chief complain of the patient. It is also the only option for patients whose orthodontic conditions are so serious that neither growth alteration nor camouflage can help solve it. Orthodontic treatment aiming to modify growth to help solve malocclusion is only possible while the patient is in active growth period. Since growth modification in growing children yields greater changes than achievable by tooth movement alone in adults, certain cases that could have been treated only orthodontically in children like increased overjet by centimeters would need surgical treatment in adults.

4.1.4 The development of orthognathic surgery

Early in the twentieth century, the surgical treatment to correct mandibular prognathism first appeared, which involved a body ostectomy by extracting a molar or premolar together with the associated block of bone. Edward Angle had some comments on a case of a patient who received this form of treatment over a century ago, he suggested that using orthodontic appliances and occlusal splints would enhance the treatment outcome if they were used together with the surgical procedure. So basically he suggested using a combined treatment approach that involves both orthodontic and surgical procedures to correct the problem. While there was steady improvement in techniques for repositioning a prominent mandible during the first half of the twentieth century, the sagittal split ramus osteotomy, introduced in 1957, marked the start of the modern period of orthognathic surgery. An intraoral method was used in this procedure, avoiding the need for a potentially damaging skin incisions. The sagittal split procedure also allowed for the increase or decrease in length of the lower jaw with the same bone incisions, allowing for the treatment of mandibular deficiency or excess. During the 1960s, Surgeons in America began to adapt and use European maxillary surgery techniques, and after a decade of accelerated advancement in maxillary surgery, the Le Fort I downfracture procedure was developed, allowing the maxilla to be repositioned in all three planes of space (Steinhäuser,1996). By the 1980s surgeons were able to reposition maxilla or mandible or even both jaws, alter the position of dentoalveolar segments as desired, and also move the chin freely in the three planes. Rigid internal fixation, which eliminated the need for jaw immobilization in the 1990s, dramatically increased patient comfort, and a greater understanding of traditional postsurgical improvements rendered surgical results more reliable and predictable (Obwegeser,2007). Larger jaw movements and intervention at an earlier age became possible for patients with the most serious skeletal problems (mostly associated with syndromes), since the advent of facial distraction osteogenesis around the turn of the century and its steady development since then.

4.1.5 How stable is outcome of orthognathic surgery

One of the biggest concerns when it comes to orthognathic surgery, is the stability of its outcome, the presence or lack of relapse and the long term preservation of the result of the surgery. Therefore relapse can be observed in two types according to the time interval they occur, the immediate and the late relapse. Immediate relapse is usually encountered immediately after surgery and its cause is usually an error in operation table, like a misplaning in surgical treatment plan, a wrong positioning of the temporomandibular joint or maybe inaccuracies in osteosynthesis. On the other side of the coin, a late relapse can appear after a noticeable time period has passed from the surgical procedure. A late relapse can be in the form of a partial or complete relapse towards the situation of the facial structures before the orthognathic surgery. Late relapse appears to have many reasons, like growth spurts, hard tissue remodeling due to the function of the masticatory system, an unstable occlusion after surgery or inability of the muscles of the face to adapt to the new relationships between jaws. Moreover, if a persistent habit exists at the function or at the orofacial muscle system, it can also be a cause of relapse (de Haan et al., 2013). It is reported that also sagittal corrections show more long term stability than the vertical corrections of the jaws (Gallego-Romero et al., 2012).

4.2. Psychological Considerations in Orthognathic Surgery Patients

Disfigurement of the facial skeleton exerts a negative effect on multiple aspects of life. Those aspects are very important and intersect in almost every activity or routine the patient practices, examples are: social life and interactions, choice of profession, opportunities, choice of partner, and personality characteristics (Özgür et al., 1998).

So it is reasonable to perform orthognathic surgery as appropriate treatment of disfigurement if it is subjectively considered as a handicap, to improve the psychology and quality of life for the patient. This is why we need to understand that the patients' perception of the quality of orthognathic surgery depends on several factors and not only aesthetics and function, but also psychological aspects. So patients' preoperative expectations of the orthognathic surgical treatment and postoperative results can show discrepancies if patients are not informed of what is possible and what is not. It should also be noted that postoperative dissatisfaction is not necessarily due to the skill of the maxillofacial surgeon; it results mainly from insufficient communication between the surgeon and patient (Rustemeyer et al., 2010).

The life satisfaction, self-esteem, and body image of an individual seeking orthognathic surgery are highly influenced by the end result of the treatment. Most issues that a maxillofacial surgeon faces arise from the worry of reaching an aesthetic profile, compared to other surgical practices in which they usually focus on the furtherance of life, they see the end result as living versus dying or health versus illness. Improving the patient's appearance is associated with the consequent relief of psychiatric and/or social problems. In this regard we can summaries the aim of orthognathic surgery as follows: an attempt to correct the patient's inability to accept how he sees himself, together with functional improvement.

The patients' satisfaction about the orthodontic treatment is likely to be higher when the pretreatment dentofacial deformity is severe and when they have lower QOL and psychological status. However, even in those patients and even after orthodontic treatment by an expert orthodontist, patients show huge variations in the level of satisfaction. To avoid disappointment or dissatisfaction after orthognathic surgery treatment clear discussion of the patient's psychological roots of the skeletal disfiguration and the image he or she has in mind after the treatment is completed, this will keep the maxillofacial surgeon aware of the important aspect of this malocclusion which is the psychological aspects and he will take into consideration the patient's point of view when constructing a treatment plan with the orthodontist.

