A COMPARATIVE STUDY BETWEEN THE DIFFERENT LEVELS OF TEMPOROMANDIBULAR JOINT ARTHROSCOPY IN THE MANAGEMENT OF TMJ INTERNAL DERANGEMENT (A RANDOMIZED CLINICAL TRIAL)

02/02/2022

ABSTRACT

Introduction: Temporomandibular disorders (TMD) are common conditions with an estimated prevalence rate of 5 to 12% of populations, whereas only 3 to 4% of patients get suitable treatment. Nowadays, minimally invasive arthroscopy has eliminated the use of many of the more complex surgical procedures. Numerous intra-articular operative arthroscopic techniques have been reported in the literature since the advent of temporomandibular joint (TMJ) arthroscopy. However, randomized controlled trials regarding outcomes are lacking nor are there strong evidence supporting one operative technique over another.

Aim: to compare the three levels of TMJ arthroscopy in the management of temporomandibular joint internal derangement to develop standardized patient selection criteria and treatment options to be used by all investigators.

Subjects: The study will be conducted on 30 patients with TMJ internal derangement **(Wilkes III)**. Patients will be randomized into three groups:

Group I: 10 patients will be treated with level (I) arthroscopy (Lysis and lavage).

Group II: 10 patients will be treated with level (II) arthroscopy (operative arthroscopy).

Group III: 10 patients will be treated with level (III) arthroscopy (operative arthroscopy + disc repositioning and fixation)

Methods: All patients will be assessed clinically and radiologically by using MRI preoperatively to assess disc position. Then patients will be operated on randomly by either level. Then follow-up will be done for all patients for 6 months.

Results: Results will be tabulated and statistically analyzed.

Keywords: TMJ arthroscopy, Internal derangement, Wilkes III, Arthroscopy levels, Arthroscopic discopexy, operative arthroscopy, Lysis and lavage.

INTRODUCTION

The temporomandibular joint (TMJ) is the only diarthrodial articulation of the human joints. It is known as ginglymo-arthrodial joint and is formed by the bony articulations of the mandibular condyle with the glenoid fossa of the temporal bone. Interposed between the condyle and the fossa is a piece of dense avascular fibrous connective tissue namely the TMJ disc. The disc divides the joint into superior and inferior compartments, which normally do not communicate with each other. The condyle and disc are in a normal anatomic relationship if the posterior band of the disc is located above the condylar head when the mandibular condyle is centrically positioned in the fossa.[1]

The prevalence of temporomandibular disorders (TMD) is thought to be greater than 5% of the population. [2] Lipton and colleagues [3] showed that about 6% to 12% of the population experience clinical symptoms of TMD. Patients with TMD symptoms present over a broad age range; however, there is a peak occurrence between 20 and 40 years of age.[4] TMD symptoms are more prevalent in women than men. Women tend to develop TMD during their premenopausal years. The reasons behind the sexual disequilibrium in TMD prevalence are not entirely clear, but some have suggested a hormonal influence.[5-7]

Temporomandibular disorders (TMD) are a broad group of clinical problems involving the masticatory musculature, the temporomandibular joint, surrounding bony and soft tissue components, and combinations of these problems. Temporomandibular disorder (TMD) can result from any defect of one or both. Any problem that prevents this composite system of muscles, bones and joints from working in harmony may result in this disorder. Symptoms may be unilateral or bilateral and involve the face, head or jaw. The American Academy of Orofacial Pain (AAOP) classification divides TMD broadly into muscle related TMD (myogenous), and joint- related TMD (arthrogenous). The two types can be present at the same time, making diagnosis and treatment more challenging.[8]

The etiology of temporomandibular disorders is multifactorial. It includes trauma (such as traumatic injuries from eating, wide jaw opening, and dental management), bruxism (refers to a non-functional grinding and clenching of the teeth), malocclusion (causes inappropriate pressure on the joint), Stress and psychiatric illness. TMD is clinically characterized by pain in the temporomandibular region or in the muscles of mastication, pain radiating behind the eyes, in the face, shoulder, neck and/or the back, headaches, ear-ache or tinnitus, jaw clicking, locking or deviation, limited jaw opening, clenching or grinding of the teeth, dizziness and sensitivity of the teeth lacking oral disease. Pain is the most frequent symptom for

which patients seek medical attention.[8]

