Research protocol

Assessing the precision of a device intended to assist surgeons during temporomandibular joint arthroscopy by optimizing the placement of the working cannula in relation to the arthroscope

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Protocol Synopsis:

Arthroscopy of the temporomandibular joint (TMJ) is a well-established surgical procedure for treating various TMJ disorders. The technique involves inserting an arthroscope into the joint cavity, followed by the insertion of a working cannula through which the surgeon's instruments pass. Successfully inserting the working cannula requires advanced surgical skills and extensive clinical experience, as mastering this technique has a steep learning curve. Incorrect placement of the working cannula can cause iatrogenic damage to the TMJ and adjacent structures, including the facial nerve and ear. It is generally accepted that if the working cannula cannot be inserted successfully after 2-3 attempts, the procedure should be halted.

In our department, we developed a guide device we called Locator-Positioner (LOPO) to aid surgeons in precisely inserting the working cannula into the joint cavity. This device makes the insertion process predictable and straightforward. The aim is to ensure the smooth and accurate placement of the working cannula, allowing it to be immediately visible through the arthroscope, and eliminating unnecessary movements that could harm the joint tissue and nearby structures.

The prototype of the LOPO was tested on anatomical models and proved to be highly accurate. In all insertion attempts, the working cannula – guided by the device – was placed precisely and became immediately visible by the arthroscope.

This pilot study aims to recruit up to 10 patients to test the LOPO device in a clinical setting.

Background:

Temporomandibular joint (TMJ) problems can present a wide range of symptoms, including difficulty opening the mouth, inability to close the mouth, noises during jaw movement, temporary mechanical locking episodes, and pain in the TMJ and masticatory muscles. These issues can adversely affect daily activities like eating, speaking, and yawning, thereby reducing patients' quality of life.

Arthroscopy of the TMJ was first introduced in 1976 and has since become a recognized therapeutic method for treating TMJ issues. The procedure begins with the insertion of the arthroscope into the posterior part of the joint cavity. Subsequently, a "working cannula" is placed in the anterior part of the joint cavity. The surgeon's instruments are then inserted through this working cannula during the procedure.

Similar to arthroscopy performed on other joints like the knee and shoulder, a tube is connected to the arthroscope during the procedure to flow a flushing fluid (isotonic saline or similar fluids) into the joint cavity, maintaining constant pressure within the joint space. The saline infusion is automatically triggered when the pressure drops. In TMJ surgeries, a fluid pressure of around 40 PSI is used. This lavage system ensures continuous hydro-distension (inflation with water) of the joint cavity, enabling clear vision and facilitating the surgeon's work. If the fluid pressure inside the joint drops, the joint capsule collapses onto the intra-articular structures, obstructing the view through the lens of the arthroscope.

As previously mentioned, the initial stage of the operation involves inserting the arthroscope into the rear part of the TMJ. This step is relatively straightforward because the proximity of the joint to the ear provides a visible landmark for the surgeon. The anatomical landmarks constituting the ear, eye, and cheekbone aid this approach. Conversely, inserting the working cannula into the front part of the joint is more challenging due to significant anatomical variation among individuals and lack of easy landmarks to rely on. Therefore, facial skin landmarks cannot reliably guide this insertion and the triangulation technique was described as an alternative. This technique involves creating a spatial relationship between three points: the arthroscope, the target area within the joint, and the working cannula's entry point. The term "triangulation" refers to the coordination between the visual axis of the arthroscope and the working cannula's path. The surgeon uses the arthroscope to guide the working cannula to the correct position within the joint. Successful insertion of the working cannula hinges on three conditions: 1) ensuring it avoids damaging nearby vital structures both during and after insertion, 2) positioning it directly within the arthroscope's field of view in the front part of the joint for immediate visibility, and 3) achieving successful insertion on the first attempt, with a maximum allowance for additional 1 or 2 attempts if necessary.

Successful arthroscopy relies on accurately placing the working cannula ideally on the first attempt, and at most on the second or third attempts. Multiple attempts to insert the cannula can lead to puncturing of the joint capsule, causing leakage of the irrigation fluid (saline) and swelling of the face. This edema not only discomforts the patient but also compromises sufficient inflation (hydro-distension) of the joint cavity, thereby complicating the surgical procedure. Scientific literature generally advises halting the procedure after few unsuccessful attempts to insert the working cannula into the correct position.

