Assessment of concentric needle technique for the management of temporomandibular joint internal derangment.

A Randomized controlled Trial.

تقييم تقنية قنتين متداخلتين متمركزتين فى علاج الأضطراب الداخلى لمفصل الفك.

تجربة منضبطة معشاه.

Protocol submitted to

Faculty of Dentistry, Cairo University

In partial fulfillment of
the requirements for Master Degree in Oral and Maxillofacial Surgery

Submitted by:

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B.D.S. Misr International University 2016

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2020

Code: Omfs 3.3.7

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Protocol checklist

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Evidence based committee (reviewers)

Name	Signature	Date
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Research plan committee

Name	Signature	Date
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2.		

I- Administrative information:

1. **Title:**
   Assesment of concentric needle technique for the management of temporomandibular joint internal derangement.
   A Randomized control Trial.

2. **Protocol registration:**

3. **Protocol version:**
   First version.

4. **Funding:**
   Self-funding.

5. **Roles and responsibility:**
   1- Prof. Dalia Radwan Abdel khalek (DRAK)
   - Professor of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University.
   - The Senior Supervisor responsible for laying out the research plan, auditing the whole research process and reviewing surgical planning, interventions and final manuscript.

   2- Dr Abdelmoez Mohamed Elsharkawy (AME)
   - - Lecturer of Oral and Maxillofacial Surgery, Faculty of Dentistry,Cairo university
   - Associate Supervisor responsible for auditing patients' inclusion to the study, case preparation, supervising the surgical intervention and guidance with manuscript writing.

   3- Dr. Mahmoud Ahmed El Farmway (MAEF)
   - Lecturer of Oral and Maxillofacial Surgery, Faculty of Dentistry,Sinai University El Kantra branch.
   - Associate Supervisor responsible for auditing patients' inclusion to the study, case preparation, supervising the surgical intervention and guidance with manuscript writing.

   4- Ahmed Adel Hassan Mahmoud (AAHM)
   - Master's degree candidate, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University.
   - Teaching Assistant in Faculty of Dentistry,Sinai University El Kantara branch.
   - Principal investigator responsible for patients' inclusion to the study, case preparation, surgical intervention under supervision of instructors, postoperative data collection and manuscript writing.

II- Introduction:

6. Background and rationale:

- **Research question:**
  Is the concentric needles technique a better technique than the traditional two-distant needles technique in TMJ Arthrocentesis?

- **Statement of the problem:**
  Locating the outflow needle in TMJ arthrocentesis is the challenging step in the two-distant needles technique especially for operators with limited experience which might require multiple insertions increasing the risk of injury to blood vessels and nerves together with patient's discomfort, pain and escape of fluids into the pericapsular tissues.

- **Rationale for conducting the research:**
  The research population will be divided into two groups. Group A(control group) will be treated by two-distant needles arthrocentesis technqiue and Group B will be treated by two - concentric needles arthrocentesis technqiue.

- **Review of literature:**
  Internal derangement is a common dysfunction of the temporomandibular joint. According to classification of Research Diagnostic Criteria for TMD there are 3 main types of internal TMJ derangement: disc displacement with reduction and disc displacement without reduction with limited mouth opening and disc displacement without reduction without limited mouth opening. The prevalence of disc displacement is about 41% in TMD patients. The most common type is disc displacement with reduction characterized by clicking.[123] Disc displacement with reduction can occur in 33% of asymptomatic individuals.[4]

  Arthrocentesis is a simple, safe and minimally invasive technique for the treatment of TMJ disorders. Significant improvements have been reported in terms of reduction in TMJ pain and clicking in the TMJ following arthrocentesis.[567]Most common intra-articular injections in arthrocentesis procedures are steroids,sodium hyaluronate,saline and lacted ringer solution.[89]Arthrocentesis is effective for washing out bradykinin, interleukin-6 and protein.[10]

  The technique of two distant needles is done as follows ; Local anaesthetic block of auriculotemporal nerve and infiltration into the areas of joint penetration is done first. Surgical field is draped and painted with Povidone-iodine 5%.External auditory canal is protected from accumulation of blood and fluid using vaselinized gauze.. A line was drawn from the lateral canthus of the eye to midpoint of tragus (canthal-tragus line), the first mark was made 1mm infront of the tragus and 2mm below the line representing the posterior extent of glenoid fossa, and the second mark was made 20 mm anterior to midtragal point and 10 mm below canthal-tragus line representing the height of articular eminence.[5]A 20

gauge needle is then inserted into the upper joint space at the glenoid fossa and 2ml of Ringer's solution are injected to distend the upper joint space. A second 20 gauge needle is inserted in the area of the articular eminence to establish a free flow of the irrigating solution through the upper joint space. Then, the joint is irrigated with 100-300 mL of Ringer's solution.[11]