4.3. Orthognathic Surgery Patients Quality of Life

Patients presented with malocclusion, especially the ones who need surgical correction, tend to have a lower quality of life (QOL) in addition to higher anxiety (Rustemeyer et al., 2010). Quality of life can be defined as the individual's perception of their position in life which is differs according to the culture and value systems in which they live and is also related to their, expectations, goals, standards plus concerns. Psychology is an important part of orthognathic surgery procedure in order to rehabilitate the patient so that he gets a consequent relief of psychiatric and social problems. It is known that orthognathic surgery patients also seek psychological stability associated with a better appearance that is acceptable to their society. Orthognathic surgery patients usually experience improved functional and psychosocial status after surgical orthodontic treatment. The psychological factors and the aesthetics in those patients exerts a strong influence on their life quality (Azuma et al., 2008). Most of today's orthognathic surgery patients have strong expectations on the postsurgical facial profile, so the quality of life improves highly if these patients experience aesthetic improvement in facial profile postsurgically.

The patients' comprehension of the quality of the outcome of orthognathic surgery depends on many factors, these factors include aesthetics and function, in addition to the psychological aspects. Subsequently, patients' preoperative desires and expectations of orthognathic surgery and postoperative treatment outcome might have discrepancies if patients are not informed clearly of what is possible and what is not (Rustemeyer et al., 2010).

The patients' values play an important role in planning the treatment, because the success of treatment should also be evaluated in terms of patient's perceptions of what was gained as a postoperative outcome (Özgür et al., 1998).

4.4. Sequence of Treatment in Orthognathic Surgical Cases

When a patient is identified with a dentofacial abnormality that requires surgical repair, both the surgeon and the orthodontist must conduct a thorough examination and evaluation. The surgeon checks the patient and evaluates the available records before discussing the treatment choices with the patient and his family. As a final result of the therapy, the surgeon hopes to meet both functional (occlusal) and facial aesthetic goals. On the other hand, after taking impressions, the orthodontist gathers complete records, which comprise lateral and panoramic radiographs, face and occlusal radiographs, and dental models. The surgeon and orthodontist then collaborate to examine and organize the available data into a recommended treatment plan, which is then communicated and discussed with the patient and his family. The treating doctors seek a signed written consent that details the detailed treatment processes and adverse effects once all parties have agreed on the treatment option.

4.5. Planning Orthognathic Surgery

Orthognathic surgery needs collaboration between orthodontic and surgery departments. Diagnostic casts, X rays, intraoral, and extraoral photographs are all used and studied to arrive at the desired therapy.

4.6. Complications in Treatment of Orthognathic Surgery Patients

4.6.1 Complications in treatment as a result of inadequate treatment planning

Insufficient and improper presurgical treatment planning are most common cause of the problems or unfavorable outcomes encountered in patients going through orthognathic surgical treatment (Klein et al., 2019). It is important that the patient's chief complaint and expectations, are clearly understood and perceived by the clinicians. The findings, treatment objectives and the general arrangement of the overall treatment procedures should be discussed and settled upon by the surgeon and orthodontist prior to starting treatment.

Whenever the situation allows, the requirement for orthognathic surgical procedure ought to be decided before any tooth movement has been begun so that orthodontic treatment can be initiated as productively and successfully as conceivable (Klein et al., 2019). miscommunication between treating doctors can bring about insufficient or increased dental decompensation, extended treatment time, delay, or on the other hand possibly an increase in magnitude of the operation (example, what could be a single jaw surgery turns into a double-jaw surgery). When the orthodontists and the surgeons work as a team to structure a precise diagnosis and treatment plan, control and provide feedback to one another during the preoperative and postoperative orthodontic phase, and confirm using the appropriate appliances in addition to the postsurgical treatment strategies, patients will have a great chance for a successful treatment outcome. On the other hand miscommunication between treating team can cause an inappropriate or insufficient treatment. It is thus recommend to create a regular communication meetings between orthodontist and surgeon throughout the whole treatment process, it is also recommended that frequent progress dental casts are being constructed to ensure adequate decompensation of the teeth.

4.6.2 Complications resulting from presurgical orthodontic procedures

The aims for presurgical orthodontic phase can be summarized as follows:

1- Decompensation of the teeth to reduce the amount of the dental discrepancy making it as close as possible to the skeletal discrepancy. This is achieved by dental decompensation in all the planes; the sagittal plane, the vertical plane, and transverse plane.

2- Elimination of all the dental interferences that would impede establishing the desired final occlusion.
3- Evaluation of tooth size discrepancies that might affect intercuspation when achieving the ideal postoperative overjet and overbite.

The previous aims must be carefully planned before the initiation of treatment, the final treatment plan should also be approved by both the surgeon and the orthodontist before starting the presurgical phase.

4.6.3 Complications resulting from postsurgical orthodontic care

Precise postsurgical orthodontic treatment is of prime importance for successful final outcome. The duration of postsurgical orthodontic care relays on many different factors, among which:

1- how careful the presurgical orthodontic set up was to the desired outcome.
2- The patient's level of compliance with elastics after surgery.
3- How similar the predicted surgical plan was to the actual surgical positioning of the jaw or jaws.

It is preferred that postoperative patients are followed regularly by both the surgeon and the orthodontist. Regular controls ensure that patients are adhering with instructions like proper elastic use. uncontrolled elastic use can cause distortion of the dentoalveolar relationship and jaw position.

4.7. Prediction of Orthognathic Surgery Outcome

Surgical orthodontic treatment approach involves diagnosis followed by treatment planning, and then correction of the skeletal deformities either starting with presurgical orthodontic phase or by surgery first approach vital (Donatsky et al., 2009). In the past, surgeons and orthodontists performed treatment planning by clinical examination, photographs, manual alteration of lateral cephalograms tracing, manual surgical simulation performed through cut and paste profile cephalometric tracings. Those techniques were time consuming and did not show adequate accuracy because of the factor of human error during tracings and the distortion in radiographs. It was also not possible to accurately predict or permit the patient or treating doctors to visualize and predict treatment (Donatsky et al., 1992, 1997; Ferguson and Luyk, 1992).Visualized treatment objectives (VTOs) are vital predictive measures to visualize and predict the final treatment results before the end of treatment. Computerized VTOs permits the use of many different software programs available to the doctors in order to perform growth prediction, orthodontic decompensation, and prediction of orthognathic surgical outcomes prior to initiating the treatment.

