A multicenter, prospective, randomized controlled trial of surgical versus conservative treatment of ADDWoR

Research Background and Significance

Temporomandibular joint disorder (TMD) represents a health condition affecting the temporomandibular joint (TMJ), the muscles involved in mastication, and related structures, with a prevalence rate ranging between 30-40% in the general population [1-3]. The frequency of cases and outpatient visits are on the rise each year. The onset of TMD is often subtle, but as it progresses, it can substantially damage the TMJ's structure and function. This progression can result in functional impairments in activities such as eating, speaking, and breathing and, in severe cases, lead to extensive dental and maxillofacial deformities. These developments can profoundly affect the quality of life of those afflicted [4-7].

Articular disc displacement without reduction (ADDWoR) is a commonly observed subset of TMD, affecting about 35.7% of patients [8]. In ADDWoR, the articular disc, typically positioned over the condyle, shifts to lie before it. This abnormal positioning prevents the disc from returning to its original place during the jaw's opening and closing actions, leading to restricted jaw movement and forward displacement of the mouth. The condition also causes the articular disc to stress the bilaminar zone, resulting in discomfort in the joint. Symptoms can extend to include ear-related issues like tinnitus and hearing impairment, as well as headaches. In more advanced stages, ADDWoR can lead to the perforation of the articular disc and degradation of the condylar bone, among other structural changes. These complications can escalate to severe dental and facial deformities and mental health issues like depression and anxiety, deeply affecting the life quality of those suffering [9]. The consensus on imaging diagnostic criteria is grounded in research findings. For instance, Magnetic Resonance Imaging (MRI) has been established as having excellent reliability in diagnosing disc displacements, both with and without reduction [10]. Moreover, MRI shows good agreement with clinical examinations in diagnosing disc displacement with reduction (DDR), disc displacement without reduction (DDWoR), and normal disc position [11]. Clinical tests have also detected normal disk position and displacement with reduction. However, they are less accurate in predicting MRI diagnosis of (DDWoR) in the TMJ [12].

On the other hand, Cone Beam Computed Tomography (CBCT) has proven to be a significant tool in diagnosing the bony change associated with ADDWoR. The fusion of CBCT with MRI images enhances the diagnostic precision for anterior disc displacement and related bone changes, providing an in-depth view that combines soft tissue details from MRI with CBCT's bone clarity[13]. CBCT's capability to detect early-stage osteoarthritic changes, especially in patients with increased mouth opening, is crucial for early detection and treatment [14]. The use of CBCT-3D imaging for accurately determining condyle

position is essential for precise diagnosis and effective management of disc displacement [15]. Furthermore, CBCT is recommended for further examination in TMJ pathologies, particularly when MRI confirms anterior disc displacement without reduction or disc deformity, highlighting its role in comprehensive diagnostic assessments [16]. Thus, CBCT is invaluable in diagnosing and monitoring treatment progress in cases of anterior disc displacement.

The conservative management of ADDWoR has been effectively illustrated in studies, including one by Afroz et al. This research indicates that a regimen combining non-steroidal anti-inflammatory drugs (NSAIDs), stretching exercises, and stabilization splint therapy can markedly ameliorate symptoms and enhance functionality in such cases [17]. NSAIDs are widely used in the management of TMJ ADDwoR, particularly for pain relief and reducing inflammation. Their effectiveness can be enhanced when combined with physical therapy and other conservative treatment methods[18, 19]. Furthermore, the stabilization splints can be an effective tool in the management of TMJ ADDwoR, particularly in improving mandibular movement and reducing pain. However, the effectiveness may vary depending on the individual case and the specific characteristics of the splint used[20, 21]. These methods, encompassing patient education, mandibular manipulation, and exercise therapy, have played a pivotal role in pain relief and the restoration of movement in patients with ADDWoR [22]. These conservative strategies provide a comprehensive approach to managing ADDWoR, focusing primarily on alleviating symptoms and improving functional capacity[22].

Conservative treatment for TMJ's ADDWoR offers several advantages, including its non-invasive nature, lower risk, and cost-effectiveness. Therapeutic exercises, in particular, facilitate rapid recovery of jaw function [20]. However, these treatments also have limitations, such as a high recurrence rate of symptoms and a primary focus on symptom management, often requiring extended treatment periods [23]. Surgical intervention, specifically focusing on the reduction and stabilization of the TMJ disc, is a fundamental therapeutic strategy for managing ADDWoR. The literature strongly supports that surgical repositioning of the articular disc effectively prevents secondary condyle resorption, a prevalent issue associated with ADDWoR, especially critical during growth phases where ongoing condyle resorption presents significant risks. Studies have demonstrated that disc reduction surgery can restore the TMJ's normal anatomy and growth potential [24-26]. Furthermore, research by Zhang et al. has shown that procedures such as articular disc reduction and anchoring can markedly alleviate symptoms like joint pain and restricted mouth opening, thereby enhancing TMJ functionality. These procedures have achieved a success rate exceeding 95% in treating ADDWoR, effectively reducing joint dysfunction and structural degradation [27-29]. While surgical treatment for TMJ ADDWoR offers benefits such as rapid effectiveness, shorter treatment duration, and lower recurrence rates, it demands significant surgical expertise. It entails higher costs than conservative methods[30]. Despite its effectiveness, as Machoň et al. (2012) emphasize, the procedure is technically intricate and involves risks inherent to invasive surgeries, requiring a careful assessment of the potential benefits and risks [31]. Additionally, the higher

costs associated with surgical treatment can make it less accessible for some patients compared to more affordable conservative approaches.

Despite being more invasive and carrying increased risks and potential complications compared to conservative treatments, surgical approaches provide long-term benefits. They offer a crucial means of preventing the progression of disorders that could lead to severe complications [32]. We hypothesize that surgical intervention is more effective than conservative treatment in improving joint function, patient perception, condylar bone remodeling, and TMJ disc status in patients with ADDWoR, with lower recurrence rates of ADDWoR over a 24-month period.

This study evaluates the effectiveness of various treatments for adult ADDWoR. The treatments range from conservative methods like exercise therapy and topical and systemic medication to direct open surgical interventions to reduce ADDWoR.

Research objectives

Primary objective.

1. To systematically evaluate and compare the effectiveness of conservative and surgical interventions in managing ADDWoR.

Secondary objective

1. To assess whether there were differences between the two treatment groups in terms of

- improvement in TMJ function in patients at one month, six months, 12 months, and 24 months;
- Subjective patient perception at one month, six months, 12 months, and 24 months;
- Condylar bone remodeling at 12 months, 24 months;
- TMJ disc status at 1, 6, and 24 months;
- Surgical recurrence rate of irreducible anterior displacement of the TMJ disc at 24 months.

Methodology:

Trial design

This project is a A multicenter prospective randomized controlled trial, including patients diagnosed with ADDwoR who have received either conservative or surgical treatment (Fig. 1).