The technique of concentric needle is done as follows; a 27-gauge, 50- mm-long needle is inserted into a 21-gauge, 38-mm needle. The longer 27-gauge needle does not block the end of the larger needle hub from which the solution outflows. In this way, joint irrigation is performed through the inner needle with the solution outflow through the outer needle hub. Irrigation through this concentric-device combination allows single puncture of the TMJ with a single needle.[12]A horizontal line is drawn from the corner of the eye to the tragus and a puncture mark is made 10 mm from the tragus and 0.5 mm below this line.[13] The concentric-needle unit is inserted into the upper joint space while the patient is asked to open the mouth halfway to allow entry of the needle. Once it is inside the joint space, lavage is performed with lactated Ringer solution.[12]The advantages of the single-needle method include the use of a single puncture for both irrigation and outflow, hence achievement of efficient arthrocentesis without the need for a second needle, decreasing the risk of losing the correct place during inserting the needle.This also leads to less patient discomfort, a lesser risk of infection, and less bleeding.[14]Another advantage of a single puncture technique is that it reduces patient pain in the postoperative period so this reduces the need for extra care postoperatively. The amount of local anesthesia is much less for a single puncture than that needed for a double-puncture or arthtrocentesis, thus reducing the complications due to local anesthetics.A single-needle technique reduces the risk of facial nerve injury, because an anteriorly positioned second needle can traumatize the facial nerve, which lays anteriorly and medially to the glenoid fossa, just where the second needle is inserted.[15]

7. Objective of the study:

- **Aim of the study:**

  The aim of the study is to evaluate the effectivenes of using two concentric needles in comaprsion with the normal traditional two distant needles.

8. Trial design:

Randomized control trial.

III- Methodology:

A) Participants, intervention and outcomes

9. Study setting:

Patients will selected from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University.

10. Eligibility criteria:

a. Inclusion criteria:

1- Patients with age ranges from 18-60.
2- Patients with painful clicking.
3- Patients free of systemic conditions that might affect the TMJ or interfere with carrying out the surgical procedure (osteoarthritis, rheumatoid arthritis, uncontrolled diabetes).

b. Exclusion criteria:

1- Patients out of the specified range group
2- Patients with painless TMJ clicking.
3- Patients with osteo-arthritic changes of the TMJ.
4- Patients with systemic conditions that might affect the TMJ or interfere with carrying out the surgical procedure (osteoarthritis, rheumatoid arthritis, uncontrolled diabetes).
5- Patients with previous TMJ surgeries.

11. Group Allocation

Patients will be randomly allocated to one of the two groups using computer randomization.

12. Interventions:

- Diagnostic procedure:

a) Patient questionnaire: a questionnaire will be recorded by the examiner including: Chief complaint, Personal data, medical history.
b) Consent: Informed consent will be obtained from patients regarding the surgical procedure and inclusion in the study.
c) Clinical examination: oro facial examination with specific emphasis on the TMJ regarding pain, clicking, maximum inter-incisal mouth opening and lateral excursions.

- operative procedures:

TMJ arthrocentesis will be performed under local anesthesia.

- External auditory canal is protected from accumulation of blood and fluid using vaselinized gauze.

- The surgical field will be scrubbed and draped in a standard sterile fashion.

A-The standard two – distant needles technique:

Local anaesthetic block of auriculotemporal nerve and infiltration into the areas of joint penetration is done first. Surgical field is draped and painted with Povidone-iodine 5%.External auditory canal is protected from accumulation of blood and fluid using vaselinized gauze.. A line was drawn from the lateral canthus of the eye to midpoint of tragus (canthal-tragus line), the first mark was made 1mm infront of the tragus and 2mm below the line representing the posterior extent of glenoid fossa, and the second mark was made 20 mm anterior to midtragal point and 10 mm below canthal-tragus line representing the height of articular eminence.[5]A 20 gauge needle is then inserted into the upper joint space at the glenoid fossa and 2ml of Ringer's solution are injected to distend the upper joint space. A second 20 gauge needle is inserted in the area of the articular eminence to establish a free flow of the irrigating solution through the upper joint space. Then, the joint is irrigated with 100-300 mL of Ringer's solution.

B-The concentric-needle cannula technique:

The technique of concentric needle is done as follows; a 27-gauge, 50- mm-long needle is inserted into a 21-gauge, 38-mm needle. The longer 27-gauge needle does not block the end of the larger needle hub from which the solution outflows. In this way, joint irrigation is performed through the inner needle with the solution outflow through the outer needle hub. Irrigation through this concentric-device combination allows single puncture of the TMJ with a single needle. Local anaesthetic block of auriculotemporal nerve and infiltration into the areas of joint penetration is done first. Surgical field is draped and painted with Povidone-iodine 5%.External auditory canal is protected from accumulation of blood and fluid using vaselinized gauze. A horizontal line is drawn from the corner of the eye to the tragus and a puncture mark is made 10 mm from the tragus and 0.5 mm below this line. The concentric-needle unit is inserted into the upper joint space while the patient is asked to open the mouth halfway to allow entry of the needle. Once it is inside the joint space, lavage is performed with lactated Ringer solution.

