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Anterior Capsulotomy in Arthroscopy of the Temporomandibular Joint – ACTA-TMJ: Study Protocol for a Multicenter Prospective Randomized Controlled Trial

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Abstract

Restricted mouth opening and pain are common in anterior disc displacement without reduction of the temporomandibular joint (TMJ). Operative arthroscopy may include an anterior capsulotomy, but the incremental benefit of routinely adding this step to a standardized level II procedure remains uncertain. A multicenter, parallel-group, randomized, participant- and assessor-blinded controlled trial is designed to compare level II temporomandibular joint arthroscopy with lavage and coblation treatment of synovitis performed with or without an anterior capsulotomy. Adults with radiological confirmed anterior disc displacement without reduction who failed at least three months of conservative management and have an indication for level II arthroscopy are eligible. Eligibility is re-confirmed arthroscopically. Seventy-two participants are allocated 1:1, stratified by center. The primary outcome is maximal interincisal opening at 12 months. Secondary outcomes include pain intensity and the trajectory of maximal interincisal opening over follow-up. This trial will provide pragmatic evidence on whether performing an anterior capsulotomy is effective in operative temporomandibular joint arthroscopy without increasing adverse events.

Highlights

- Multicenter study protocol for a blinded randomized controlled trial in TMJ arthroscopy.
- Effectiveness of anterior capsulotomy within a standardized level II arthroscopy protocol.
- Standardized inclusion criteria and surgical treatment with coblation of synovitis and postoperative rehabilitation in both groups.
- Experienced TMJ arthroscopy surgeons, both members of ESTMJS and AST-MJS, with comparable surgical technique in different TMJ centers.

1. Introduction

Temporomandibular disorders comprise a heterogeneous set of conditions affecting the temporomandibular joint, masticatory muscles, and associated structures [1]. Anterior disc displacement without reduction is a frequent intra-articular disorder associated with pain, restricted mandibular motion, and functional limitation [2]. When conservative management fails, minimally invasive surgical options such as arthrocentesis and arthroscopy are commonly considered [3]. Operative temporomandibular joint arthroscopy allows diagnostic inspection of the superior joint space and targeted lavage, lysis of minor adhesions, and treatment of synovitis [4, 5].

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Anterior capsulotomy (anterior capsular release) is intended to increase joint mobility by releasing the anterior capsule and anterior recess; however, the incremental benefit of routinely adding anterior capsulotomy to a standardized level II procedure remains uncertain [6–8]. The present study is designed to isolate the effect of anterior capsulotomy while standardizing other operative steps across groups.

The aim of the study is to evaluate the added value of performing an anterior capsulotomy by comparing maximal interincisal opening at 12 months after level II temporomandibular joint arthroscopy performed with anterior capsulotomy versus without anterior capsulotomy.

Table 1. Eligibility criteria.

Inclusion criteria	Exclusion criteria
• Age > 18 years • Failure of $\geq$ 3 months conservative therapy • Clinical and radiological diagnosis of unilateral or bilateral anterior disc displacement without reduction • Indication for unilateral or bilateral level II TMJ arthroscopy	• Previous TMJ surgery (other than arthrocentesis) • Facial trauma within 4 weeks • Contralateral TMJ pathology other than disc displacement without reduction • Severe medical problems or mental illness • Pregnancy • Intra-operative adhesions outside anterior recess

2. Materials and Methods

2.1. Study design and setting

A prospective, multicenter, parallel-group, randomized controlled trial with participant and outcome-assessor blinding was designed. The trial is conducted at two specialized TMJ centers: Instituto Português da Face (Lisbon, Portugal) and Ospedale Santa Maria della Misericordia di Udine (Udine, Italy). The protocol for the study was approved by the Comissão de Ética do Instituto Português da Face on 05/01/2026 (Ref N° PT/IPFace/RCT/0112/02). Approval of the ethical committee in Udine still needs to be obtained prior to recruitment of participants.

2.2. Participants

Adults aged over 18 years with clinical and radiological diagnosis of unilateral or bilateral anterior disc displacement without reduction, and an indication for level II temporomandibular joint arthroscopy are eligible. Participants must have undergone at least three months of conservative therapy without significant improvement. Exclusion criteria include previous temporomandibular joint surgery (with the exception of arthrocentesis), recent facial trauma within the last 4 weeks before the study, pregnancy, severe medical or mental illness, contralateral temporomandibular joint pathology other than disc displacement without reduction, and intra-operative finding of clinically relevant adhesions outside the anterior recess. This intra-operative exclusion criterion may limit generalizability to patients with more advanced intra-articular disease and in patients where it is not possible to access the joint correctly via arthroscopy. Written informed consent will be obtained from each patient before inclusion in the study. An overview of all eligibility criteria can be found in Table 1.

2.3. Interventions

All procedures are performed under general anesthesia. In both groups a standardized level II arthroscopy in the superior joint space is performed using a two-portal technique, including diagnostic inspection, continuous irrigation and lavage, lysis of small adhesions as required, and coblation treatment of synovitis using standardized settings. In the experimental group, an anterior capsulotomy is additionally performed at the anterior recess under direct visualization.

2.4. Postoperative care

Postoperative management is standardized across centers: no postoperative splint, immediate self-administered early and intensive physiotherapy (forced opening) for four weeks, ibuprofen 600 mg three times daily for one week (or paracetamol in case of allergy), and avoidance of hard food for one week.

Each patient will be followed up during specific time points until the final follow-up. At each follow-up moment the necessary information will be collected as illustrated in Table 2.