4.8. Computer Programs for Orthognathic Surgery Simulation

In recent years, computer technology has infiltrated almost every area of human life. This is true for dentistry in general and orthodontics in particular. Computers made early inroads into the dental field in the early 1970s (Upton et al., 1997). Digital technology was first used by orthodontists for the digitization of cephalometric radiographs for orthodontic diagnosis and later for orthognathic surgery. Ricketts not only covered the use of cephalometric radiographs for orthodontic diagnosis, treatment planning, and growth prediction in great detail, but also reevaluated the use of cephalometric radiographs for orthognathic surgery. The manual cephalometric prediction of orthognathic surgery outcome are time consuming. Computer programs designed to conduct cephalometric tracings and measurements, as well as various types of analyses, have been developed as a result of continuous technical developments in computing combined with scientific advances in dental radiology (Konstiantos et al., 1994; Carter et al., 1996). For orthognathic surgery prediction, there are currently a variety of computerized cephalometric software systems available. Computerized prediction algorithms have significantly improved the clinician's ability to easily assess various postoperative profile predictions for all surgical choices (Power et al., 2005). Orthodontists and maxillofacial surgeons may use these computer software programs to quickly modify digital representations of hard and soft tissue profile tracings and then morph the pretreatment profile to create a projected treatment simulation. The software makes an automated estimate of the patient's soft-tissue profile based on chosen hard to soft tissue ratios. A prediction tracing may be used to validate the surgical plan's viability by assessing the effect of predicted surgical movement on hard and soft tissue structures. It also gives a visual estimate, which can be useful during presurgical consultations with the patient (Power et al., 2005).

4.9. Accuracy of Simulation Softwares

Presurgical planning and prediction of hard and soft tissue changes in profile related to orthognathic surgical correction of dentofacial deformities are vital (Donatsky et al., 2009). The accuracy of computer assisted surgical prediction is a major concern, and many clinicians have come to opposing conclusions after using different computer programs to simulate the treatment outcome, therefor reliability of the various computer programs should be thoroughly investigated (Kaipatur et al.,2009). The relationship between presurgical predictions and actual postsurgical hard tissue changes has been investigated in many studies to examine the accuracy as related to orthognathic surgery and show varying degree of accuracy (Kahnberg et al., 1990; Polido et al., 1990, 1991; Donatsky et al., 1992, 1997; Ferguson and Luyk, 1992; Hillerup et al., 1994; Cousley and Grant, 2004; Power et al., 2005). Prediction of soft tissue changes related to orthognathic surgical treatment is still a major challenge when the accuracy of the preoperative prediction is evaluated (Carter et al., 1996; Upton et al., 1997; Schultes et al., 1998; Gaggl et al., 1999; Jones et al., 2007; Pektas et al., 2007).

According to presurgical and postsurgical lateral cephalometric radiographs, ratios between final obtained hard tissue and final obtained soft tissue changes were evaluated in several cephalometric studies (Mansour et al., 1983; Carlotti et al., 1986; Rosen, 1988; Jensen et al., 1992; Lin and Kerr, 1998; Gaggl et al., 1999).

Cephalometric analysis for soft tissue prediction plans and evaluation of the predicted plans compared to the obtained final soft tissue in addition to the differences between the preoperative soft tissue predictions and the postoperative actual outcomes were only carried out in a few computerized cephalometric based studies, (Hing, 1989; Konstiantos et al., 1994; Carter et al., 1996; Aharon et al., 1997; Gerbo et al., 1997; Upton et al., 1997; Schultes et al., 1998; Jones et al., 2007; Pektas et al., 2007). Some researchers suggested that the main factor causing inaccuracies between preoperative predicted and postoperative achieved soft tissue changes is the inaccurate preprogrammed soft tissue to hard tissue ratios in different computer systems (Carter et al., 1996; Upton et al., 1997). One more factor could be, that it is not possible to predict the changes in soft tissue separately if we do not take into considerations the actual outcome of the planned hard tissue changes.

5. MATERIAL and METHODS

5.1. Patient Selection

For this retrospective study, Presurgical cephalometric simulations and postsurgical cephalometric radiographs of patients who had orthognathic surgery were collected. All these patients underwent orthognathic surgery in the department of surgery after an initial orthodontic treatment, in the Department of Orthodontics, Faculty of Dentistry, Marmara University. The patients were chosen from the archive data of Marmara University, Faculty of Dentistry, Department of Orthodontics. This study's inclusion criteria are:

1- Patients who underwent orthognathic surgery at Marmara university hospital.

2- Presence of posttreatment cephalometric radiographs obtained 1- 4 months after surgery.

3- Presence of pre-surgical simulation using Nemoceph program.

The exclusion criteria were:

1- Patients with craniofacial anomalies or craniofacial syndromes (including patients with cleft of lip and palate.

2- Patients with missing presurgical simulation.

3- Patients with incomplete or of poor quality records.

Following these criteria, 30 patients (14 males, 16 females) with average age of 2 ± 3 years were selected from the archive data of Marmara University, Dental School, Department of Orthodontics, Istanbul, Turkey. The study was approved by the Ethical Committee of the Institute of Health Sciences of Marmara University in 2l.12.2020 with the protocol number of 2020-475 (Enc. 1)

5.2. Data Collection and Assessment

Once all the patients who met all the inclusion criteria were identified a list with their names was prepared, their postsurgical lateral cephalograms were calibrated using Sella-Nasion line as a reference and then traced using NemoCeph orthodontic software (2018), the simulation of the orthognathic surgery for those patients were also collected from NemCeph software. The cephalometric parameters of interest and their definitions are shown in Table 1. The measurements from simulation tracing and postsurgical tracing were recorded on an excel sheet in preparation for the statistical analysis.