Internal derangement of the temporomandibular joint (TMJ) is one of the most common temporomandibular disorders. In 1983, Dolwick [9] defined it as an abnormal relation between the temporomandibular disc with respect to the mandibular condyle, the temporal fossa, and the temporal eminence of the TMJ. Anterior disc displacement, with or without reduction, perforation of the retrodiscal tissue or the articular disc, and degenerative changes of the disc and/or the joint surfaces, may be present. Clinically, it may be accompanied by pain, limitation of mouth opening, clicking, and locking.[10]

In 1989, Wilkes [11] first established a classification to correlate clinical and radiological signs with surgical findings. The Wilkes classification consists of 5 stages based on clinical, radiologic, and intraoperative findings as follows:

Stage	Clinical Findings	Radiologic Findings	Surgical Findings
I	Painless clicking No locking No restricted motion	Slight anterior disk displacement that reduces on opening Normal osseous contours	Normal disk form Slight anterior disk displacement
II	Occasional painful clicking Intermittent locking Headaches	Slight anterior disk displacement that reduces on opening Early disk deformity Normal osseous contours	Thickened disk Anterior disk displacement
III	Frequent pain Joint tenderness Headaches Locking Restricted motion	Anterior disk displacement that does not reduce on opening Moderate disk deformity Normal osseous contours	Disk deformed and displaced Variable adhesions No bone changes
IV	Chronic pain Headaches Restricted motion with crepitus	Anterior disk displacement that does not recapture on opening Marked disk deformity Degenerative osseous changes	Disk perforation, displacement, and adhesions Degenerative changes in condyle and/or fossa
V	Variable pain Joint crepitus	Anterior disk displacement that does not recapture on opening Marked disk deformity Degenerative osseous changes	Disk perforation, displacement, and adhesions Degenerative changes in condyle and/or fossa

Diagnosing TMD requires a focused history and physical examination. Pain and limited range of motion are accepted symptoms of TMJ dysfunction. In general, patients with true intra-articular pathology have pain that is localized to the involved TMJ, which is increased with mandibular movement or masticatory function. Failure to reproduce pain localized directly to the involved TMJ, stimulated with masticatory load and/or movement, is a warning that the main cause of pain may not be intra-articular, even with magnetic resonance imaging (MRI) confirmed disc displacement. [12] Radiographic studies can also be used as supplemental diagnostic tools. Periapical radiographs can be used to rule out dental pathologies as a cause of referred pain. Cone beam computed tomography scans and panoramic radiographs will provide detailed imaging of the joint's bony structures but not the articular disk. MRI is the modality of choice for examining the disk position and morphology (gold standard). MRI may also show degenerative bony changes. MRI findings should not alone dictate treatment strategies. One must combine patients' clinical presentation, signs, and symptoms along with TMJ imaging when developing a treatment plan. The surgeon must treat the patient, not the MRI. Studies have revealed MRIs in asymptomatic subjects demonstrate disc displacement in the range of 32-38%.[12] On MRI, joint effusions are radiographic signs of inflammation and an important finding in true intra-articular pathology.[13] Inflammation indicates a transition from adaptive to pathologic changes within the joint. The MRI diagnosis of

anterior disk displacement uses the most superior aspect of the condyle (12 o'clock position) as a reference point. Anterior disk displacement is defined radiographically when the posterior disk tissue is located anterior to the 12-o'clock condylar position. Disk displacement may occur in asymptomatic patients such that all radiographic findings must be placed in clinical context before beginning TMJ treatments.[14]

Diagnostic arthroscopy provides the most important information determining the intra-articular surgery to be performed. Arthroscopic diagnosis is based on visual inspection of the pathologic intra-articular tissues. The most common intra-articular pathologies are synovitis, adhesions, osteoarthritis, anterior disc position, disc perforation and inflamed synovial plicae. Less common intra-articular pathologies include synovial chondromatosis, pigmented villonodular synovitis, crystalline arthropathies and neoplasia.[15]