Study Groups

Conservative treatment group

Surgical treatment group

Sample Size Calculation

The sample size calculation was performed using IBM SPSS Statistics for Windows, Version 26.0 (Armonk, NY: IBM Corp.). Based on a two-sided test with an alpha of 0.05 and a power of 90%, and anticipating a dropout rate of 10%, the total sample size needed is 90 participants, with 45 allocated to each treatment group. This calculation takes into account the expected differences in primary outcomes between the conservative and surgical treatment groups, with input parameters derived from previous studies.

Randomization and blinding

Randomization:

This process involves selecting an appropriate software tool, inputting the total participant count, and setting up two distinct groups for the surgical and conservative treatments. As participants enroll, the software assigns them randomly to one of these groups, often using a simple method like odd and even numbers for differentiation. This approach ensures an unbiased allocation of participants to each treatment category, which is essential for the trial's integrity. Throughout the trial, the randomization process is documented and monitored for consistency and fairness.

Blinding:

is not feasible in this study due to the distinct and visible differences between surgical and conservative treatments. The nature of each intervention makes it clear to both patients and clinicians which treatment is being administered, preventing the possibility of maintaining blinding.

Participants

Inclusion criteria:

1. Adults aged 18-60 years
2. Clinically and MRI-confirmed diagnosis of anterior disc displacement without reduction
3. Symptoms such as pain and limitation of mouth opening.
4. Subjective disease duration of more than three months**.**

Exclusion criteria

1. ASA > 2
2. Insufficient disc length or calcification that prevents disc repositioning surgery, etc.
3. Received TMJ-related treatment within the last six months.

Collaborative units

1. Jilin University Stomatology Hospital
2. Lanzhou University Stomatology Hospital
3. Wuhan University Stomatology Hospital
4. Guangzhou Medical University Stomatology Hospital)

Project Progress Schedule

First Stage (2024): Detailed project planning, preparation, and patient enrollment.

Second Stage (2025-2026): Surgical implementation, clinical data collection, and analysis.

Third Stage (2026): Article writing and project completion.

Diagnostic criteria

Clinical and MRI Correlation:

TMJ pain associated with ADDwoR correlates well with MRI diagnoses of internal derangement. This suggests that clinical diagnostic criteria can reliably predict MRI diagnoses of this condition.

MRI confirmed the diagnosis (posterior boundary of the joint disc). Before the 11:30 hour hand position), the articular disc is still in front of the condyle in the open position.

CBCT confirms the diagnosis of the bony changes associated with ADDwoR relative to the anterior slope of the condyle in the oblique sagittal position of joint

Functional Diagnostic Examinations:

Clinical examination and mandibular movement recordings are valid and reliable methods for diagnosing TMJ disc displacement. These examinations can be effective.

Visual Inspection: The clinician visually inspects the jaw and surrounding areas for any signs of asymmetry, swelling, or other abnormalities.

Palpation: The TMJ and associated muscles are palpated to detect areas of tenderness, muscle tightness, or joint irregularities.

Listening for Sounds: The clinician listens for any clicking, popping, or grating sounds during jaw movements, which indicate disc displacement.

Checking Jaw Function: The clinician observes and assesses the range of motion during jaw opening, closing, and side-to-side movements. Limitations or deviations in these movements can suggest TMJ problems.

Mandibular Movement Recordings:

Electronic Devices: Specialized electronic devices like jaw trackers or electromyography (EMG) can be used to record and analyze jaw movements in detail.

Measuring Jaw Motion: These devices measure the speed, smoothness, and symmetry of jaw movements, providing quantitative data that can help diagnose TMJ disorders.

Detecting Deviations: Abnormal movement patterns, like deflections or restrictions in jaw movement, can indicate disc displacement.

Interventions:

This study is designed to recruit 90 patients diagnosed with ADDWoR, dividing them into two groups of 45 participants each. One group will receive surgical treatment, while the other will undergo conservative treatment for TMJ ADDWoR (Fig. 4). Post-treatment evaluations will be conducted to assess the impact of these interventions. The evaluations will concentrate on changes in the patient's symptoms and the structural and functional aspects of the joint, both before and after the treatment modalities. These assessments will occur at multiple time points: prior to treatment initiation (T0) and at one month (T1), six months (T2), twelve months (T3), and twenty-four months (T4) following the treatment. Employing this longitudinal approach will yield in-depth insights into patient responses and the effectiveness of surgical and conservative treatments in improving joint function and structure.

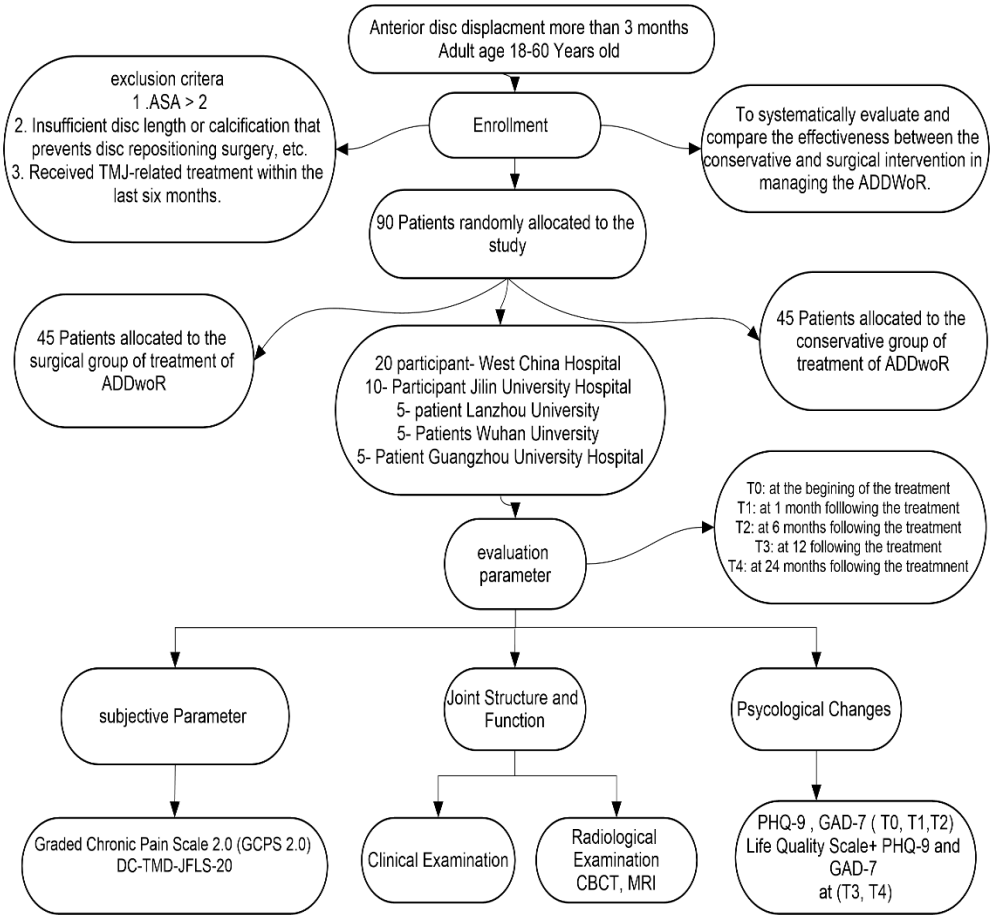


Figure 1: Showing a flowchart of the study design.