The postsurgical measurements obtained were compared to the predicted values produced preoperatively.

Table 1: Definitions of the evaluated parameters

SNA angle	The angle between sella, nasion and A points, formed at nasion point
SNB angle	The angle between sella, nasion and B points, formed at nasion point
SN-Go-Me angle	The angle between sella-nasion plane and mandibular plane
SN-PP angle	The angle between sella-nasion plane and palatal plane
ANS-Me/N-Me ratio	The ratio of anterior nasal spine- menton distance to nasion-menton distance
Ar-Go/N-Me ratio	The ratio of articulare-gonion distance to nasion-menton distance (Posterior face height to anterior face height ratio)

5.3. Statistical Analysis

The statistical analysis of the data in this study was carried out by the IBM SPSS Statistics software for Windows, version 25.0 Armonk, NY: IBM Corp. Descriptive analyses were presented using means, standard deviations, and ranges for continuous data. The Intra-observer method error was investigated by measuring again the 50% of the total sample (15 subjects), after 4 weeks from the initial measuring. For the analysis of reliability regarding parameter measurements, intraclass correlation coefficient was calculated. Relationships between the variables were determined using Spearman's Correlation Coefficients. Wilcoxon signed rank test was used for comparisons between the two time intervals. A 5% type-I error level was used to infer a statistical significance. Statistical significance level was established at $P < 0,05$. G*Power 3.1.9.2 (Universität Düsseldorf, Düsseldorf, Germany) was used to calculate the post-hoc power of the results. Bland & Altman plot analysis was performed to evaluate the agreement between the predicted values and the actual postoperative measurements.

6. RESULTS

6.1. Reliability Test

Method error for the studied parameters are shown in Table 2. Intraclass Correlation Coefficient was found to be close to 1 for all the measurements as detailed in Table 2. All the measurements were found to be reliable. The errors were non-fatal and did not affect the results of our measurements.

Table 2: Single observer's agreements between repeated measurements

		Intraclass Correlation[b]	95% Confidence Interval Lower Bound	Upper Bound
SNA	Single Measures	,994[a]	,992	,997
	Average Measures	,993[c]	,993	,998
SNB	Single Measures	,993[a]	,992	,996
	Average Measures	,993[c]	,996	,996
SN-Go-Me	Single Measures	,991[a]	,996	,992
	Average Measures	,996[c]	,991	,995
SN-PP	Single Measures	,992[a]	,993	,993
	Average Measures	,994[c]	,992	,991
ANS-Me/N-Me	Single Measures	,994[a]	,991	,997
	Average Measures	,994[c]	,992	,993
Ar-Go/N-Me	Single Measures	,992[a]	,991	,993
	Average Measures	,993[c]	,993	,992

6.2. Measuring the Concordance Between Simulated and Actual Values of the Parameters

The mean differences (x) and their standard deviations (SD) between the predicted and actual measurements were as follows: SNA: x= 0.766 , SD=3.6, SNB: x=0.6667, SD=2.22, SN-Go-Me: x=0.9333, SD=3.96, Sn-PP: x=1.267, SD=2.74, ANS-Me/N-Me: x=0.3733 SD=2.21, Ar-Go/N-Me: x=0.89, SD=3.92. The differences between the two measurements in all parameters were distributed within two standard deviations below and above the mean with SNA , Ar-Go/N-Me , and ANS-Me/N-Me each had one outlier, SNB had no outlier, SN-Go-Me and SN-PP each had three outliers .

The mean differences (X ± standard deviation) between the predicted and actual measurements, and the significance (P) are shown in Table 3, the only statistically significant difference between predicted values and actual outcome was encountered with SN-PP parameter.

Table 3: One sample statistics and p value for all included parameters

N = 30	**Presurgical simulation**	**Postsurgical outcome**	**Difference**	**P value**
SNA	80.76 ± 4.2	81.53 ± 4.9	-0.766 ± 3.60	0.254
SNB	80.73 ± 4.6	80.06 ± 4.4	0.667 ± 2.21	0.110
SN-Go-Me	37.3 ± 6.48	38.26 ± 6.8	0.933 ± 3.95	0.206
SN-PP	9.93 ± 4.03	11.2 ± 3.7	-1.266 ± 2.74	0.017
ANS-Me/N-Me	55 ± 2.9	55 ± 2.65	0.373 ± 2.21	0.362
Ar-Go/N-Me	66.4 ± 3.8	65.5 ± 6	0.89 ± 0.715	0.223

The graphs representing distribution of the differences for each parameter were constructed by plotting the difference between actual and predicted values on the x axis against the mean on the y axis as listed below:

1- Sella-Nasion-A point (SNA)

Differences between actual and predicted values of SNA were distributed above and below the mean within 2 standard deviations as shown in Figure 1 with only one outlier.