Different methods have been proposed to treat this entity, beginning with conservative approaches. Occlusal splint therapy, medical treatment based on nonsteroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants, and physical treatment are the most common options among conservative methods. Those refractory cases in which no effective improvement in terms of pain and mandibular function is obtained are amenable to further surgical treatment.[16]

Initially, surgical treatment for an internal derangement generally consisted of a discectomy, regardless of the type of internal derangement that was present.[17] However, in 1979, Farrar and McCarty [18]described surgical repositioning of the disc (discoplasty), showing that it was not necessary to remove the disc in most instances. Nevertheless, there were still instances where removal of the disc was necessary, because large, irreparable perforations, malformation of the disc, or calcification of the disc made it impossible to perform a discoplasty.[19]

During the period when most surgeons were performing open surgical procedures for internal derangements of the TMJ, a small group of surgeons was beginning to experiment with arthroscopic surgery. First introduced by Ohnishi in 1975, this modality opened a new era in the diagnosis and treatment of such conditions.[20]

Initially, arthroscopic treatment of patients with an internal derangement consisted mainly of lavage of the joint to remove tissue breakdown products and inflammatory cytokines and the lysis of any adhesions that were present. Eventually, other intra-articular surgical manipulations such as mechanical debridement, lateral capsular release, and disc repositioning and fixation by suturing or by electrocauterization, lasering, or sclerosis of the retrodiscal tissue were added.[19]

Surgeons have described three levels of TMJ arthroscopy, Level I the

most basic, involving arthroscopic lysis and lavage (L&L) with diagnostic evaluation, Level II (operative arthroscopy) involves arthroscopic lysis, lavage, needle working instrument used for operative maneuvers including visualized lysis of adhesions or targeted-tissue medication injections, lateral pterygoid myotomy or botulinum toxin injection and retrodiscal coagulation. Level III includes more advanced procedures, double punctures, triangulation and visualized intraoperative maneuvers, including removal of pathology, debridement, motorized shaving, synovial biopsies, disc mobilization or disc repositioning with stabilization (discopexy) either by sutures or a resorbable pin.[15]

According to Al-Moraissi et al, on the hierarchy of different treatments for arthrogenous TMDs, they concluded that there is new evidence that minimally invasive procedures are significantly more effective than conservative treatments for both pain reduction and improvement of maximal interincisal opening (MIO). In contrast to traditional concepts mandating exhaustion of conservative treatment options, minimally invasive procedures, therefore, deserve to be implemented rather early, i.e., as soon as patients do not show a clear benefit from an initial conservative treatment.[21]

According to Santana Santos et al, comparing the effectiveness of open discopexy versus arthroscopic techniques, the available evidence showed an overall decrease in pain score and an improvement in mouth

opening after TMJ surgeries with discopexy. Changes in the (MIO) were greater after arthroscopic disk repositioning compared to the open-joint procedure.[22]

Nowadays, minimally invasive surgery has become the 1st choice as it is a quick procedure, less postoperative complications, short hospital stay, early rehabilitation, and return to work.[23]

According to Murakami on the rationale of arthroscopic surgery of the TMJ, he stated that, although various arthroscopic disc repositioning and suturing techniques were reported, the success rate was comparable to arthroscopic lysis and lavage, and the documentation by postoperative imaging was insufficient.[24]

According to Israel: Numerous intra-articular operative arthroscopic techniques have been reported in the literature since the advent of temporomandibular joint (TMJ) arthroscopy. However, Ideal randomized controlled trials regarding outcomes are lacking nor are their strong evidence supporting one operative technique over another.[15]

Nowadays, minimally invasive procedures have eliminated the use of many of the more complex surgical procedures. Despite such advancements, however, clinicians are still encountering some difficulty in successfully treating many of these patients and finding the answers to these problems will

depend on future developments.

A review of the literature reveals that there is lack of randomized clinical trials to compare between the three levels of TMJ arthroscopy in the management of TMJ internal derangement.

The null hypothesis states that there will be no significant difference between the three levels of TMJ arthroscopy. Consequently, by doing the necessary studies and comparing the results, we can accept or reject this theory to finally develop guidelines and standardized patient selection criteria that can be followed by all researchers.

