The assessment of maxillary stability in Bimaxillary orthognathic patients treated by mandible-first approach versus maxilla-first approach; Randomized controlled clinical trial.

Department of Oral and Maxillofacial Surgery, Faculty of Oral & Dental Medicine, Cairo University

In partial fulfillment of the requirements for the Doctorate degree

Submitted by:

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M.D.S 2016

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23\11\2017

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Title:

The assessment of maxillary stability in Bimaxillary orthognathic patients treated by mandible-first approach versus maxilla-first approach; randomized controlled clinical trial**.**

Trial registration:

The study is to be registered on ClinicalTrials.gov

Organization: CairoU

User Name: MHamdy

Registration no:

Protocol version:

SPIRIT

Funding:

Self-funding

Roles and responsibilities:

1. **Ass. Prof. Dr. Niven Askar (NA)**
   - Assistant Professor of Oral and Maxillofacial Surgery - Cairo University
   - The senior supervisor
   - Assessment of the procedures
2. **Dr. Tarek El-Faramawi (TF)**
   - Lecturer Oral and Maxillofacial Surgery - Cairo University
   - Assistant supervisor
   - Sequencing generation
   - Surgical procedures
3. **Dr. Mohamed Hamdy (MH) (Principle Investigator)**
   - Assistant Lecturer of Oral and Maxillofacial Surgery - MSA University
   - Researcher
   - Data collection
   - Assisting in the surgical procedures
   - Follow up with the patients

Introduction:

The rehabilitation of function, esthetics and stability are the objectives of any orthognathic surgery. The long term stability of the surgical procedures which has been the research target in the recent years is affected by the direction of the surgical movement.(Venkategowda et al., 2017)

Bimaxillary orthognathic surgery is important to manage a wide range of abnormalities related to the jaws. The regular method of performing Bimaxillary surgery has always been to start repositioning the maxilla first, stabilize it, and then reposition the mandible. However, the revolution in methods of rigid internal fixation has allowed the change in this traditional sequencing whereby the mandible is repositioned and stabilized first, followed by maxilla repositioning.(Perez and Ellis, 2011)

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Many surgeons believe that in Bimaxillary surgery one jaw has to be repositioned and stabilized first before repositioning of the second jaw. Back in the days of internal wire fixation, the maxilla was the only jaw that could be adequately stabilized. Therefore the maxilla was repositioned and stabilized first as an initial and regular step in bimaxillary cases. The factor that has allowed surgical repositioning of the mandible first is the existence of stable internal fixation devices (plates and/or screws). As a result, if the mandible is to be repositioned first, it is essential to perform stable rigid internal fixation.(Perez and Ellis, 2011)

There are some essential requirements to perform the mandible first surgery. The most important one is the need to achieve stable internal fixation of the mandible after the osteotomy. The factor that allowed repositioning of the mandible as an initial surgical step is the availability and existence of stable internal rigid fixation.(Béziat et al., 2009)

(Park et al., 2015) reported that in patients of skeletal class III who underwent bimaxillary orthognathic surgery with surgery first approach had a relapse rate of 57.9%. While patients treated by the conventional three stage method had a 26.3% relapse rate

The main advantage of performing the mandible first is eliminating the greater error in malocclusion and condylar position that occur after performing the maxilla first. Thus by following the mandible first sequence the surgeon can achieve a stable occlusion with minimum errors.(Perez and Ellis, 2011)

Objective of the study:

To find out if the mandible-first approach provides a stable maxilla than the traditional maxilla first approach

Trial design:

Double-blinded randomized controlled clinical trial

Materials and Methods:

Study setting:

Outpatient clinics of the Department of Oral &Maxillofacial surgery, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt

Eligibility criteria:

Inclusion Criteria for participants:

1. Patients with skeletal class III malocclusion requiring bimaxillary orthognathic surgery
2. Patients free from any systemic disease
3. Patients who approved to be included in the trial and signed the informed consent
4. Patients with no signs or symptoms of temporomandibular disorders.