2.5. Randomization and allocation concealment

Randomization is performed centrally with a computer-generated sequence using variable block sizes, stratified by center. Allocation concealment is maintained with sequentially numbered, opaque sealed envelopes prepared by a statistician not involved in clinical care. Because adhesions outside the anterior recess are an intra-operative exclusion criterion, randomization is performed only after diagnostic arthroscopic inspection confirms eligibility.

2.6. Blinding

Participants and outcome assessors are blinded to allocation. The operating surgeon and operating room staff are unblinded. Operative reports include a restricted-access section documenting whether anterior capsulotomy was performed, and follow-up assessments are conducted by a blinded assessor.

2.7. Outcomes

The primary outcome is maximal interincisal opening at 12 months, measured in millimeters between incisal edges (or equivalent landmarks if incisors are missing). Secondary outcomes include pain intensity on a 0–10 visual analogue scale at 4–6 weeks, six months, and 12

Table 2. Schedule of assessments and follow-up moments.

Assessment	Screening/Baseline	Surgery	4–6 Weeks	6 Months	12 Months
Eligibility criteria, consent	X				
Medical history, medications	X				
Radiologic confirmation	X				
MIO (mm)	X		X	X	X
Pain VAS (0–10)	X		X	X	X
Adverse events / complications		X	X	X	X
Concomitant therapies / analgesics	X		X	X	X

The 4–6 week visit window allows routine postoperative scheduling. The 12-month visit is the primary endpoint assessment.

months; change in maximal interincisal opening from baseline to the last follow-up moment; analgesic consumption; adverse events; and exploratory subgroup comparisons for unilateral versus bilateral disc displacement.

2.8. Sample size

The trial is powered on the primary endpoint, maximal interincisal opening (MIO, mm) at 12 months. We consider a 5-mm between-group difference clinically relevant. Published TMJ minimally invasive intervention studies report postoperative mouth opening variability typically in the ~5–7 mm SD range, so a conservative SD = 7 mm was assumed for planning [9, 10].

Using a two-sided alpha of 0.05, 80% power, with 1:1 allocation, and a conservative SD of 7 mm, the base requirement is 62 participants (31 per group). To ensure equal numbers per arm at each center (18 per arm per center) and to allow for approximately 14% attrition or missing primary endpoint assessments, the final target enrollment is 72 participants (36 per group; 36 per center). The planned primary analysis uses ANCOVA adjusted for baseline MIO and center, which is expected to improve statistical efficiency; therefore, this sample size is considered acceptable and conservative for the planned effect size.

2.9. Statistical analysis

The primary analysis will follow the intention-to-treat (ITT) principle including all randomized participants in their allocated group. A per-protocol analysis will be performed as sensitivity analysis excluding major protocol deviations. The primary endpoint (12-month MIO) will be analyzed using an ANCOVA model with treatment group as a fixed effect and baseline MIO and center as covariates. Estimated mean differences with 95% confidence intervals will be reported. Pain VAS and repeated MIO measurements will be analyzed using linear mixed-effects models (participant as random intercept) including time, treatment, and time-by-treatment interaction, adjusting for baseline values and center. Adverse events will be summarized descriptively by group. Efforts will be made to minimize missing data through reminder calls and flexible scheduling windows. If the primary endpoint is missing for more than 5% of participants, multiple imputation under a missing-at-random assumption will be considered as a sensitivity analysis.

2.10. Ethics and trial registration

The trial will be conducted in accordance with the Declaration of Helsinki, ICH-GCP principles, and applicable Portuguese and Italian regulations. Ethics approval will be obtained at both participating institutions prior to participant enrollment. All participants will provide written informed consent. Personal data will be handled in compliance with the EU General Data Protection Regulation (GDPR).

3. Results

3.1. Trial status

Recruitment was scheduled to begin on 6 January 2026. Primary completion and study completion are planned for 31 July 2027. At the time of manuscript preparation, outcome data were not yet available.

3.2. Planned reporting

Participant flow, baseline characteristics, protocol adherence, and adverse events are planned to be reported according to CONSORT guidance for randomized controlled trials. The primary and secondary outcomes are planned to be presented with effect estimates and confidence intervals, with prespecified subgroup exploration for unilateral versus bilateral disease.

4. Discussion

Anterior capsulotomy is frequently used during operative temporomandibular joint arthroscopy, yet its routine use has been supported mainly by heterogeneous evidence and mixed operative protocols [11–13]. The present trial is designed to isolate the added contribution of anterior capsulotomy by standardizing lavage and synovitis treatment with coblation in both groups and excluding clinically relevant adhesions outside the anterior recess before randomization. If anterior capsulotomy results in a clinically meaningful improvement in mouth

opening without increasing adverse events, its systematic inclusion could be justified [14]. Conversely, similar outcomes between groups would suggest that routine anterior capsulotomy may be unnecessary in this patient population, potentially simplifying operative arthroscopy and reducing intra-articular manipulation.

Strengths include the multicenter design, participant and assessor blinding, a pragmatic postoperative rehabilitation pathway, and a prespecified statistical approach adjusted for baseline function and center. Limitations include the inability to blind surgeons and potential variability in arthroscopic findings despite standardization efforts. The trial is expected to provide clinically actionable evidence for surgeons managing anterior disc displacement without reduction.

5. Conclusion

This multicenter randomized controlled trial will evaluate whether adding anterior capsulotomy to a standardized level II temporomandibular joint arthroscopy improves maximal interincisal opening at 12 months compared with arthroscopy without anterior capsulotomy in patients with anterior disc displacement without reduction. The results are expected to clarify the role of anterior capsulotomy as a routine adjunct in operative temporomandibular joint arthroscopy.

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Data Availability Statement: No datasets were generated or analyzed for this study protocol. Additional protocol information is available from the corresponding author on reasonable request.

Author Contributions

All authors contributed to study conception and protocol design; drafting and critical revision.

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