Conservative Treatment

Treatment with stabilizing splints: This part uses transparent resin materials called stabilizing jaw pads covering all maxillary occlusal surfaces (Fig. 2). The jaw plane shall be kept flat. During the median occlusion, the functional tip of the mandibular teeth.

The patient shall be in uniform contact with the occlusal surface of the jaw pad, and there is no cross-cross relationship between the cusp and the fossa. The patient wears the occlusal plate for 24 hours, re-examining and grinding every 2 to 4 weeks. After adaptation, the patient can return once a month. After the occlusion is stable, the occlusal plate is removed for six months.

Mouth opening training (wide mouth opening for 3 months + 3 months + adding lateral and anterior post-extension) + abstinence from hard food (1 year).

Occlusal adjustment treatment: In this part of the examination, occlusal adjusting paper is used with different thicknesses to determine occlusal interference points by allowing patients to occlude in the middle, laterally and protrusively, repeatedly confirm the interference points, finally determine occlusal interference points, adjust and grind occlusal interference points, and restore uniform and non-interference contact of the whole mouth.

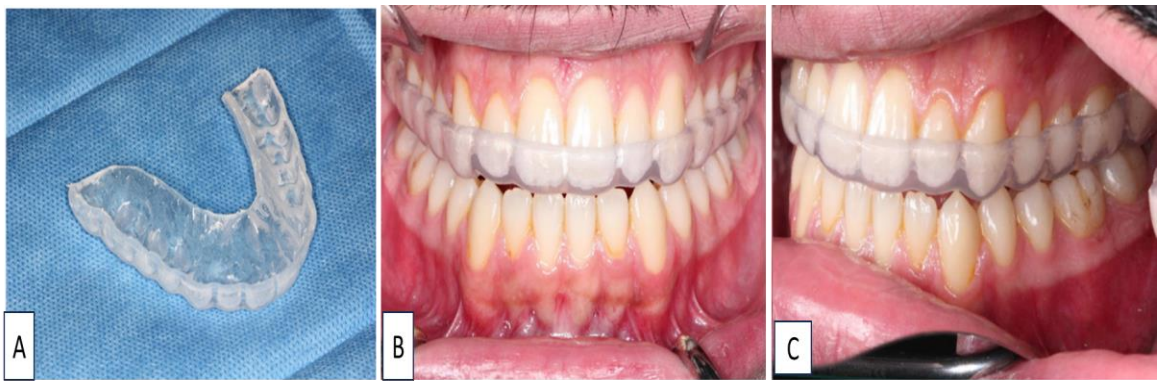


Fig. 2 A. Stabilization Splint. B. Frontal view of the Soft Rubber Splint. C. Lateral view of the Soft Rubber Splint[33].

Medications:

Non-steroidal anti-inflammatory drugs (NSAIDs) play a significant role in the management of anterior disc displacement without reduction. Research indicates that NSAIDs are effective in managing this condition[19]. Moreover, NSAIDs like Meloxicam have shown significant efficacy in alleviating pain associated with temporomandibular joint disorder (TMD), which includes anterior disc displacement without reduction [18]. other studies suggests that NSAIDs can offer short-term symptomatic relief for

acute pain in similar conditions, demonstrating their role in managing discomfort and inflammation associated with disc displacement[34].

Surgical Treatment:

This trial involves a standard open approach to the temporomandibular joint (TMJ) disc, utilizing nasotracheal intubation and a standard endural incision without an anterior release. This technique minimizes post-operative scarring. A flap is created in the subcutaneous fat above the temporoparietal fascia, and dissection proceeds inferiorly through the fascia.

The flap elevation reveals the zygomatic arch and the TMJ capsule. Upon accessing the superior compartment of the TMJ, the disc is examined for its shape, size, and any perforations. The displaced disc is released using electrocautery or fine scissors, approximately 2-3mm anterior to the disc[35-37]. For repositioning, a 2.0 mini-screw with a slotted tail is drilled in, positioned 8 to 10 mm below the posterior condylar slope (refer to Fig. 3). The disc is then anchored back into place using two non-resorbable sutures, with horizontal mattress sutures securing the junction of the disc and the retrodiscal tissue. One suture is inserted through the medial side of the posterior band and another through its lateral side. To ensure the sutures remain tight, six to seven knots are tied. Postoperatively, Mouth opening training (wide mouth opening for three months + 3 months + adding lateral and anterior post-extension) + abstinence from hard food (1 year).

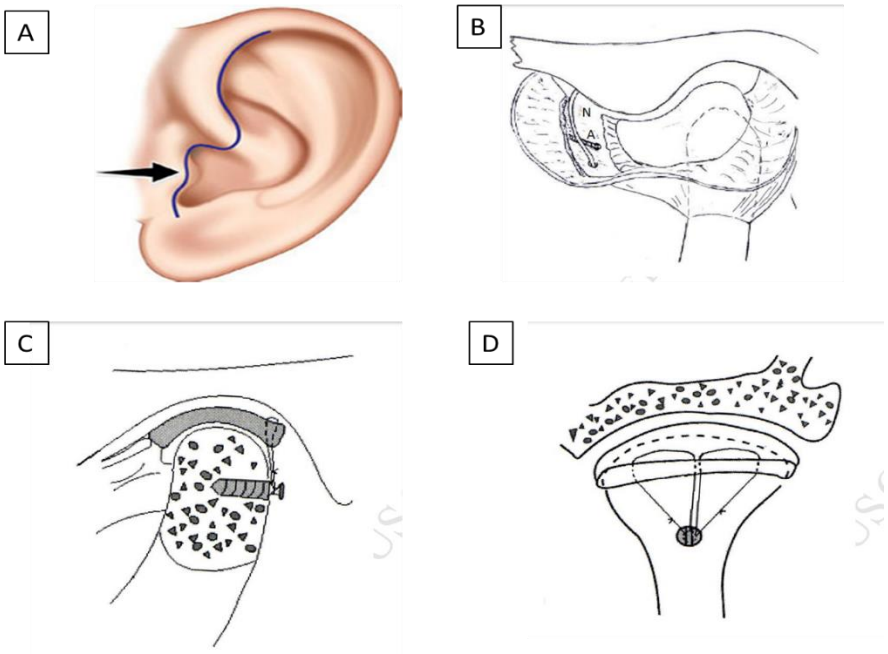


Figure 3: Surgical Approach of the ADDwoR A) Modified Endural Incision **B)** Anterior release of the displaced disc **C)** 2.0 mm mini-screw with a slot in the tail is drilled 8 to 10 mm inferior to the posterior condylar slope **D)** Two Horizontal matrix suture matrix to fix the disc in position.