Furthermore, repeated attempts increase surgical risks, including potential damage to facial nerve branches, blood vessels in the face, and the auditory canal, as well as heightened post-operative pain.

Bibliography:

- The main investigator's experience in TMJ arthroscopy:
    - Abboud W, Yarom N, Yahalom R, Joachim M, Reiter S, Koren O, Elishoov H. Comparison of Two Physiotherapy Programs for Rehabilitation after Temporomandibular Joint Arthroscopy. International Journal of Oral and Maxillofacial Surgery. 2018; 47: 755-761.
    - Abboud W, Hirschorn A, Yahalom R. The Role of Arthroscopy in the Diagnosis and Treatment of Temporomandibular Joint Disorders. The Journal of the Israel Dental Association. 2016; Vol. 33, No. 3.
    - Abboud W, Nadel S, Yarom N, Yahalom R. Arthroscopy of the Temporomandibular Joint for the Treatment of Chronic Closed Lock. Israel Medical Association Journal. 2016; 18: 397-400.

    - Abboud W, Givol N, Yahalom R. Arthroscopic Lysis and Lavage for Internal Derangement of the Temporomandibular Joint. Annals of Oral and Maxillofacial Surgery. 2015; 5:158-162.
    - Abboud W, Yahalom R, Givol N. Treatment of Intermittent Locking of the Jaw in Wilkes Stage II Derangement by Arthroscopic Lysis and Lavage. Journal of Oral and Maxillofacial Surgery. 2015; 73:1466-1472.
    - Abboud W. Novel Guide Device for Temporomandibular Joint Arthroscopy. International Journal of Oral and Maxillofacial Surgery. 2020; 49: 1217-1219.
- Surgical techniques for introducing the arthroscope and working cannula into the TMJ:
    - Monje Gil F, Hernandez Vila C, Moyano Cuevas JL, Lyra M, Pagador JB, Sanchez Margallo FM. Validation of a simulator for temporomandibular joint arthroscopy. Int J Oral Maxillofac Surg. 2016 Jul;45(7):836-41. doi: 10.1016/j.ijom.2016.01.010. Epub 2016 Feb 3. PubMed ID: 26850940
    - Verde L, Munoz-Guerra MF, Rodriguez-Campo FJ, Escorial V. Temporomandibular Joint: Approach to the Intermediate Space by Triangulation With Transillumination Reference. J Oral Maxillofac Surg. 2023 Jun;81(6):684-688. doi: 10.1016/j.joms.2023.02.008. Epub 2023 Mar 6. PubMed ID: 36893793
    - Peserico-DalFarra P, Gagliardi-Lugo AF. Training simulation for oral and maxillofacial surgeons based on the techniques of arthroscopy in the temporomandibular joint. Br J Oral Maxillofac Surg. 2019 Nov;57(9):929-931. doi: 10.1016/j.bjoms.2019.08.003. Epub 2019 Aug 22. PubMed ID: 31445774
    - Slavin AB. Comments on "single-cannula technique for operative arthroscopy using holmium:YAG laser". J Oral Maxillofac Surg. 2012 May;70(5):1014; author reply 1014. doi: 10.1016/j.joms.2012.02.011. No abstract available. PubMed ID: 22538020
    - McCain JP, Hossameldin RH. Advanced arthroscopy of the temporomandibular joint. Atlas Oral Maxillofac Surg Clin North Am. 2011 Sep;19(2):145-67. doi: 10.1016/j.cxom.2011.06.001. No abstract available. PubMed ID: 21878249

Reasoning behind conducting the experiment:

We developed a guide device referred to as Locator-Positioner (LOPO) designed to assist surgeons in accurately and precisely inserting the working cannula into the TMJ. Following the initial insertion of the arthroscope into the joint, which is a relatively straightforward procedure, the LOPO is attached to the outer part of the arthroscope (remaining external to the skin of the face). The LOPO then provides guidance to the surgeon on where and how on the skin to insert the working cannula to precisely align with the end of the arthroscope found within the joint.

Importantly, the LOPO does not enter the patient's body at any point during the operation and should not touch or rest on the skin of the patient's face. It securely attaches to the outer part of the arthroscope, indicating the insertion point and guiding the cannula at the correct angle. Following successful testing on anatomical models, where it demonstrated exceptional accuracy, we aim to evaluate its clinical effectiveness in up to 10 patients to draw conclusive findings.