Exclusion criteria for participants: (Ritto et al., 2014) (Liebregts et al., 2017) (Jun-Young Paeng 2012)

1. Patients with cleft lip and palate "can have an unfavorable effect on facial growth (LARRY M. WOLFORD, 2002)"
2. Patients receiving chemotherapy or radiotherapy "due to the risk of low bone quality and healing (JW, 2003) "
3. Patients who refused to be included in the trial

Interventions:

a) Diagnosis

All patients are diagnosed and selected according to inclusion and exclusion criteria

Comprehensive clinical examination and understanding of patient's chief complains and needs.

Standard preoperative patient photographs (Frontal, Profile, 45°, smile, and dental occlusion)

Primary alginate* upper and lower impressions are made for the selected patients to make dental models

Bite registration is obtained by modeling wax**.

Cone beam computed Topography (CBCT) *** with 3D photogrammetry imaging of the patient wearing their wax bite.

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b) Surgical planning

Group I diagnostic data are used for computer-aided planning & designing the computer aided surgical waver (figure A) to check the final position of the maxilla first then the mandible and condyle in the planned position using specialized software†

Group II diagnostic data are used for computer-aided planning & designing the computer aided surgical waver to check the final position of the mandible first and the condyles then the maxilla in the planned position using specialized software

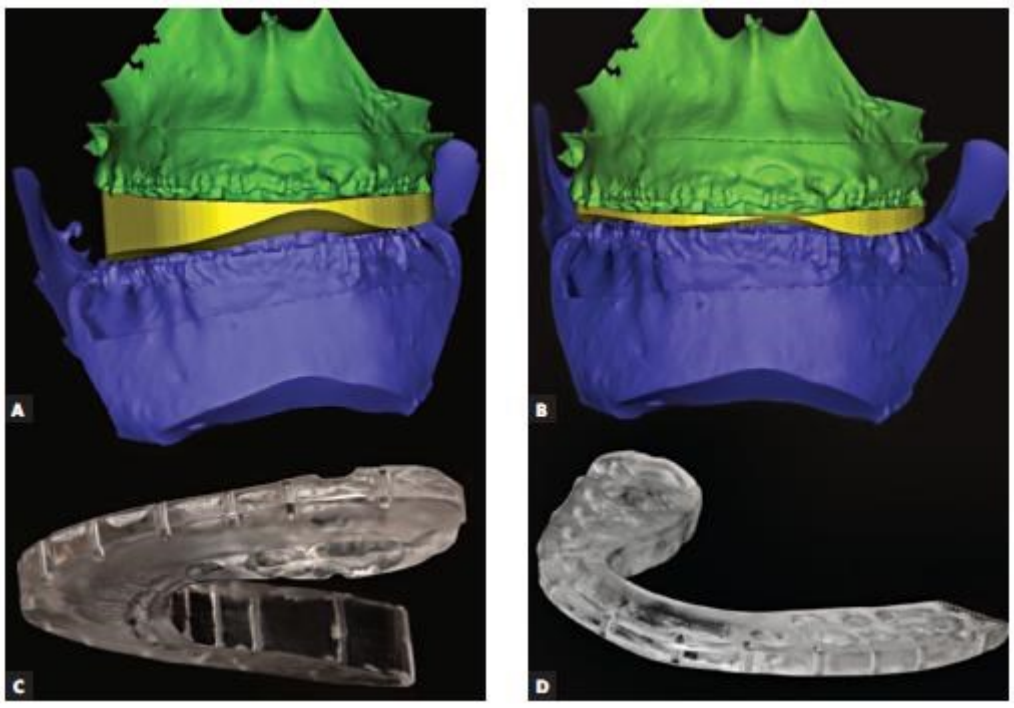

Figure A shows the surgical waver (Vale F and Maló L, 2016)

c) Intra-operative procedures:

Local anesthesia is injected intraorally along the incision line.

Scrubbing and draping of the patient are carried out in a standard fashion.