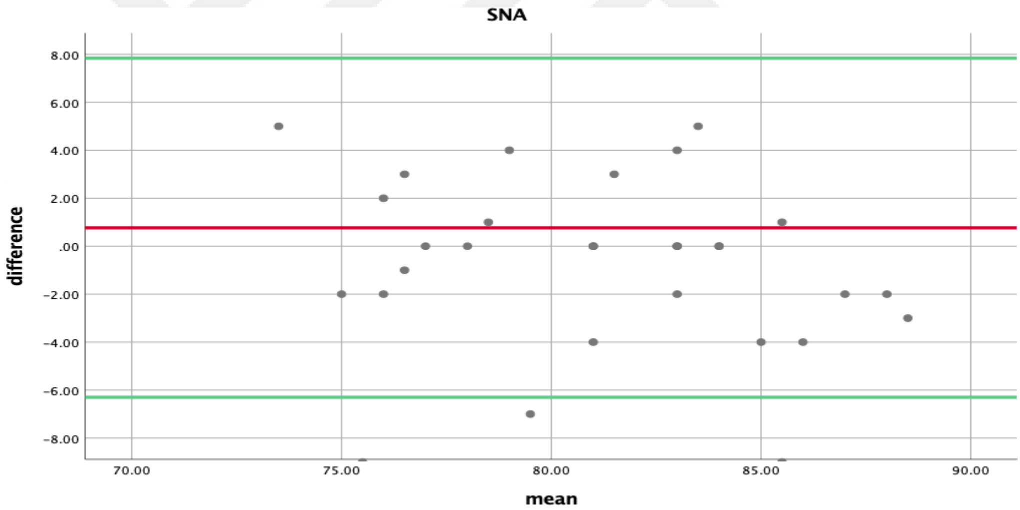


Figure 1: A graph of Difference Vs Mean for SNA presurgical and post-surgical measurements

2- Sella-Nasion-B point (SNB)

Differences between actual and predicted values of SNB were distributed above and below the mean within 2 standard deviations as shown in Figure 2 with no outliers.

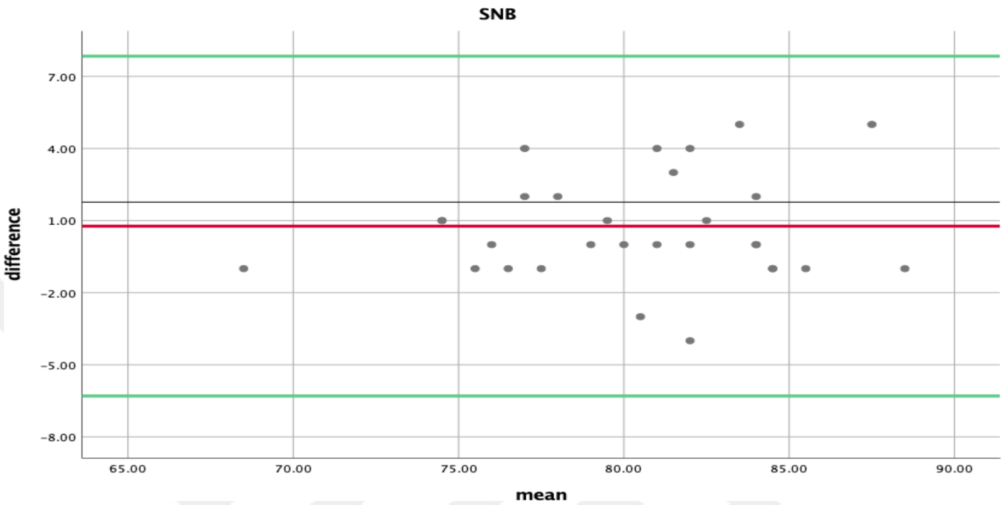


Figure 2: A graph of Difference Vs Mean for SNB presurgical and post-surgical measurements.

3- Sella-Nasion-Gonion-Menton (SN-Go-Me)

Differences between actual and predicted values of SN-Go-Me were distributed above and below the mean within 2 standard deviations as shown in Figure 3 with 3 outliers.

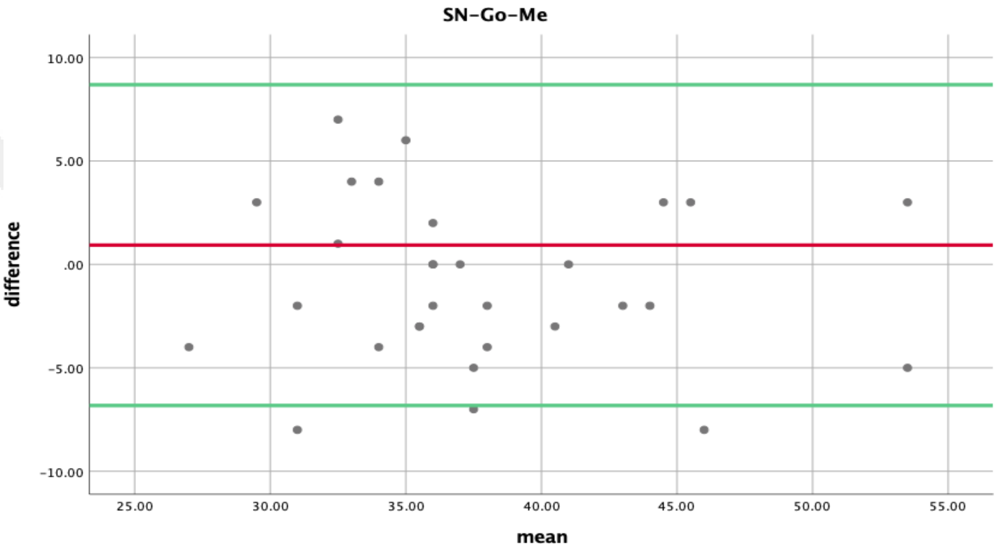


Figure 3: A graph of Difference Vs Mean for SN-Go-Me presurgical and postsurgical measurements

4- Sella-Nasion-Palatal plane angle (SN-PP)

Differences between actual and predicted values of SN-PP were distributed above and below the mean within 2 standard deviations as shown in Figure 4 with 3 outliers.