Description of the device:

The guide device consists of two arms of equal length, each being a double parallelogram. A connector holds both arms and permits movement by changing the angle between them (Fig 1). One arm is intended to hold the arthroscope while the other arm holds the working cannula. Owing to the double parallelogram design, after attaching the instruments (arthroscope and working cannula) their ends have to meet, and this is true in the whole range of motion of the guide device, so that while changing the angle between the two arms of the LOPO, the meeting point between the tip of the arthroscope and the tip of the working cannula keep their intimate relation (Fig 1 and 2).

During surgery, after the arthroscope is introduced into the joint cavity, the guide device is mounted on the base of the arthroscope via one arm. The other arm receives the working cannula, and owing to the double parallelogram design, it directs it to the ideal puncture site and insertion vector and depth into the joint cavity, where it has to meet the tip of the arthroscope (Fig 3). This results in immediate visualization of the working cannula by the arthroscope and maintains optimal spatial positions between the two portals. The connector between the two arms of the device enables changing the angle between them while maintaining the relative position of the tip of the cannula to the tip of the arthroscope.

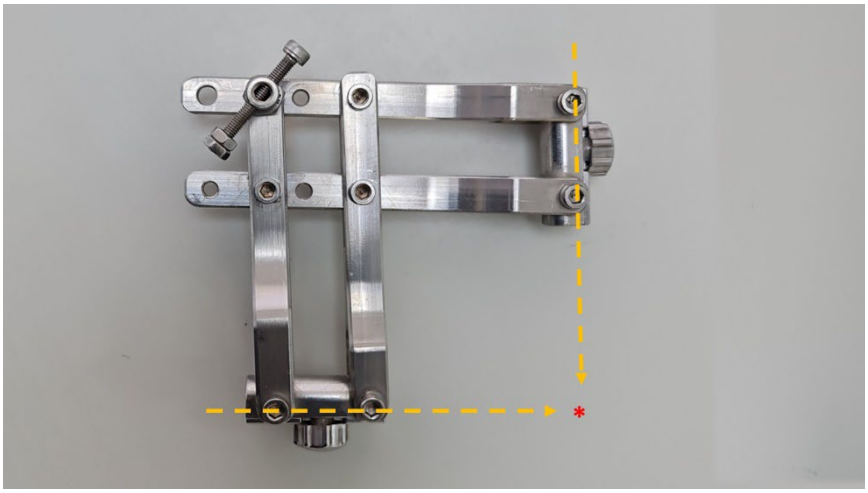
The connector can also be locked thus fixating the angle between the two arms.

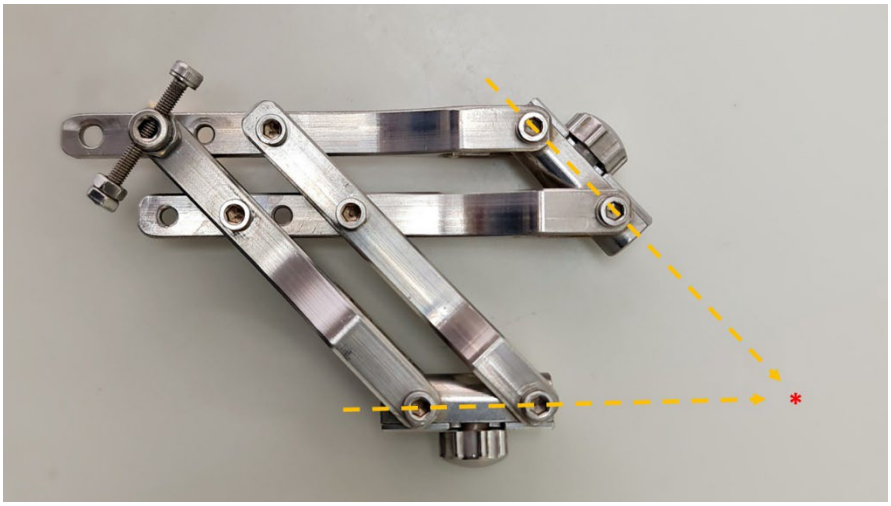
Throughout the range of motion, the working cannula will always reaches the tip of the arthroscope. The LOPO does not enter the body because only the ends of the arthroscope and the working cannula are inside the body while the device is externally positioned and held by the surgeon.

The LOPO is designed to address the challenges of determining the insertion point on the skin for the working cannula, the correct angle for insertion into the joint cavity, and the proper penetration depth. In addition, it maintains the optimal spatial orientation between the arthroscope and cannula throughout surgery. Its main goal is to ensure that the working cannula is inserted accurately and becoming immediately visible via the arthroscope on the first attempt, and them maintaining the correct spatial relationship between the arthroscope and the working cannula throughout surgery.