AIM OF THE STUDY

To compare between the three levels of TMJ arthroscopy in the management of TMJ internal derangement in the following points:

Primary aims are to assess:

1. Pain score using the visual analog score (VAS).[25]
2. Presence or absence of clicking.
3. Mouth opening measuring the maximal interincisal opening in MIS.
4. Lateral excursion movement.
5. Protrusive movement.

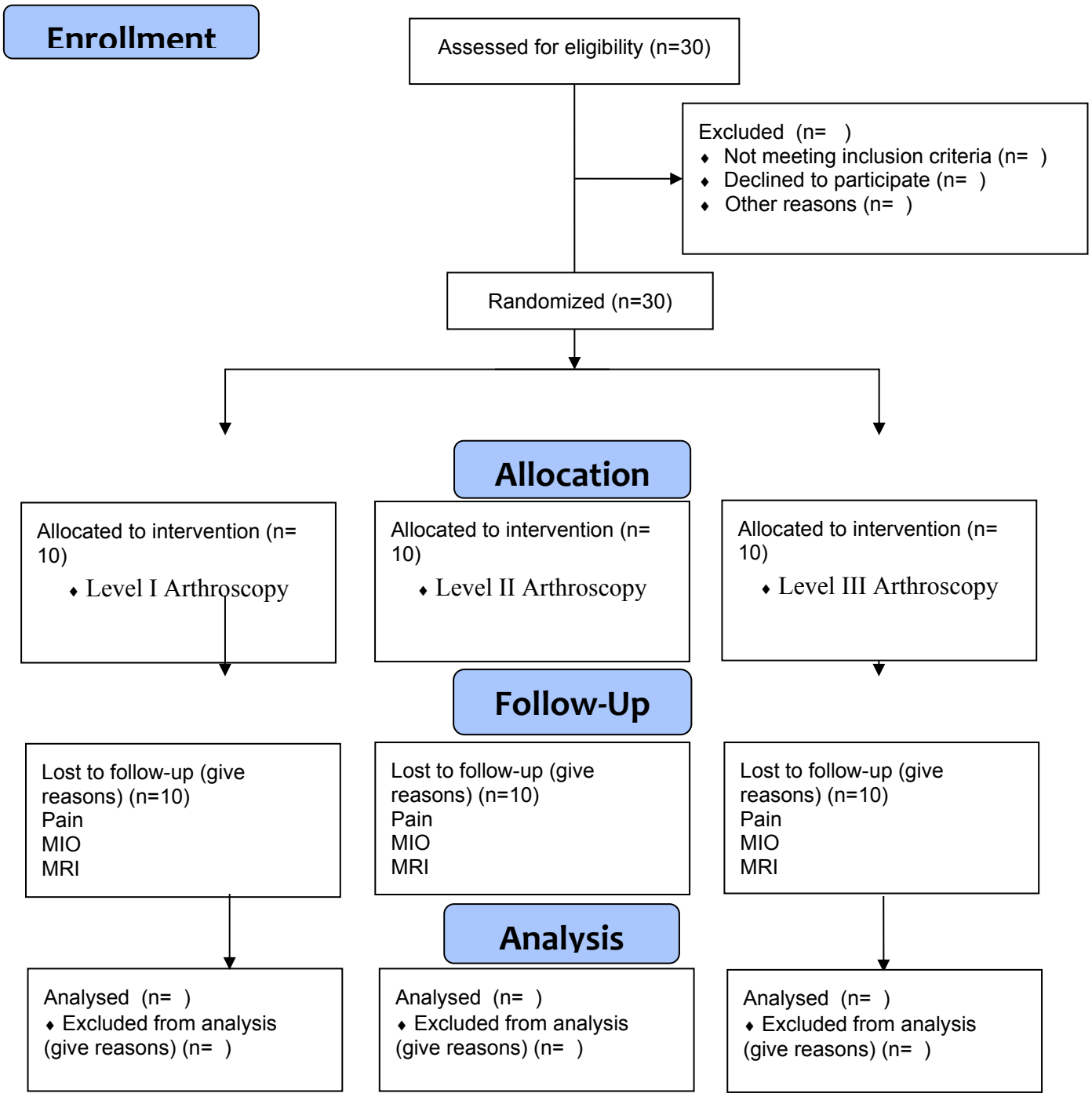
Secondary aims are to assess:

1.Operative time.