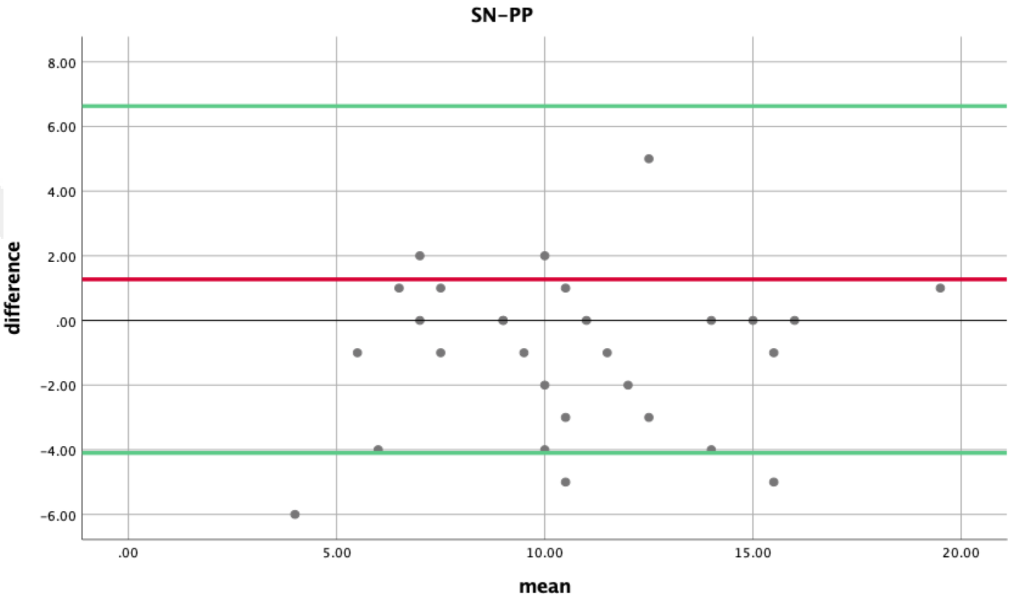


Figure 4: A graph of Difference Vs Mean for SN-PP presurgical and postsurgical measurement

5- ANS-Me/N-Me

Differences between actual and predicted values of ANS-Me/N-Me were distributed above and below the mean within 2 standard deviations as shown in Figure 5 with one outlier.

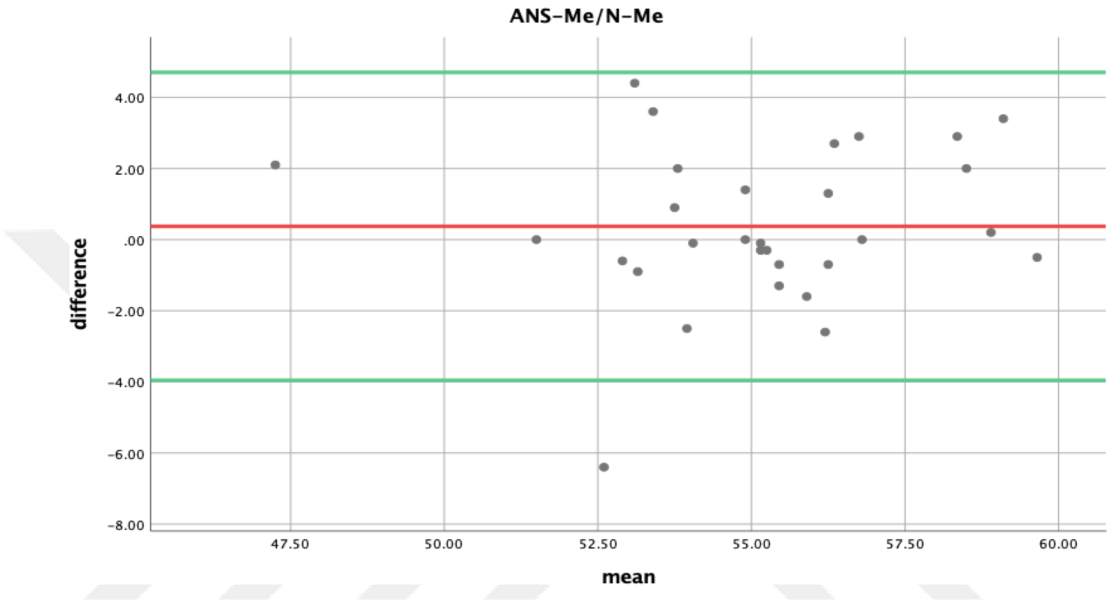


Figure 5: A graph of Difference Vs Mean for ANS-Me/N-Me presurgical and post-surgical measurements

6- Articulare-Gonion-Nasion-Menton ratio (Ar-Go/N-Me)

Differences between actual and predicted values of Ar-Go/N-Me were distributed above and below the mean within 2 standard deviations as shown in Figure 6 with one outlier.