A vestibular intraoral incision for maxilla & Sagittal split incision for mandible are carried out. Dissection and reflection to reach the bone

Maxillary & mandibular osteotomies are carried out.

Complete mobilization of maxillary and mandibular segments

Reposition and fixation of the maxillary & mandibular segments using the surgical waver

The incisions are closed with continuous mattress absorbable sutures¥.

d) Postoperative

Patients will start antibiotics 4 hours after the last intraoperative dose (Amoxicillin / Clavulanic acid 625 mg every 8 hours) for 5 days

Patients will start analgesics (NSAIDs every 6 hours) for 3 days

Mouthwash (Chlorhexidine 0.12%) will be prescribed for 2 more weeks.

e) Strategies to improve adherence to intervention

Postoperative orthodontic treatment is necessary after the operation to obtain the final stable occlusion

f) Concomitant care

None needed

g) Follow up & Evaluation

- Post-operative treatment is started immediately postoperative (4 hours)
- The patients are scheduled for follow-up visits weekly for a month then on a monthly basis for 5 more months
- At 1 week and 6 months postoperatively CBCT using same parameters is ordered to calculate the difference between the immediate post-operative and the late post-operative results. (Ritto et al., 2014) (Liebregts et al., 2017) (Jun-Young Paeng 2012, J. Valladares-Neto et al., 2013)
- Patients are referred back to the orthodontist to receive his postsurgical orthodontics
- The technique is evaluated by applying hard tissue parameters to compare the immediate post-operative (P0) with the late postoperative result (P1) using 3D Cephalometry and image fusion

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Outcomes:

Type of outcome	Outcome	Measuring tool:	Unit:
Primary outcome:	Maxilla stability	Cone beam computed tomography (cbct) (Ann et al., 2016)	mm
Secondary outcome:	Patient satisfaction	Questionnaire(Rustemeyer et al., 2010)	numerical

Participant timeline:

		Study Period					
	Enrollment	**Allocation**	**Post-allocation**				**Close-out**
Time Point	**-t_1**	**0**	**t_1**	**t_2**	**t_3**	t4	**t_5**
Enrolment:							
Eligibility Screen	9\2017-9\2018						
Informed Consent	1 week after eligibility of candidate						
Pt. preparation		After consent signature					
Interventions:							
Planning and surgical guide fabrication			1 week after patient preparation				
Surgical procedure				1-3 months after start of planning			
Postoperative CBCT scans					1-3 weeks after surgery		
Assessments							
Superimposition, data collection and statistical analysis						6 months after surgery	
Editing and closing							6 months after surgery

Sample size:

The aim of this study is to assess the stability of mandible-first and the traditional maxilla-first approach. Based on the previous paper by (Esteves, 2014) and (Venkategowda, 2017), If there is truly no difference between the immediate post-operative and late post-operative, then 12 patients in each group are required to be 80% sure that the limits of a two-sided 95% confidence interval will exclude a difference in means of more than 1.5.

Statistical methods:

Data management and Statistical analysis will be done using Statistical Package for Social Sciences, Version 21.0 (SPSS, IBM) for Windows. Numerical data will be expressed as mean and standard deviation (SD). Comparisons between 2 measurements will be done by paired t test. Comparisons between 2 groups will be done by independent t test or Mann Whitney test. P value<0.05 will be considered significant. All tests will be two tailed. SD = 1

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Recruitment:

Outpatient Clinics of department of Oral & Maxillofacial Surgery in Faculty of Oral and Dental Medicine are screened, screening will continue until the target population is achieved.

Recruitment Strategy:

The Outpatient Clinics of department of Oral & Maxillofacial Surgery in Faculty of Oral and Dental Medicine utilizes "Patient Lists" for identifying and recruitment of potential subjects to the research. Once identified in the database, patients potentially eligible for this study are contacted by MH who explains the study and ascertains the patient's interest. If interested, the patient is seen in the clinical research clinics where more detailed evaluations and preparations are made. (Appendix A)

Allocation:

Sequence generation:

Participants are randomly assigned by MH and TF to either control or interventional group with a 1:1 allocation.