Figure 1: the yellow lines represent the path of insertion of the arthroscope and working cannula. The red asterisk represents the meeting point of both. Through all range of motion

of the LOPO device (changing the angle between its' two arms), the ends of both instruments maintain their relations to one another.





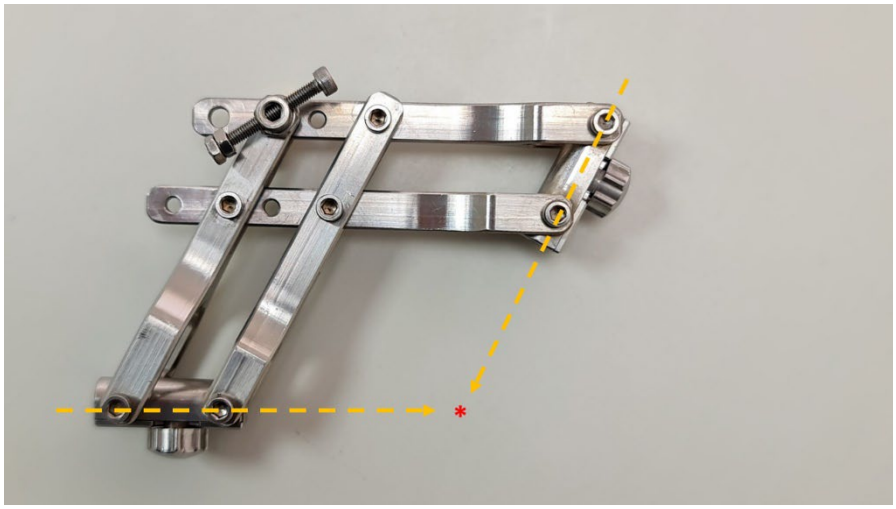


Figure 2: the LOPO with the arthroscope and working cannula mounted on it.

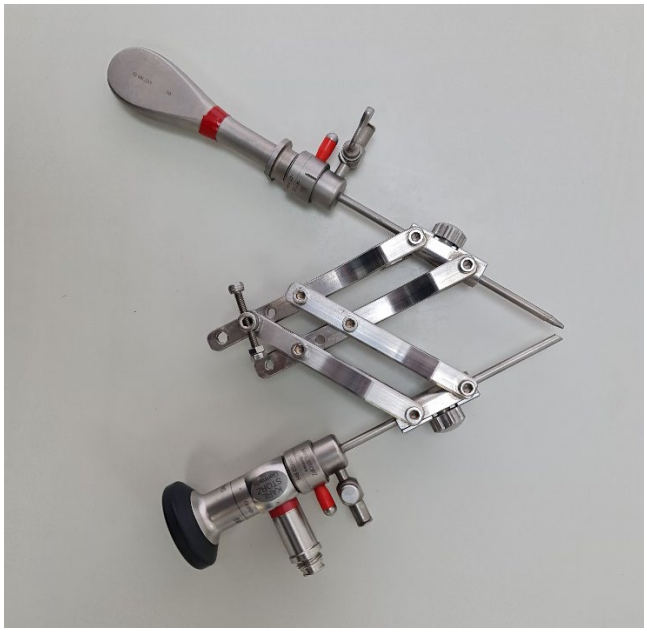
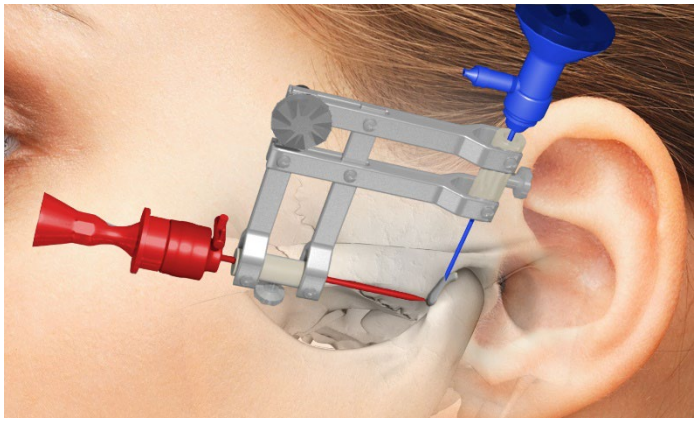


Figure 3: illustration demonstrating the relations between the TMJ, arthroscope (blue), working cannula (red), and LOPO guide device (grey).