- Post-operative care:

Patients will be prescribed Augmentin 1gm 2 hours before procedure and 24 hours after procedure as a prophylaxis.Brufen 600 mg will be taken after the procedure.The patient will be instructed to take Alphintern 2 tablets before food 3 times daily.

13. Outcomes:

Prioritization of outcome	Outcome	Method of measurement	Unit of measurement
Primary outcome	pain	Visual analogue scale	Score
Secondary outcome	complications	Edema,Nerves and arteries injuries	Inspection and Palpation

14. Participant timeline:

	Study Period		
	Enrollment	**Allocation**	**Post-allocation**
Time Point	**$-t_1$**	**0**	**t_1**
Enrolment:			
Eligibility Screen Informed Consent			
Pt. preparation			
Interventions:			
Surgical procedure			
Assessments			
Assessment of pain,outflow rate and complications			**1 day post-opeartive**

15. Sample size:

20 cases (10 study group+ 10 control group)

16. Recruitment:

Patients will be selected according to inclusion & exclusion criteria from the outpatient clinic of the Oral and Maxillofacial Surgery Department – Cairo University

Screening of patients will continue until the target population is achieved.

Identifying and recruiting potential subjects is achieved through patient database.

B) Data collection, management and analysis:

17. Data collection methods:

Data will be collected by AAHM,DRAK,MAEF,AES

Telephone numbers of all patients included the study will be recorded as a part of the written consent

All patients will be given a phone call at the time of the pre-determined follow up dates

18. Data management

All data will be entered electronically

Patient files are to be stored in numerical order and stored in secure and accessible place

All data will be maintained in storage for 1 year after completion of the study.

19. Statistical method

Using clincal sample size calculator for intervention study; with 0.05 alpha error and power of the study 0.80, And sampling ratio is 1.

According to literature In concentric needle technique, 1 day postoperative pain was found to be (mean: 4.100, sd 2.183), and In 2-needle technique, 1 day postoperative pain was found to be (mean: 6.600, sd 1.430)[16].

Sample size calculated to assess of concentric needle technique for the management of temporomandibular joint internal derangment is 20 patients (10 in each arm of the study).

*Sampling technique: *

A convenient sample of pain of TMJ patients who will come to the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University during the study period with the inclusion and exclusion criteria will be assigned into study.

Each patient will be randomly allocated to either arm of the study using concealed random allocation technique. The random allocation will be repeated till reaching total sample size calculated.

C)Data monitoring:

20. Data monitoring:

No formal data monitoring committee will be needed since most of studies in Faculty of Dentistry are with known minimal risks.

21. Harms:

-Pain.

-Swelling and edema.

-Nerves injury: Zygomatic,Temporal and Auricotemporal nerves

-Arteries injury.

To avoid injury to nerves and arteries: sticking to proper anatomical landmarks
In case of nerve injuries: Stop the insertion of the needle and redirect it
In case of arteries injuries: -Apply pressure by gauze
-Use cold packs and antibiotic in case of hematoma

22. Auditing:

Auditing of the study design will be done by the evidence based committee – Faculty of Oral and Dental Medicine – Cairo University.

IV. Ethics and dissemination:

23. Research ethics approval:

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

24. 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.

25. Informed consent:

The Researcher will introduce the trial to patients and will discuss the trial with patients. The purpose, the nature of this study and detailed surgical procedure with possible complications will be also discussed. Patients will then be able to have an informed discussion with the participating consultant. The Researcher will obtain written consent from patients willing to participate in the trial. All, consent forms have been translated into Arabic

26. Confidentiality

All study-related information will be stored securely. All participant information will be stored in locked file cabinets in areas with limited access. All patients' records will be digitized and stored securely on MZ personal computer.

27. Declaration of interests

The study is self-funded. No conflict of interest

28. Access to data

All Principal Investigators will be given access to the data sets. All data sets will be password protected.

29. Post-trial care

All patients will be followed up until complete healing and satisfactory results occur.

30. Dissemination policy

Study results will be published as partial fulfilment of the requirements for Master degree in Oral and maxillofacial surgery. Topics suggested for presentation or publication (International Journal of Oral and Maxillofacial Surgery IJOMS) will be circulated to the authors.