Allocation—concealment mechanism

Participants are randomized by MH and TF. Allocation concealment is ensured, as the service will not release the randomization code until the patient has been recruited into the trial.

Allocation—implementation

All patients who give consent for participation and who fulfill the inclusion criteria are included and randomized. Randomization is done by TF.

In return, TF will send an answer form to NA who is not involved in assessing outcome of the study. This form will include a randomization number. In every surgery closed envelopes with printed randomization numbers on it will be available. For every randomization number, the corresponding code for the surgical stent group of the randomization list will be found inside the envelopes.

NA will open the envelope and will find the type of surgical approach to be conducted in this patient.

MH is not allowed to receive information about the group allocation.

The allocation sequence will be generated by computer sequence. Throughout the study, the randomization will be conducted by TF in Oral & Maxillofacial Surgery department in order to keep the data management and the statistician blind against the study condition as long as the data bank is open.

The randomization list remains with TF for the whole duration of the study. Thus, randomization will be conducted without any influence by MH.

Blinding:

Assessments regarding clinical recovery will be conducted by TF blind to treatment allocation. Due to the nature of the intervention, MH cannot be blinded to allocation, but are strongly instructed not to disclose the allocation status of the participant at the follow up assessments. NA will feed data into the computer in separate datasheets so that MH and TF can analyze data without having access to information about the allocation.

Data Collection methods:

Primary Outcome:

Maxillary Stability:

Maxillary stability is assessed using cone beam computed tomography (CBCT) (Ann et al., 2016). In this study linear deviation between the immediate post-operative and the late post-operative positions will be calculated using mimics computer software. Where; the early and late post-operative CBCTs are superimposed by means of the reference markers

Secondary Outcome:

Patient Satisfaction:

Patient satisfaction (Rustemeyer et al., 2010) is assessed through the questionnaire answered by the patient preoperatively at T0 and 6 months postoperatively.

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Data collection, management and analysis:

Data is collected by TF & MH

Accuracy of the mandibular and maxillary approaches:

- The angular and linear measurement differences (ΔT) between the immediate post-operative (P0) and the late postoperative result (P1) are calculated using the CBCT cuts.
- 9 hard tissue landmarks (**CoLt**, left condyle; **CoRt**, right condyle; **UI**, upper incisor; **LI**, lower incisor; **Me**, menton; **MnMLt**, first mandibular molar on left side; **MnMRt**, first mandibular molar on right side; **MxMLt**, first maxillary molar on left side; **MxMRt**, first maxillary molar on right side), and 3 hard tissue planes (Maxillary, Mandibular & occlusal) are analyzed systematically with respect to the 3D facial coordinates (MidFacial plane MFP, Frankfort horizontal FHP, and coronal plane CP) to obtain linear and angular measurements. (B. Li et al., 2013; Zinser et al., 2013) (Appendix B)
- In order to assess inter-observer reliability, 2 maxillofacial surgeons performed the linear & angular analyses. In order to assess intra-observer reproducibility, each assessor made 2 sets of recordings. Both
- Reliabilities are qualified using Pearson's intra-class correlation coefficient test giving a value between +1 and −1 inclusive, where 1 is total positive correlation, 0 is no correlation, and −1 is total negative correlation.

Data management

Data Forms and Data Entry

All data are entered electronically by TF and MH. Original study forms will be entered and kept on file at the participating site.

Participant files are to be stored in numerical order and stored in a secure and accessible place and manner. Participant files are maintained in storage for a period of 1 year after completion of the study.

Data Transmission and Editing

The data entry screens resemble the paper forms approved by the Protocol Chair Assistant Professor.

Security and Back-Up of Data

All forms and videos related to study data are kept in locked cabinets by MH. Access to the study data is restricted. A complete back up of the primary database is performed twice a month. Back-ups of periodic data analysis files are kept.