2.Post operative MRI (disc position).

CONSORT

TRANSPARENT REPORTING of TRIALS



Study design

This study will be a randomized controlled clinical trial, with 1:1:1 ratio and will be reported according to CONSORT guidelines [26]

PICO Question

Do patients with TMJ internal derangement treated with arthroscopy level I compared to arthroscopy level II or arthroscopy level III show better maximal interincisal opening and less pain?

Settings and Location:

Participants will be selected from the Maxillofacial and Plastic Surgery Department, Faculty of Dentistry, Alexandria University, Egypt.

Sample size calculation

The size was estimated based on 5% alpha error and 80% study power. The mean (SD) improvement in Maximum Interincisal Opening (MIO) after 6 months compared to the preoperative measurements was 6.09 (7.05) mm for Level I arthroscopy, (10) 6.7 (5.25) mm for Level II arthroscopy, [27] and 18.5 (2.1) mm for Level III arthroscopy. [28] Based on difference between independent means using F test and pooled SD = 4.8 mm, the minimum sample size was calculated to be 9 joints per group, increased to 10 joints to make up for lost to follow up cases. Total sample = number per group x number of groups = 10 x 3 = 30 joints. Sample size was based on Rosner's method [29] calculated by G*Power 3.1.9.7. [30]

Randomization

Participants will be randomly assigned using online program (**www.random.org)** in order to allocate participants to the group.

Allocation Concealment

Sequentially numbered opaque sealed envelopes will be used to conceal allocation. One set of envelops will be created to guarantee they were opaque, sealed and sequentially numbered.

Blinding

The patients will be blinded to the treatment group.

Intervention

Group I: 10 patients will be treated with level (I) arthroscopy (Lysis and lavage).

Group II: 10 patients will be treated with level (II) arthroscopy (operative arthroscopy).

Group III: 10 patients will be treated with level (III) arthroscopy (operative arthroscopy + disc repositioning and fixation).

Eligibility Criteria

Inclusion criteria

The patients with TMJ internal derangement will be divided into 5 stages according to Wilkes Classification. [11] Only patients with stage III will be

included in this study.

Exclusion criteria

1. Medically unfit patients.
2. Patients with TMDs secondary to malocclusion.
3. Psychological instability.
4. Patients operated before for other TMJ problems.

Materials

In all procedures, 1.9 mm, 30-degree optical device, sleeves, sharp and blunt trocars, adhesion knives, an exploratory probe, a bipolar electrode (Karl Storz Endoscopy, Tuttlingen, Germany) and coblator.

A specific material for pin placement is A third custom-made cannula (2.7mmdiameter) with a distal parallel double window (10 _ 2 mm) for direct view control of pin fixation, a long 1.5-mm rotatory drill for perforating disc and condyle, and an impactor with hammer (fixation kit).

Resorbable pins are Smart Nail (ConMed, Linvatec, Tampere, Finland),1.5mm_ 16mmsize (head of pin 2.5mmin diameter and flange of 1 mm) and manufactured of polylactic acid copolymer (Self-Reinforced 96L/4D PLA). The mean degradation period was standardized between 18 and 26 months. [31]

Pre-surgical evaluation

All patientswill be subjected to full history taking, full clinical examination and investigations including preoperative MRI and Panoramic x-ray to assess the dental condition.

Surgical technique

1- **All procedures will be done under general anesthesia (nasotracheal intubation).**

2- **The triple-channel arthroscopic technique of McCain et al is used[32]**

After the first puncture of the fossa, a systematic diagnostic arthroscopy is carried out. A second puncture is carried out aiming at the anterior recess under direct arthroscopic visualization (Level I).