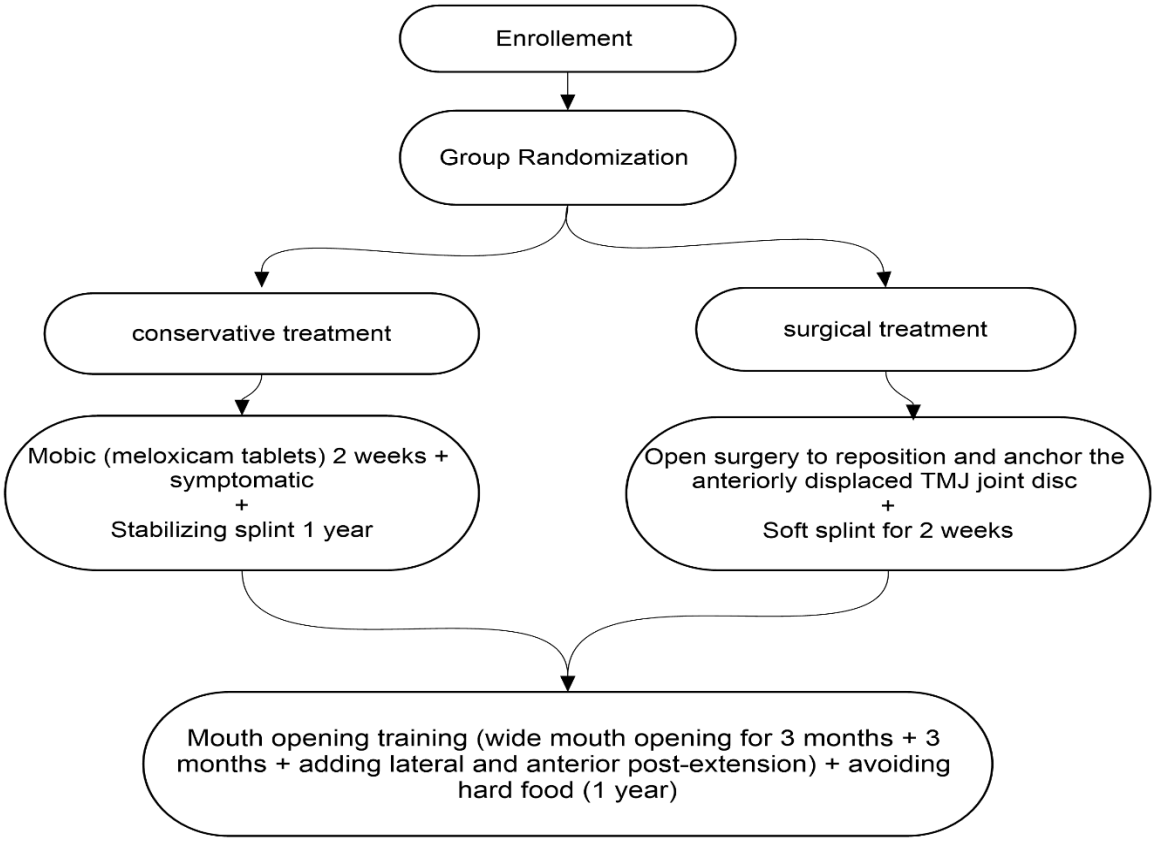


Figure 4: Flowchart showing the guidelines for treatment

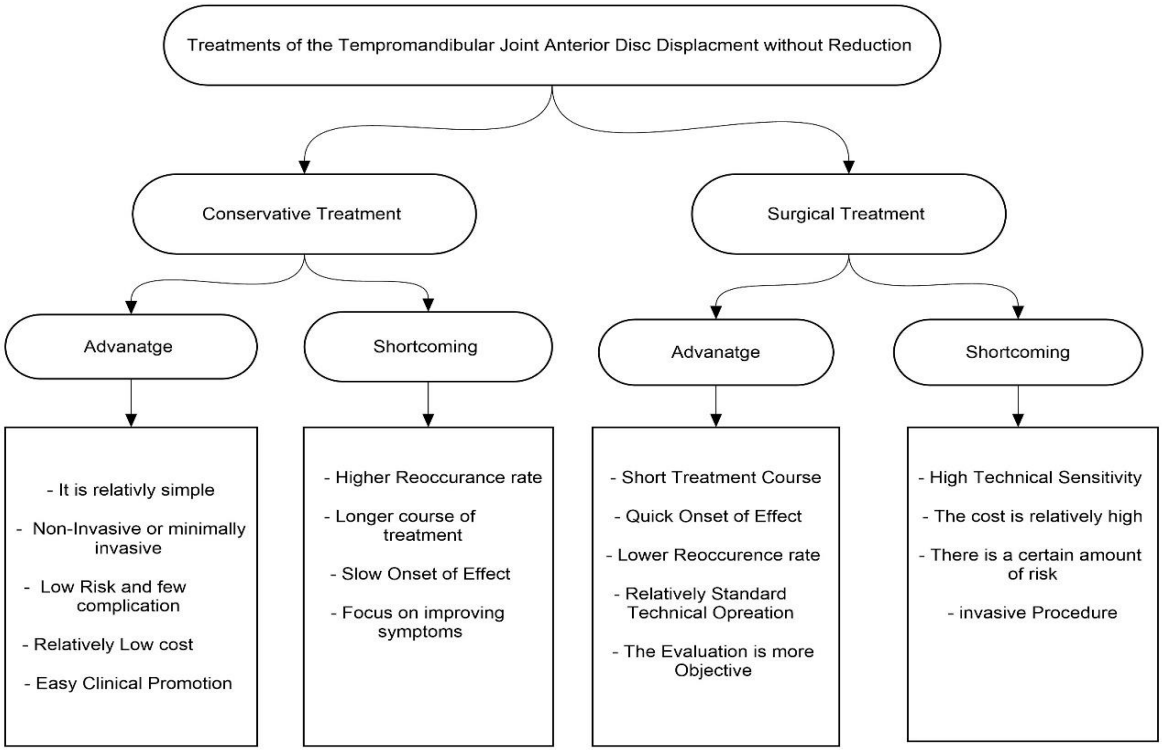


Figure 5: Flowchart showing the advantages and shortcomings of the surgical and conservative treatment

Conditions for withdrawal or termination of the study

Patient withdrawal:

1. The patient asked to withdraw from the clinical study.
2. The patient cannot complete relevant examinations as required, which affects the data collector.
3. Patients undergoing other joint treatment schemes during the trial;
4. The patient has other diseases or serious complications during the trial and needs treatment or rescue, which may affect the study plan.