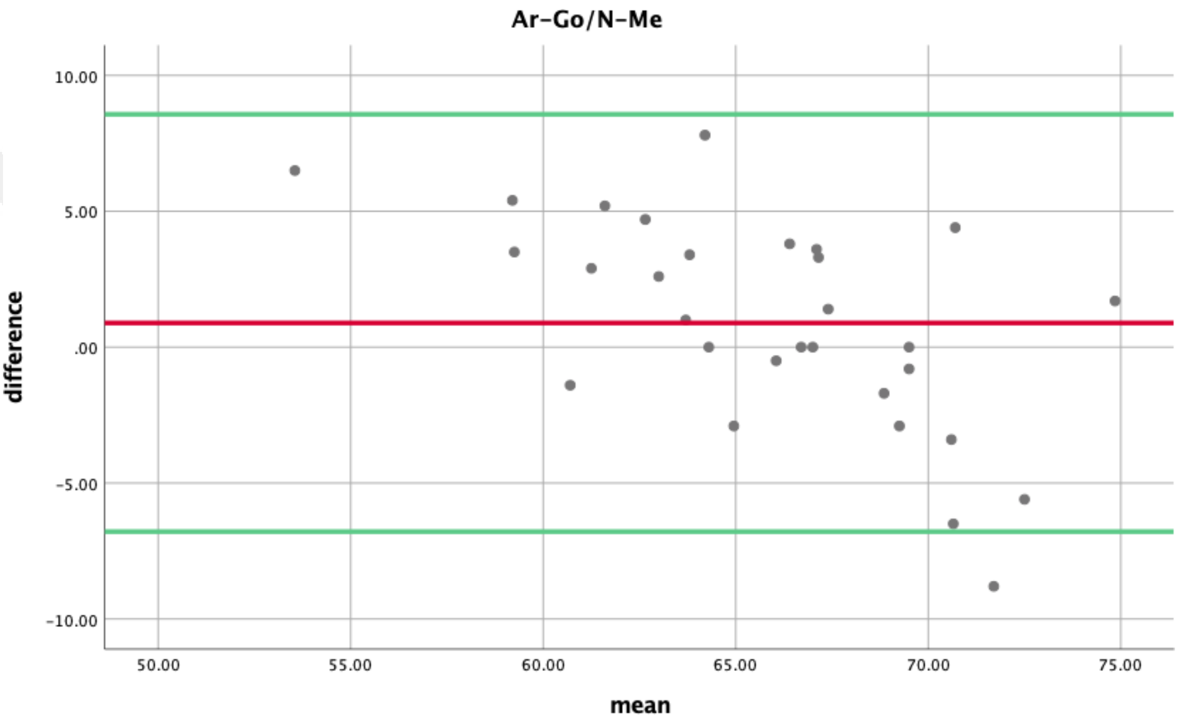


Figure 6: A graph of Difference Vs Mean for : Ar-Go/N-Me presurgical and post-surgical measurements

7. DISCUSSION and CONCLUSION

Orthognathic surgery can be defined as the combined orthodontic-surgical approach to correct dentofacial disfiguration in order to improve facial aesthetics, dental aesthetics , and stable functional occlusion. Precise presurgical planning is essential to ensure ideal surgical outcomes (Rustemeyer et al., 2010).

This study was performed to examine the concordance of presurgical digital simulations with the postoperative outcomes. Simulation was done based on two dimensional movement of maxilla and or mandible, wafer was then fabricated based on the digital simulation.

The results of our study shows that NemoCeph software generates simulations which generally coincide with the postsurgical outcomes.

The NemoCeph software allows the practitioner to create a simulation of the surgery using the cephalometric radiograph of the patient by manipulating the position of the mandible and or the maxilla, as shown in Figure 7 and Figure 8. Extra oral photos of the patient can also be superimposed on that simulation as shown in Picture 1 and Picture 2, making it easier for the orthodontist to explain the final results for the patient.

The simulation produces a large number of angular and linear parameters, including dental, skeletal, and soft tissue readings that are predicted following surgery. More than one simulation can be produced for each patient; for example, moving the mandible in all possible orientations to assess various surgical techniques results in several simulations for the same patient.

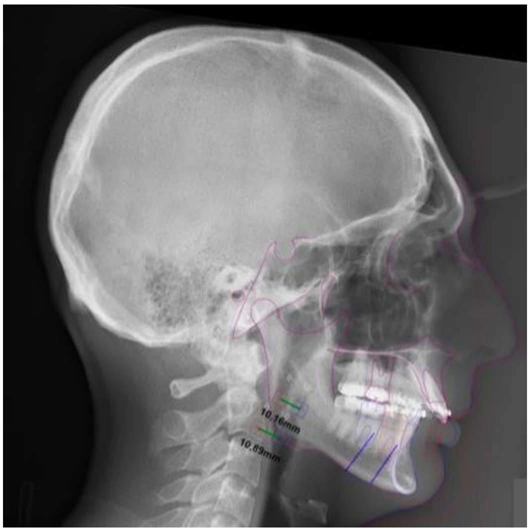


Figure 7: Cephalometric simulation of the surgery for a class II patient created by Nemoceph software

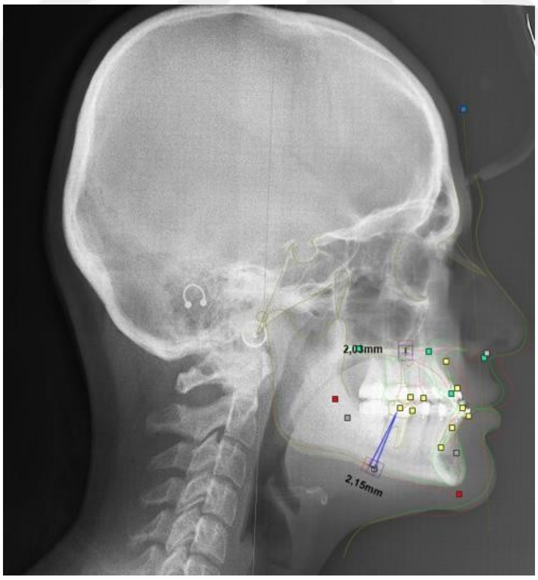
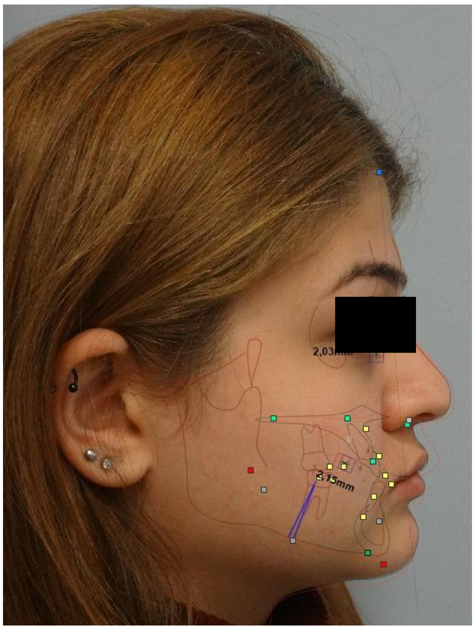


Figure 8: Cephalometric simulation of the surgery for a class III patient created by Nemoceph software

Picture 1: Superimposition of extraoral photo on cephalometric simulation for a class II patient created by Nemoceph software



Picture 2: Superimposition of extraoral photo on cephalometric simulation for a class III patient created by Nemoceph software

The measurements of each parameter were recorded before surgery (simulations generated by the software) and after surgery (actual outcomes) and as seen in the plots or graphs in the statistical analysis section, the differences between the two measurements in all parameters were distributed within two standard deviations below and above the mean with small number of outliers ranging from 1-4 with the maximum number of outliers (3) was spotted for the SN-PP angle.