3- **Anterior release: *(Level II)***

Through the working cannula additional local anesthesia is injected to avoid post-operative pain and to decrease bleeding; it can also reduce the risk of masticatory muscle nerve injury. A Knife, coblation or laser probe are used to cut the anterior attachment of the disc and the neighboring part of the lateral pterygoid muscle. The incision line is located approximately 2–3 mm anterior to the anterior band of the disc and is

carried out across the whole width from medial to lateral. The depth of the anterior release is no more than 2 mm to avoid breaking large blood vessels and damaging the masticatory muscle nerve in the anteromedial synovium.

5- Retrodiscal scarification or contracture

Retrodiscal tissue is contracted using bipolar cautery, laser, or coblation. The target area of the retrodiscal contracture is generally the boggy and redundant synovium found lateral to the oblique protuberance. Contracture is visible during the procedure, but the most significant contracture occurs 2 to 3 weeks postoperatively as the scar thickens. The purpose of the contracture is to enhance the posterior positioning of the disc and hold it there. The posterior synovectomy and the scar contracture are also done to reduce volume of the joint space so the disc can sit more posteriorly.

6- Disc reduction

After the anterior release is completed, the obturator is positioned at the anterior margin of the disc and the disc is pushed backwards. The obturator slides along the surface of the disc and arrives in the posterolateral recess. The retrodiscal tissue is pushed down inferiorly and posteriorly.

7- Disc fixation: (Level III)

A disc fixation can be accomplished in 1 of 2 ways. The first and more traditional way is the suture discopexy. A second way is by rigid fixation with either resorbable or titanium screws. Regardless of the methodology of fixation, the disc is held in reduction during the course of the fixation. The target area of fixation is the posterior lateral corner of the disc-condyle assembly, the area of the lateral pole where the disc attaches to the condyle.

Postoperative management

Antibiotics and nonsteroidal anti-inflammatory drugs are routinely prescribed for 5 days. The softness of the postoperative diet should be decreased slowly. Exercises to improve mouth opening are explained to the patient and start 1 week after operation.

In patients with significant postoperative occlusal changes, a splint is recommended. It is designed to raise the bite and prevent contact between upper and lower incisors and canines. Due to the resulting distalization of the bite force, joint loading is reduced, which contributes to the joint's rehabilitation. The appliance should be left in place around the clock during the first ten postoperative days, then used at night for four additional weeks.[34]

Follow up

- Pain assessment using VAS (Visual Analogue Scale) [25]

- Clicking (improvement or persistence).
- Range of motion [33] including: maximal interincisal opening, lateral excursion movement and Protrusive movement
- Post-operative MRI at 6 months for detection of disc position.
- All patients will be followed up at 1, 3, 6 months.

ETHICAL CONSIDERATIONS

Research Ethics Committee approval

The research protocol will be approved by the Research Ethics Committee of Alexandria University Faculty of Dentistry (IRB No. 001056 – IORG 0008839) prior to any research-related activities

All research activities involving human subjects will abide with the Declaration of Helsinki [34] and other ethical guidelines adopted by the Research Ethics Committee of Alexandria University Faculty of Dentistry.

The benefits to the participant and/or the community

1. Treatment of patients with internal derangement with minimally invasive surgery (TMJ arthroscopy).
2. Short hospital stay with early recovery and rapid return to work.

The risks to the participant and/or the community

1. The need for long-term follow-up postoperative.
2. The exposure to radiation in MRI which is needed for follow-up at 6 months.

Anonymity and Confidentiality

The anonymity and confidentiality of the participants will be preserved by not revealing their names and identity in the data collection, analysis and reporting of the study findings.

The identity of participants will be kept confidential or anonymous and the assurances extend beyond protecting their names to also include the avoidance of using self-identifying statements and information.

DATA MANAGEMENT & STATISTICAL ANALYSIS

Data will be collected and analyzed statistically using ANOVA test to compare between the three groups.