Harms

The possible adverse effects of the procedure include

1. inaccurate translation of surgical plan which is managed by elastics
2. numbness to the lower lip which is temporary for a duration of 3-6 months and is managed by vitamins
3. Pain which is temporary and managed by analgesics

Auditing

Auditing will be done in thesis defense session

Ethics and dissemination:

Research ethics approval

This protocol and the template informed consent form is reviewed by the Ethics Committee of Scientific Research - faculty of oral and dental medicine – Cairo University

Protocol amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the Council of oral and maxillofacial surgery department

Consent or assent

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Introduction of the trial and discussion with the patient is carried out by MH. The purpose, the nature of this study and detailed surgical procedure with possible complications is also discussed. Patients are then being able to have an informed discussion with the NA. Written consent from patients willing to participate in the trial is obtained by MH. All, consent forms have been translated into Arabic (Appendix C)

Confidentiality

All study-related information is stored securely by MH. All participant information is stored in locked file cabinets in areas with limited access. All patients' records are digitized and stored securely on MH personal computer.

Declaration of interests

The study is self-funded and there is no conflict of interest to declare

Access of data

MH, TF, and NA are given access to the data sets. All data sets are password protected. To ensure confidentiality, data dispersed to project team members are blinded of any identifying participant information.

Ancillary and post-trial care

All patients are followed up until complete healing and satisfactory reconstruction results occur by MH

Dissemination policy

Study results are published as partial fulfillment of the requirements for PHD degree in Oral and maxillofacial surgery by MH.

Topics suggested for presentation or publication are circulated to the authors.

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Appendices

Appendix A: Diagnostic chart

Mandible-first Project

Diagnostic chart

Patient No. ……..

Name: _____

Age: _____ **Date of birth:**

Sex: _____

Weight: _____ **Height: _____**

Occupation: _____

Address: _____

Contact No.: _____

Chief Complain:

□ Appearance

□ Speech

□ Chewing

□ Pain

□ Other; mention _____

Type of dentofacial deformity

□ Skeletal class II

□ Skeletal Class III

□ Open bite

□ Cross bite

□ Facial asymmetry

□ other; mention _____

_____

Medical history

……

…..

……

…..

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TMJ examination

History of signs and symptoms

- **Pain in joint area or muscles of mastication**
- **Joint noise (clicking, Crepitus)**
- **Limitation of mouth opening**

Clinical examination of TMJ

- **Range of mandibular motion**
- **Opening**
- **Right laterotrusive**
- **Left laterotrusive**
- **Protrusive**
- **Palpation of**
  - **The joint area**
  - **Muscles of mastication**
  1. **Masseter**
  2. **Temporalis**
  3. **Medial pterygoid**
  4. **Temporalis tendon**
  5. **Functional manipulation of lateral pterygoid**
- **Joint Noise**
- **Any other detected abnormality _____**

Appendix B: Assessor chart

	Assessor 1	**Assessor 2**
Distance from Frankfort horizontal plane (mm) Me MnMLt/MnMRt LI MxMLt/MxMRt UI CoLt/CoRt		

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Distance from coronal plane (mm)		
Me		
MnMLt/MnMRt		
LI		
MxMLt/MxMRt		
UI		
CoLt/CoRt		
Distance from midfacial plane (mm)		
Me		
MnMLt/MnMRt		
LI		
MxMLt/MxMRt		
UI		
CoLt/CoRt		
Plane angulation relative to Frankfort horizontal (°)		
Maxillary plane		
Mandibular plane		
Occlusal plane		
Plane angulation relative to midfacial plane (°)		
Maxillary plane		
Mandibular plane		
Occlusal plane		
Plane angulation relative to coronal plane(°)		
Maxillary plane		
Mandibular plane		
Occlusal plane		

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Appendix C:

Consent

Patient name:

Age:

Address:

I have approved to be enrolled in this research project and the researcher has explained all the surgical procedure and its expected outcomes and common complications that could happen and their management

.

Patient signature **Researcher signature**

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