Termination of the study

1. The study highlighted a significant error in the clinical strategy, making it challenging to gauge the effectiveness of the treatment.
2. During execution, if vital discrepancies in the research plan are identified, and the plan is still followed, it becomes problematic to assess the treatment's impact accurately.

Criteria for Case Discontinuation

Definition of Discontinuation: Participants who have signed the informed consent form and met the eligibility criteria for the trial are considered discontinuation cases at any point and for any reason,

provided they have not finished the designated treatment cycle.

Reasons for discontinuation may include:

1. Participants cannot complete the necessary assessments as required or choose alternative treatment methods during the study.
2. During the observation period, participants who become unreachable or are lost to follow-up, including those who have undergone successful surgery but cannot complete the full treatment, hinder complete data collection and impact the effectiveness assessment.
3. Participants experiencing severe adverse reactions, adverse events, or complications deemed inappropriate for the clinical trial are withdrawn from the study.

Outcomes:

Primary outcomes

Joint Function Assessment:

1. **ADDWoR Common Clinical Symptoms:** Evaluation of specific symptoms associated with ADDWoR, such as pain, joint noises, and limitations in mouth opening.
2. **Joint Function Index:** Quantitative assessment of joint function, possibly including measures like range of motion, strength, or functionality of the jaw joint.
3. **Occlusal Force Detection:** Measurement of the bite force, which can be indicative of the functional status of the temporomandibular joint (TMJ).

Secondary outcomes

Joint Structure Assessment:

1. **Articular Disc Morphology Analysis: MRI** Evaluation of the shape, position, and integrity of the articular disc using Magnetic Resonance Imaging. This helps in understanding the structural changes in the disc associated with ADDWoR.
2. **Condyle Remodeling Analysis:** CBCT Assessment of changes in the bone structure of the condyle using CBCT. This analysis can reveal bone remodeling or resorption in the TMJ.
3. **Disc-Condyle Position Analysis:** CBCT Evaluation of the spatial relationship between the articular disc and the condyle. This can provide insights into the alignment and displacement issues within the TMJ.

Evaluation will be performed at the following stages:

(T0): at the beginning of the treatment

(T1): one month after operation

(T2): Six months after the operation

(T3) 12 months after the operation

(T4) 24 months after the operation

Follow-up Schedule

1. At one-month post-treatment (Timepoint 1, T1), patients will undergo clinical evaluations, Magnetic Resonance Imaging (MRI) assessments, and will be assessed using the Graded Chronic Pain Scale (version 2.0), the DC-TMD Jaw Function Limitation Scale-20 (DC-TMD-JFLS-20), the Patient Health Questionnaire-9 (PHQ-9), and the General Anxiety Disorder-7 (GAD-7) scale.
2. At six months post-treatment (Timepoint 2, T2), the follow-up will include clinical evaluations, Cone Beam Computed Tomography (CBCT) imaging, MRI assessments, and evaluations utilizing the Graded Chronic Pain Scale (2.0), DC-TMD-JFLS-20, PHQ-9, and GAD-7.
3. At twelve months post-treatment (Timepoint 3, T3), the evaluation protocol will consist of clinical examinations, CBCT imaging, and a Patient Satisfaction Assessment.
4. At twenty-four months post-treatment (Timepoint 4, T4), patients will be subjected to clinical examinations, MRI assessments, a Patient Satisfaction Assessment, and evaluations employing the Graded Chronic Pain Scale (2.0), DC-TMD-JFLS-20, PHQ-9, and GAD-7, similar to the protocol at T3.

Measurements of the outcomes

Joint Function Indexes

1. **RDC/TMD:** The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) is a diagnostic tool for classifying and diagnosing temporomandibular disorders (TMD). It employs a dual-axis system: Axis I focuses on the physical diagnosis of TMD, categorizing various subtypes like myofascial pain and disc displacement; Axis II assesses psychosocial aspects, including pain-related disability and psychological factors. RDC/TMD is crucial for accurate TMD diagnosis and treatment planning in clinical practice. It also standardizes TMD research, ensuring consistency and reliability in studies. This index recognizes TMD's multifaceted nature, encompassing physical and psychological dimensions. The index used for evaluation at the T0.
2. **The Graded Chronic Pain Scale 2.0 (GCPS 2.0**) is primarily used for assessing chronic pain severity and its impact on daily life. It gauges pain intensity and evaluates how pain interferes with personal and social activities, aiding healthcare providers in developing targeted treatment plans. Additionally, GCPS 2.0 is a valuable tool for monitoring the progress and effectiveness of chronic pain treatments, ensuring tailored and effective pain management strategies. Which comprehensively assesses joint function by scoring mandibular motor function, was the main variable indicator in this study. The index used for evaluation at the T0, T1.T2, T3, and T4.

3. **The DC-TMD-JFLS-20** index is used within the context of the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD). It is designed for assessing jaw functional limitation in individuals with temporomandibular disorders (TMD). This index specifically measures how TMD affects a person's ability to perform daily jaw functions, like eating, speaking, and yawning. Clinicians use it to evaluate the functional impact of TMD on patients, aiding in both diagnosis and monitoring the effectiveness of treatments. The DC-TMD-JFLS-20 is an essential tool for understanding the practical implications of TMD on patients' daily lives. The index used for evaluation is the stages T0, T1.T2, T3, and T4.

4. **Patient Health Questionnaire-9 (PHQ-9):** This is a clinical assessment tool used to screen, diagnose, monitor, and measure the severity of depression. It consists of nine questions that correspond to the criteria for diagnosing depressive disorders as per the Diagnostic and Statistical Manual of Mental Disorders (DSM). Its primary uses include identifying the presence of depressive symptoms, determining their severity, and monitoring changes in symptoms over time, particularly in response to treatment. The PHQ-9 is widely used in both clinical settings and research to facilitate the early detection and ongoing management of depression. The index used for evaluation is the stages T0, T1.T2, T3, and T4.
5. **Generalized Anxiety Disorder-7 (GAD-7):** is a self-reported questionnaire used for screening and measuring the severity of generalized anxiety disorder. Comprising seven items, it assesses the frequency of anxiety symptoms experienced by an individual. The GAD-7 is utilized primarily to identify possible cases of generalized anxiety disorder in clinical settings and to monitor changes in anxiety levels over time, particularly in response to therapeutic interventions. This tool is valuable for both initial screening and ongoing assessment of anxiety in patients. This index evaluates the anxiety response of the patients from the stages starting from T0, T1.T2, T2, until T4.
6. **The Patient Satisfaction Score** is a crucial tool in healthcare, primarily used for evaluating and enhancing the quality of care from the patient's perspective. It directly indicates patients' experiences and satisfaction with various aspects of healthcare services, ranging from the effectiveness of treatments to the demeanor of healthcare providers and the overall hospital environment. By systematically gathering this feedback, healthcare providers can identify specific areas needing improvement, tailor services to meet patient expectations better and enhance overall patient care. Furthermore, these scores significantly guide healthcare policies and decisions, offering a patient-centered approach to evaluating healthcare quality and performance. The Patient Satisfaction Score bridges patient experiences and healthcare service optimization, fostering continuous improvement in the healthcare sector. This index will evaluate the patient's satisfaction at T3 and T4 following conservative or surgical management.