REFERENCES

1. Zhang S, Liu X, Yang X, Yang C, Chen M, Haddad MS, et al. Temporomandibular joint disc repositioning using bone anchors: an immediate post surgical evaluation by magnetic resonance imaging. BMC Musculoskelet Disord. 2010;11:262.
2. Thapliyal GK. Peterson's Principles of Oral & Maxillofacial Surgery. Med J Armed Forces India. 2006;62(1):89-.
3. Lipton JA, Ship JA, Larach-Robinson D. Estimated prevalence and distribution of reported orofacial pain in the United States. J Am Dent Assoc. 1993;124(10):115-21.
4. Manfredini D, Guarda-Nardini L, Winocur E, Piccotti F, Ahlberg J, Lobbezoo F. Research diagnostic criteria for temporomandibular disorders: a systematic review of axis I epidemiologic findings. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2011;112(4):453-62.
5. Abubaker AO, Raslan WF, Sotereanos GC. Estrogen and progesterone receptors in temporomandibular joint discs of symptomatic and asymptomatic persons: a preliminary study. J Oral Maxillofac Surg. 1993;51(10):1096-100.
6. Milam SB, Aufdemorte TB, Sheridan PJ, Triplett RG, Van Sickels JE, Holt GR. Sexual dimorphism in the distribution of estrogen receptors in the temporomandibular joint complex of the baboon. Oral Surg Oral Med Oral Pathol. 1987;64(5):527-32.
7. Aufdemorte TB, Van Sickels JE, Dolwick MF, Sheridan PJ, Holt GR, Aragon SB, et al. Estrogen receptors in the temporomandibular joint of the baboon (Papio cynocephalus): an autoradiographic study. Oral Surg Oral Med Oral Pathol. 1986;61(4):307-14.
8. Seifeldin SA, Elhayes KA. Soft versus hard occlusal splint therapy in the management of temporomandibular disorders (TMDs). Saudi Dent J. 2015;27(4):208-14.
9. Dolwick MF, Katzberg RW, Helms CA. Internal derangements of the temporomandibular joint: fact or fiction? J Prosthet Dent. 1983;49(3):415-8.
10. González-García R, Rodríguez-Campo FJ. Arthroscopic lysis and lavage versus operative arthroscopy in the outcome of temporomandibular joint internal derangement: a comparative study based on Wilkes stages. J Oral Maxillofac Surg. 2011;69(10):2513-24.
11. Wilkes CH. Internal derangements of the temporomandibular joint. Pathological variations. Arch Otolaryngol Head Neck Surg. 1989;115(4):469-77.
12. Kircos LT, Ortendahl DA, Mark AS, Arakawa M. Magnetic resonance

imaging of the TMJ disc in asymptomatic volunteers. J Oral Maxillofac Surg. 1987;45(10):852-4.
13. Takahashi T, Nagai H, Seki H, Fukuda M. Relationship between joint effusion, joint pain, and protein levels in joint lavage fluid of patients with internal derangement and osteoarthritis of the temporomandibular joint. J Oral Maxillofac Surg. 1999;57(10):1187-93; discussion 93-4.
14. Liu F, Steinkeler A. Epidemiology, diagnosis, and treatment of temporomandibular disorders. Dent Clin North Am. 2013;57(3):465-79.
15. Israel HA. Intra-articular operative temporomandibular joint arthroscopy. Frontiers of Oral and Maxillofacial Medicine. 2020;3.
16. González-García R, Gil-Díez Usandizaga JL, Rodríguez-Campo FJ. Arthroscopic anatomy and lysis and lavage of the temporomandibular joint. Atlas Oral Maxillofac Surg Clin North Am. 2011;19(2):131-44.
17. Kiehn CL, Desprez JD. Meniscectomy for internal derangement of temporomandibular joint. Br J Plast Surg. 1962;15:199-204.
18. Farrar WB, McCarty WL, Jr. The TMJ dilemma. J Ala Dent Assoc. 1979;63(1):19-26.
19. Laskin DM. Temporomandibular disorders: the past, present, and future. Odontology. 2007;95(1):10-5.
20. Onishi M. [Arthroscopy of the temporomandibular joint (author's transl)]. Kokubyo Gakkai Zasshi. 1975;42(2):207-13.
21. Al-Moraissi EA, Wolford LM, Ellis E, 3rd, Neff A. The hierarchy of different treatments for arthrogenous temporomandibular disorders: A network meta-analysis of randomized clinical trials. J Craniomaxillofac Surg. 2020;48(1):9-23.
22. Santos TS, Pagotto LEC, Santos Nascimento E, Rezende da Cunha L, Serra Cassano D, Gonçalves JR. Effectiveness of disk repositioning and suturing comparing open-joint versus arthroscopic techniques: a systematic review and meta-analysis. Oral Surg Oral Med Oral Pathol Oral Radiol. 2021;132(5):506-13.
23. Abdelrehem A, Hu YK, Yang C, Zheng JS, Shen P, Shen QC. Arthroscopic versus open disc repositioning and suturing techniques for the treatment of temporomandibular joint anterior disc displacement: 3-year follow-up study. Int J Oral Maxillofac Surg. 2021;50(10):1351-60.
24. Murakami K. Rationale of arthroscopic surgery of the temporomandibular joint. J Oral Biol Craniofac Res. 2013;3(3):126-34.
25. Huskisson EC. Measurement of pain. Lancet. 1974;2(7889):1127-31.
26. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Bmj. 2010;340:c332.
27. Muñoz-Guerra MF, Rodríguez-Campo FJ, Escorial-Hernández V, Brabyn PJ, Fernández-Domínguez M, Naval-Gías L. Modified arthroscopic