The main finding of our study is that deviations of actual outcome from the predicted values were low and thus prediction accuracy high for the sagittal parameters which matches the results of previous studies (Schneider et al., 2005, Sharifi et al., 2008, Rustemeyer et al., 2010). On the other hand the vertical parameters showed more deviations from the predicted values, a similar observation found by Schneider (Schneider et al., 2005).

We might attribute this deviation to many reasons, one reason would be the transfer of the planned vertical and rotational jaw movements to the waver by use of a study model. Another reason of deviations might be during the fabrication of the waver, e.g., face bow registration transfer or the movement performed for model surgery (Sharifi et al., 2008). Since our sample includes patients that were operated by different teams thus the wafer fabrication process was not standardized, and many laboratories were involved in the fabrication. The facebow transfer process requires careful attention, due to the fact that this step was also performed by many orthodontists for our sample this might add to the sources of deviation. Another explanation is that locating reference points might vary on the lateral cephalogram from preoperative to postoperative image because of different radiographic quality (Donatsky et al., 1992, Schneider et al., 2005, Sharifi et al., 2008). The patients included in our sample were operated by different surgeons in different medical centers which might also add to the sources of deviations from the planned values.

A major field in orthognathic surgery that intersects with our findings is the stability of the postoperative results at the time the lateral cephalogram was taken. Stability can be defined as the preservation of skeleton and dentition in the planned position over time (Bailey et al., 2004). Inability to maintain stability or what is so called surgical relapse can be divided into short term and long term relapse. Short term relapse is what we are concerned about in our study since all the postoperative records were obtained 1-4 months after surgery. Most often short term relapse occurs due to surgical planning or model surgery errors, intraoperative surgical errors, or wound healing problems.

Since the literature lacks an evaluation or assessment of the NemoCeph software accuracy this project may be considered as the first step in the way of evaluating this software.

The NemoCeph software is used in Marmara University orthodontic department to plan the surgical treatment of the orthognathic surgery patients prior to refering them to the surgery departments, this is an essential step upon which the wafer and splint are fabricated, the surgeon receives the movements or the changes that the orthodontist is expecting him to perform. This highlights the importance of the accuracy of the software, and drives the attention to the lack of evidence based assessment of this software.Computers and softwares are invading all industries, among which health care and health services, dentistry being a very delicate field requires extensive investigation and evaluation of any digitalized techniques before one decides to adapt the technique and incorporate it in the dental practice, orthodontics is the art of details and this makes it even more sensitive to unplanned digitization of the practice. The sample size used in this study is a limited one, 30 patients were used, these patients met all the inclusion criteria, a larger sample size would be more representative, more malocclusions and different skeletal patterns enable us to widen the assessment of the software. It would also be beneficial if the patients were divided into subcategories to evaluate predictability of the simulations in different categories, and find out whether or not the deviation form predicted values was more in certain categories.Patients with skeletal cant, cleft lip and palate, or syndromes were not included in our sample, treatment of those patients is challenging to both the orthodontist and the surgeon, relying on the findings we concluded about the software it would be useful to conduct a second part of the study to evaluate the accuracy of simulations in those patients, since the surgical treatment in these cases is more complicated and involves many stages with more complex surgical movements, making any digital aid in their treatment planning very beneficial for the orthodontist and the surgeon.The results of this study should be incorporated in the development and update process of NemoCeph software by the manufacturing company, some of the features and the built in processing of the data can be developed and restructured to increase efficiency and accuracy of the presurgical simulations produced by the software.

One important element of the software-generated presurgical simulations is that they are utilized to interact with patients and their parents or partners in order to prepare them for the final profile they should expect after the operation. Because patients having orthognathic surgery treatment have disfigurations and malocclusions severe enough to make them seek and endure this invasive procedure, the psychology of the patients undergoing surgery is a delicate element, complex and lengthy therapy with significant side effects and problems, therefore if the simulations created by the program are not realistic and the patient is given a simulation of a very aesthetic If the patient and parents or partner expect a more attractive postsurgical profile but end up with a less attractive profile, this can create psychological shock or disappointment. Further research in the relevant subject is advised, including evaluating similar softwares that do the same duties and standardizing the quality of the outputs provided by such softwares. The predicted preoperative cephalometric measurements generated using NemoCeph orthodontic software showed acceptable concordance with the actual postoperative outcomes measured after surgery in surgically treated orthognathic patients. Concordance in sagittal measurements was higher compared to vertical ones. The lowest agreement was found among predicted and actual SN-PP angle. Computerized approaches are favored for predicting orthognathic procedures outcome as manual methods are time-consuming. Patients should be reminded, however, that predections are merely a guide and not the final result of surgery. The NemoCeph software is a reliable method to generate preoperative simulations, the simulations will help the treating team to communicate among each other for final detailing the results and better understanding of the treatment plan.

This study shows that, even if technology has infiltrated every aspect of medical practice, clinical judgment and the surgeon's experience are still critical components of orthognathic surgery treatment planning. Current software cannot substitute a thorough case study, the surgeon's thorough preparation, and the surgeon's ability to stick to the treatment plan. It should also be noted that prediction is merely a guide, and one that, in our opinion, is unpredictable, and that it does not take into account the complexities of the components that influence the final outcome.

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