Common clinical symptoms of ADDWoR

Mandibular movement: including mouth opening degree, mouth opening shape, forward extension and lateral movement, and other indicators such as Joint murmurs, including snapping and friction sounds;
Tenderness in the joint area, including the lateral joint capsule, the posterior region of the condyle, and the posterior condyle passing through the external auditory canal;
Tenderness of masticatory muscles: parietal area, anterior part of temporalis muscle, the middle part of the temporalis muscle, posterior part of temporalis muscle, anterior part of masseter muscle, deep part of masseter muscle, lower part of masseter muscle, posterior part of digastric muscle, inner pterygoid muscle, upper part of sternocleidomastoid muscle, the middle part of the sternocleidomastoid muscle, the lower part of the sternocleidomastoid muscle, the upper part of the trapezius muscle, and the lower part of the trapezius muscle
Rest pain and occlusal pain: both were scored by VAS, and rest pain was defined as the pain in the joint area when the patient was in the mandibular position; occlusal pain was evaluated for the pain in the joint area after the patient chewed gum for 20 seconds.
TMJ dysfunction index: including the above-mentioned mandibular movement score, joint murmur score, and joint tenderness score. The calculation method is (mandibular movement score + joint murmur score + joint tenderness score)/26.
Occlusal force: Use an occlusal force measuring instrument for occlusal measurement. The occlusal force of the patients was measured before the operation, six months after the operation, and 12 months after the operation.

Post-operative Imaging data

- MRI will be taken at the beginning of the treatment T0, after 1 month of the treatment T1, 6 months of the treatment T2, and 24 months following the treatment T4
- CBCT imaging will be collected at the beginning of treatment T0, 12 months after treatment T3, and 24 months after treatment T4.

Morphological analysis of the articular disc

MRI of the joint was taken before (T0), after 1-month (T1), after six months (T2), and 24 (T4) months after the operation.
MRI examination specification: Before scanning, the patient fills out the informed consent form for scanning, and the doctor checks the patient's information: GE Signa 1.5T magnetic resonance imaging equipment, T2WI, and PDWI sequences, matrix: 288×256, the field of view 14cm×12.6cm; the patient was supine during the examination position, the midpoint of the line connecting the two external auditory canals is in the center, the midsagittal plane of the face is perpendicular to the ground plane, and the orbital-auricular plane is perpendicular to the ground; scan the oblique sagittal and coronal

positions of the joint closure and the maximum opening of the joints on the left and right sides[38].

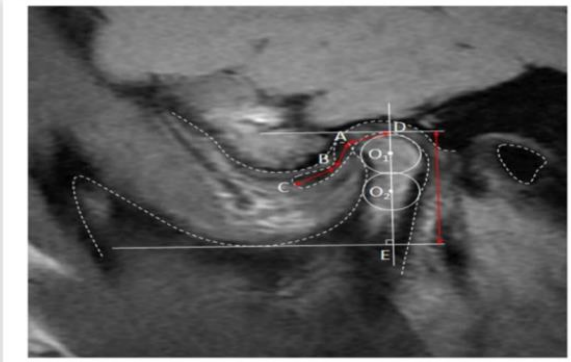


Figure 6: Showing the morphological analysis of the articular disc

Point A is located at the posterior edge of the articular disc; Point B is located in the center of the disc; Point C is located at the anterior edge of the articular disc; D point is the 12 o'clock position of the condyle; Point E is the intersection of the condyle axis with its perpendicular cut sigmoid notch. The length of the articular disc is the sum of the sizes of the AB and BC lines. The DE line shows the condyle height [38, 39].

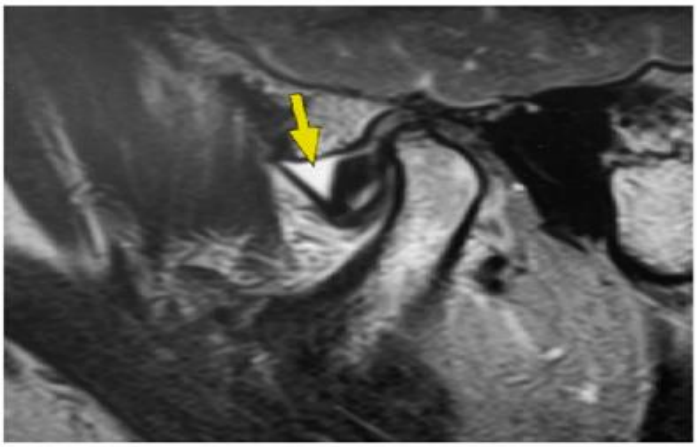


Figure 7: The yellow arrows point to fluid in the joint cavity [40].

Articular disc position

In evaluating the TMJ, the positioning of the articular disc is critical for diagnostic accuracy. Ideally, the posterior band of this disc should be located just posterior to the 12 o'clock position of the mandibular condyle, optimally between 12 o'clock and 1 o'clock [41]. This alignment is considered normal and essential for the proper functioning of the TMJ. Furthermore, the presence of joint effusion, often marked by a yellow arrow in MRI scans, indicates fluid accumulation within the joint cavity. This sign may point to inflammation or other pathological changes in the joint [39]. These diagnostic criteria, particularly the precise positioning of the articular disc, rely on accurate and detailed imaging. MRI is the preferred modality for its superior ability to visualize soft tissue structures within the TMJ.[42, 43].

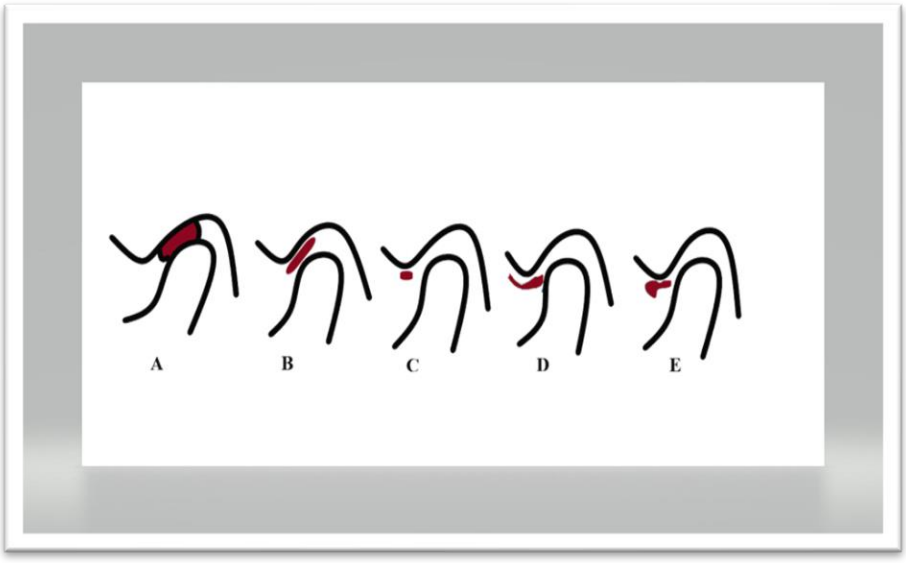


Figure 8: Showing the different morphological shapes of the articular disc (A) biconcave, (B) biplane, (C) biconvex, (D) semi-convex, (E) folded [43].