anterior myotomy for internal derangement of the temporomandibular joint: clinical and radiological results. Int J Oral Maxillofac Surg. 2020;49(10):1311-8.
28. Zhu Y, Zheng C, Deng Y, Wang Y. Arthroscopic surgery for treatment of anterior displacement of the disc without reduction of the temporomandibular joint. Br J Oral Maxillofac Surg. 2012;50(2):144-8.
29. Rosner B. Fundamentals of biostatistics: Seventh edition. Boston : Brooks/Cole, Cengage Learning, [2011] ©2011; 2011.
30. Faul F, Erdfelder E, Buchner A, Lang A-G. Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. Behavior Research Methods. 2009;41(4):1149-60.
31. Martín-Granizo R, Millón-Cruz A. Discopexy using resorbable pins in temporomandibular joint arthroscopy: Clinical and magnetic resonance imaging medium-term results. J Craniomaxillofac Surg. 2016;44(4):479-86.
32. McCain JP, Hossameldin RH. Advanced arthroscopy of the temporomandibular joint. Atlas Oral Maxillofac Surg Clin North Am. 2011;19(2):145-67.
33. Celić R, Jerolimov V, Knezović Zlatarić D, Klaić B. Measurement of mandibular movements in patients with temporomandibular disorders and in asymptomatic subjects. Coll Antropol. 2003;27 Suppl 2:43-9.
34. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. Jama. 2013;310(20):2191-4.

Informed Consent

Research Title:	**A comparative study between the different levels of tmj arthroscopy in the management of tmj internal derangement (a randomized clinical trial)**
Research Steps:	- This study is conducted in Maxillofacial and Plastic Surgery Department, Faculty of Dentistry, Alexandria University on patients having temporomandibular joint internal derangement Wilke's III. - All patients will be assessed clinically and radiologically by using MRI preoperatively to assess disc position. - Patients will be randomized into three groups: o **Group I:** 10 patients will be treated with level (I) arthroscopy (Lysis and lavage). o **Group II:** 10 patients will be treated with level (II) arthroscopy (operative arthroscopy). o **Group III:** 10 patients will be treated with level (III) arthroscopy (operative arthroscopy + disc repositioning and fixation)
Research duration:	From June 2021 to July 2023
Research place:	Maxillofacial and Plastic Surgery Department, Faculty of Dentistry, Alexandria University
Research Benefits:	To compare between the three levels of TMJ arthroscopy in the management of temporomandibular joint internal derangement to develop standardized patient selection criteria and treatment options to be used by all investigators
Side	No expected harmful side effects of the research

effects:	

I, the undersigned, acknowledge that the researcher informed me that:

1 -The research does not contradict the values and ethics of society.

2 -With an emphasis on the confidentiality of the research and my right to leave it without being held accountable and without affecting medical care

Name of the participating patient..... Signature of the participating patient (guardian)..... .....

Principal researcher's signature..Mohamed Hamza Fayad.....