V. Appendices:

31. **APPENDIX A:**

Visual analogue scale:

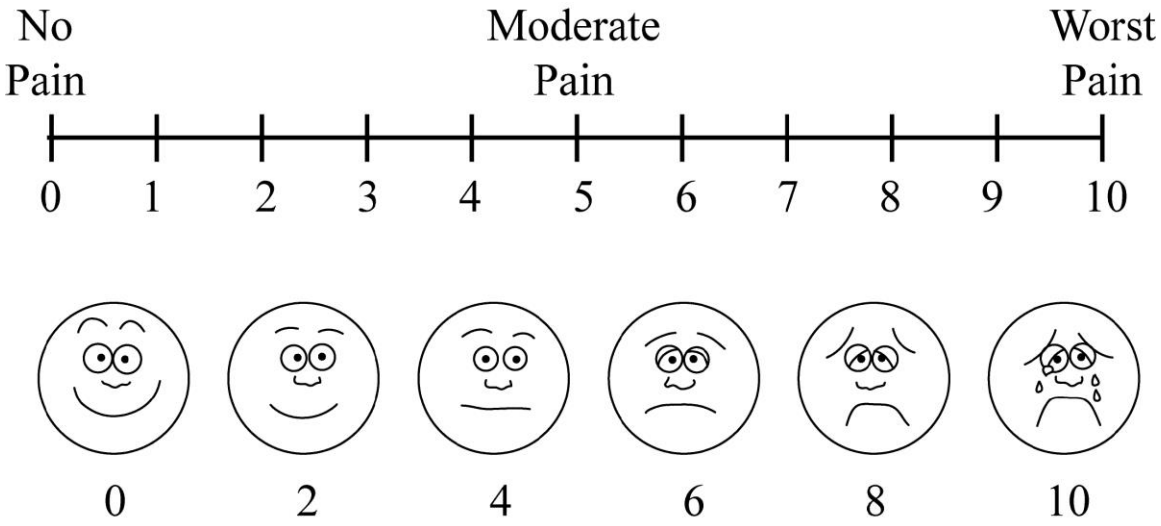

Figure-1 visual Analogue Scale [16].

32. APPENDIX B:

Patient questionnaire in English:

Name:…… **Age:…….** **Sex:……**

1-Do you have trismus ?	**Yes/No**
2-Do you hear noises or clicking when opening your jaw ?	**Yes/No**
3-Do you have pain while chewing ?	**Yes/No**
4-Do you have pain around your ears ?	**Yes/No**
5-Have you ever had jaw locking ?	**Yes/No**
6-Have you ever had injury to your face ?	**Yes/No**
7-Did you take any medications for TMJ ?	**Yes/No**

33. **APPENDIX C:**

Patient questionnaire in Arabic:

الأسم:..... **العمر:.....** **النوع:.....**

1-هل تعانى من ضيق فى فتحة الفم ؟	نعم/لا
2-هل تسمع اصوات عندما تفتح الفم ؟	نعم/لا
3-هل تحس بالألم عند مضغ الطعام ؟	نعم/لا
4-هل تحس بألم حول الأذن ؟	نعم/لا
5-هل تحس بتصلب فى الفك ؟	نعم/لا
6-هل تعرضت لأصابات او جروح فى وجهك ؟	نعم/لا
7-هل أخذت اى علاج لمفصل الفك الصدغى ؟	نعم/لا

34. **APPENDIX D:**

جامعة القاهرة
كلية طب الفم والأسنان

اقرار

اسم الشخص:..... السن:..... الواصى و صلة قرابته:.....
التليفون:..... العنوان:.....

1- لقد اطلعت بعناية و فهمت الغرض من اجراء هذا البحث و طبيعة هذه الدراسة,وهى تجربة مقارنه بين القنيه ذات الابره متحده المركز و القنيه ذات الابرتين في علاج التشويش الداخلى لمفصل الفك الصدغى و انا افهم ما هو ضرورى لأجراء هذه الأجرائات.

2- لقد ابلغنى الطبيب المعالج بالمخاطر المحتملة للعلاج و هى:

-الم

-تورم

-اصابة الأعصاب

-اصابة الشرايين

3-أوافق على التصوير والتسجيل، وجميع أنواع الأشعة والتي يتعين القيام بها في هذه الدراسة، بشرط عدم الكشف عن هويتى.

4-لقد قدمت تقريرا عن حالتى الصحية و اخبرت الطبيب ان كنت اعانى من اى امراض او حساسية.

5-اقر انى لن اشارك فى اى بحث اخ منذ بداية هذا البحث و حتى انتهائه.

ملحوظة:
-يحق للمريض الأنسحاب فى اى وقت من البحث و من حق الطبيب استعمال النتائج
-يتعهد الطبيب بالحفاظ على سرية المريض

توقيع المريض:.....
توقيع الطبيب:.....
توقيع المشرف:.....

VI. Statement of originality:

35. Statement of originality:

'This is to certify that to the best of my knowledge, the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes.'

VII. References:

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