MRI morphological analysis

Point A is located at the posterior border of the articular disc.

Point B is at the center of the articular disc.

Point C is at the anterior edge of the articular disc.

Point D represents the 12 o'clock position on the condyle.

Point E is the intersection where the axis of the condyle intersects perpendicularly with the sigmoid notch.

The length of the articular disc is the sum of the lengths of lines AB and BC. The DE line indicates the height of the condyle.

Disc Position: The posterior border of the posterior band should be positioned posterior to the 12 o'clock position on the condyle, with the ideal location being between the 12 and 1 o'clock positions.

Analysis of condyle remodeling

Joint CBCT was taken at the start of treatment T0, one year after treatment T3, and 24 months T4 after treatment.

CBCT examination was standardized; before scanning, the patient filled out the scanning informed consent form, and the doctor checked the patient's information; the patient was supine during the examination, occlusal in the cusp cross position.

Condyle 3D reconstruction: Import the DICOM data (T0, T3, T4) of the patient's joint CBCT into 3D slicer software and register the T0, T3, and T4 using voxel base registration followed by the Segmentation of each model condyle. The three-dimensional model of the condyle was reconstructed

based on the segmentation of the condyle. The model is converted to a mesh model to facilitate the measurement of bony remodeling over the condylar bone [44, 45].

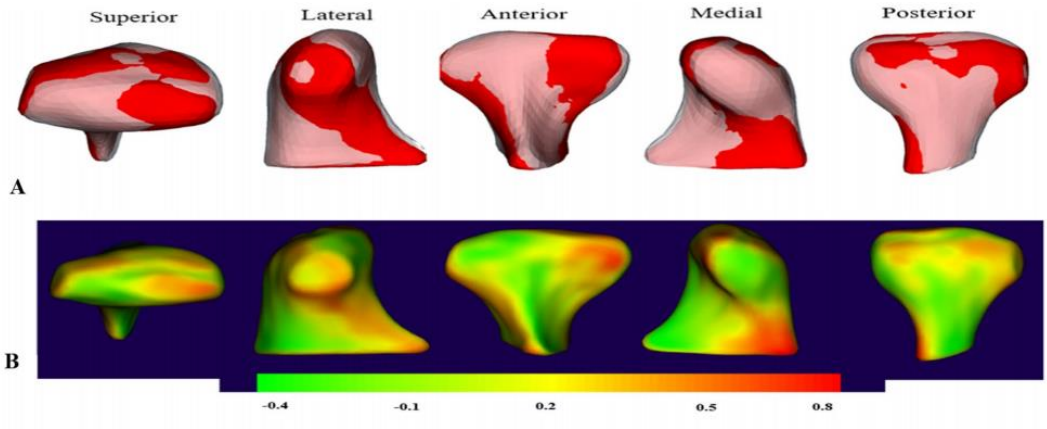
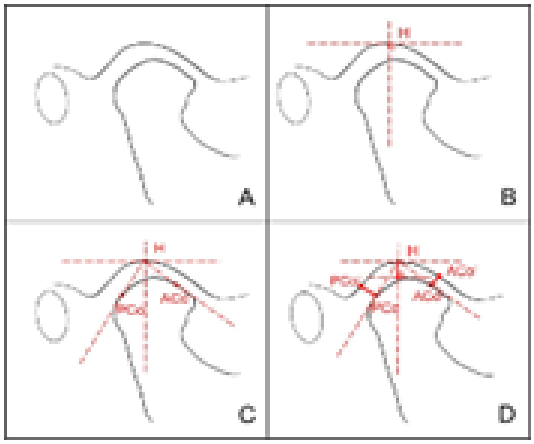


Figure. 9: Showing the condylar remodeling using the color map function of the 3-D slicer software.

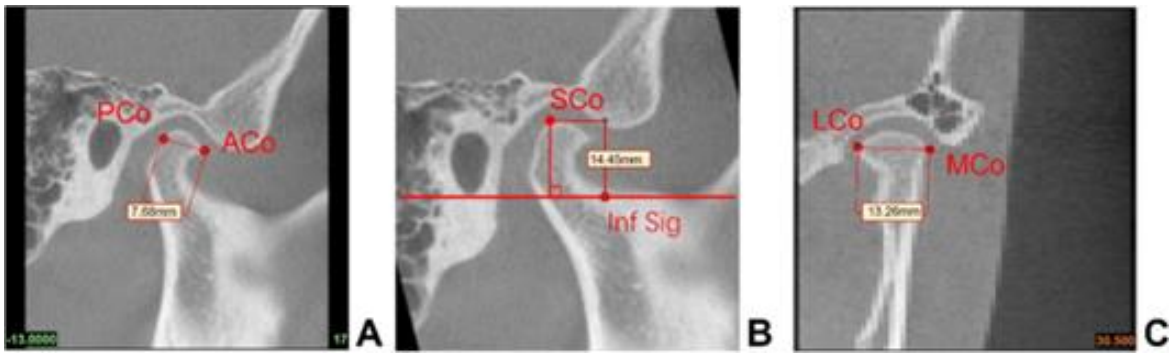
1. Observation plane

The most convex points of the condyle in the anterior and posterior slope of the articular bevel are ACo and Pco, respectively. The highest point of the articular fossa is H, and three points determine the sagittal plane.



2. Measurement of joint space

Point H is the coordinate origin, and the anterior and posterior condylar tangents are plotted to intersect the vertical lines. The width of the joint space is measured by a line perpendicular to the tangent of the condyle [46].



3. Three-dimensional measurement of the condyle

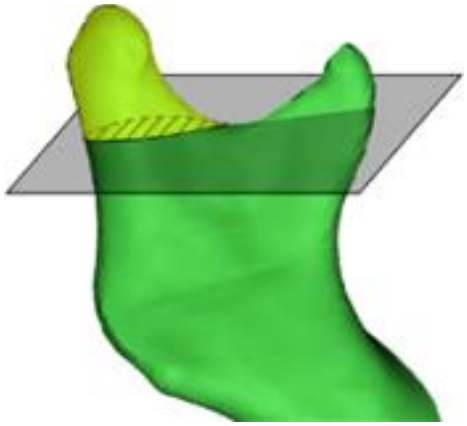
(1) Length: The distance between PCo and ACo

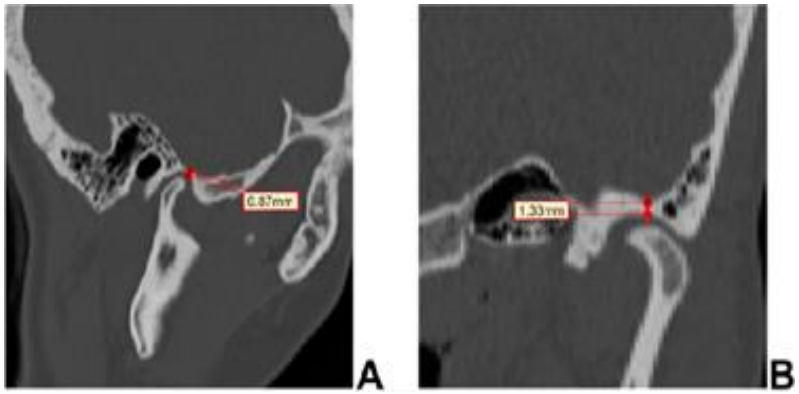
(2) Height: The vertical distance from the SCo to the lowest end of the sigmoid notch

(3) Width: Coronal position, condylar internal bump (MCo), and lateral bump (LCo); the measurement of condylar width is the linear distance between MCo and LCo.

4. The volume of the condyle

after three-dimensional reconstruction of the condyle and TMJ disc, import CBCT data into Mimics 20.0 software, the axial section, when the first opaque point appears in the joint space, the upper extent of the condyle head is determined, and the axial image is rolled from the upper region of the joint space to the lower area; When the sigmoid notch disappears, determine the lower extent of the condylar head. Measure the volume using Mimics software [47], [48].





5, Socket thickness is the shortest distance between the inferior cortex and epicortex of the socket in the sagittal plane[49].

Statistical Analysis:

Baseline characteristics analysis:

demographics (age, gender, ethnicity, etc.) and clinical parameters (disease duration, severity, etc.) are analyzed using descriptive statistics to summarize the data and ensure comparability between groups. Continuous variables (e.g., age, duration of disease) are described using means and standard deviations or medians and interquartile ranges for skewed distributions. Categorical variables (e.g., gender, presence of comorbidities) are summarized with frequencies and percentages.

The statistical analysis methods for handling primary and secondary outcomes

using both one- and two-sided tests at a significance level of 0.05. Continuous variables will be compared with t-tests (two-sided) or Mann-Whitney U tests, and categorical variables with chi-square tests or Fisher's exact tests (one-sided for directional hypotheses). To address the multiplicity issue from comparisons at multiple time points, a Bonferroni correction or other false discovery rate controlling procedures will be applied to adjust the significance threshold, thus maintaining the overall Type I error rate within acceptable bounds. This approach ensures rigorous evaluation of outcomes while mitigating the risk of false-positive findings.

Missing data

Sensitivity analysis

Missing baseline data will be interpolated using mean interpolation. If the baseline data are biased, median interpolation will be used instead.

A hybrid modeling approach will handle missing values in the follow-up measurement data.

Feasibility Analysis:

The project is based on collaboration between five reputable hospitals with rich resources in TMJ diseases. The research team has extensive experience treating TMJ disorders and applying digital technology.

Ethics and Consent

Ethical requirements

This experiment will fully comply with the ethical principles of the Helsinki Declaration and the International Ethics Guide for Biomedical Research issued by the International Committee of Medical Science Organizations, respect personality and fairness, strive to maximize the benefits of the subjects, and avoid harm as much as possible. Furthermore, we will inform all patients and their families of the relevant issues of this trial in detail before the trial, and they will also keep a copy of the informed consent form.

Data Monitoring and Harms

Benefits and Risks

The subject underwent standard surgical and non-surgical treatments, implying that any potential risks following these procedures are also typical. Appropriate preventive and emergency responses were in place in the department. In cases where the surgical procedure triggers an allergic or rejection response in the subject, resulting in wound infection and non-healing, it will be necessary to remove the anchor screw surgically. Opting for surgical intervention might reduce the duration of treatment and enhance patient satisfaction. Upon enrollment in either the surgical or non-surgical group, participants in this clinical study will be compensated with a subsidy of 500 yuan upon completion.

Safety evaluation

This experiment will compare the prospective control study on the disc condyle and space changes in patients with irreducible anterior displacement of the TMJ disc under different clinical treatment modes. The treatment methods are the mainstream methods in China, and the consent form will be signed before the treatment of relevant risks, which will not increase the additional risks to the subjects

Emergency Response Plan

(1) patients admitted to treat TMJ disorders will be fully informed about the treatment process, related charges, and precautions after admission. Patient consent will be obtained before enrolling them in the project.

(2) a strict assessment of anesthesia risk will be conducted after admission. Patients who experience

anesthesia accidents during surgery will be treated according to the surgical anesthesia accident response plan.

(3) A strict surgical plan will be formulated to control the scope of each surgical operation and avoid damage to well-known blood vessels and nerves during surgery. If significant bleeding due to vascular injury occurs during surgery, strict hemostasis must be enforced before proceeding further. In cases where well-known nerves are damaged, nerve repair and anastomosis must be performed, leading to functional impairment. Postoperative medication or physical therapy will be provided for nerve function recovery in cases of nerve injury.

(4) Before surgery, thorough surgical planning will be conducted. For patients who experience surgical failure due to intraoperative accidents or individual differences, a second surgery may be considered, or after communication with the patient and obtaining informed consent, their participation in the experiment may be canceled.

Ancillary and Post-Trial Care

Handling of Discontinuation Cases

1. In instances of discontinuation, researchers should endeavor to contact the patient through home visits, scheduled follow-ups, and phone calls, inquiring about the reasons for discontinuation and the patient's health status and completing any feasible evaluation tasks;

2. For patients who withdraw due to adverse reactions or complications, appropriate treatment interventions should be administered based on the specific circumstances;

3. Accurate records and data for cases of discontinuation should be maintained and filed for thorough analysis and statistical evaluation.

Dissemination Policy

This clinical trial adheres to rigorous standards for disseminating research findings to ensure the broadest possible impact and to contribute to the scientific community's understanding of temporomandibular joint disorders. The dissemination strategy includes:

Publication in Peer-Reviewed Journals:

The results of the trial will be submitted for publication in high-impact, peer-reviewed medical journals.

Presentations at Scientific Conferences

Key findings will be presented at relevant national and international medical and scientific conferences, facilitating direct engagement with the scientific community and fostering scholarly discussion.

Data Transparency and Accessibility

Consistent with ethical guidelines, anonymized trial data will be made available upon reasonable request, allowing for further analysis by other researchers, thus promoting transparency and replicability.

Community Engagement and Patient Education

Summarized results in layman's terms will be made available to participants and the broader patient community. This ensures that those directly affected by the research have access to the findings.

Commitments and Signatures

Commitments from the project leader and department for adherence to regulations and project completion.

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