Technical details:

- Manufacturer: Pollak Steinberg Ltd.
- Model: TMJ-DEVICE-100
- Materials: Stainless steel 303, resistant to autoclave sterilization, multi-use
- The device can be attached and detached from the arthroscope and working cannula at any stage of the operation.

Summary of existing preclinical knowledge regarding the device:

The device was tested on anatomical models between August 2017 and February 2018, and it was found to meet the objectives exceptionally well. Multiple doctors in the department,

including interns with no prior arthroscopy experience, conducted several attempts on the models. In all cases, the working cannula was guided by the LOPO device and inserted with great precision to the end of the arthroscope, where it was immediately visible by it. The experiments were conducted in the operating room at Sheba Medical Center using the same set of standard arthroscopic tools.
In this pilot experiment, we will use the same standard set of arthroscopic tools that is regularly used at Sheba Medical Center. It is important to note that the LOPO has been designed according to the dimensions of the arthroscopic tool set available at Sheba.

Goals and Endpoints
This pilot study aims to recruit up to 10 patients to test the functionality of the LOPO in clinical conditions. The outcome of the study are:
1. The number of attempts required by the surgeon to correctly place the instruments in relation to each other within the joint cavity. No more than three attempts will be made in a single operation.
2. The time elapsed from the insertion of the working cannula until it is clearly visible by the arthroscope (measured in seconds).
3. The number of cases in which the surgeon fails to correctly insert the working cannula, meaning that after three attempts, the cannula is still not properly placed in the joint and not visible by the arthroscope.
4. The improvement of mouth opening after arthroscopy.
Our hypothesis is that the LOPO will shorten the duration of surgery by helping the surgeon insert the working cannula more quickly and easily. It should allow accurate insertion of the working cannula on the first attempt, reducing scuffing of tissues, fluid leakage, swelling, and surgical risks. Using the device does not increase the known risks of surgery.

The total number of participants and how they will be recruited:
The experiment will be carried out in the Department of Oral and Maxillofacial Surgery at Sheba Tel Hashomer Medical Center.
Up to 10 participants are needed to demonstrate that the LOPO device effectively positions the working cannula regardless of anatomical variation among individuals.
Candidates for the procedure are patients diagnosed in our department with closed lock, Wilkes stage 3, based on anamnesis, clinical examination, and imaging, for whom TMJ arthroscopy is the accepted treatment. These patients will receive the standard preoperative explanation about the procedure, including its course, expected results, potential risks, the necessity for post-operative physical therapy, and the requirement to avoid hard foods for a month after arthroscopy. Additionally, they will be informed about our intention to use the LOPO device and asked for their consent. Patients who consent to using the LOPO during surgery will receive a letter for their family doctor detailing the procedure and the device.

The patients will be treated using the standard arthroscopic tool set available at Sheba, along with the LOPO device we developed.
Participants will not receive any financial compensation or other benefits. It will be explained that their participation contributes to scientific and medical advancements. Successful performance of the device in real patients will significantly advance the field of TMJ arthroscopy.

Criteria for inclusion, exclusion, and exclusion from the experiment:

- Inclusion criteria:
    - Diagnosis of lock-jaw (Closed lock of the TMJ, Wilkes stages 3) based on anamnesis, clinical, and imaging.
    - Have not undergone surgical intervention in the TMJ in the past.
    - Adult patients (over the age of 18), not pregnant, and of sound judgment.
- Exclusion criteria:
    - Patients who are minors, pregnant, or lacking judgment.
    - Previous surgical intervention of the TMJ.
- Criteria for exclusion from the experiment:
    - Patients who will not complete post-operative follow-ups as planned.

Details of the research program and clinical follow-up:

- Patients that are referred for TMJ arthroscopy at our department will be asked if they agree to participate in the LOPO experiment. Patients will receive standard treatment in terms of hospitalization and examinations.
- Follow-up reviews will take place in our clinic.
- The initial follow-up period is six months.
- Patients may be invited for further follow-up visits as a routine practice in our department.

Schedule and Flow Chart of the Experiment:

- Recruitment of 10 Participants: we estimate that we can recruit 10 participants within a year. Notably, our department performs approximately 70 arthroscopic surgeries annually (70 patients per year).
- Data Summary: the data summarization process is expected to take less than 6 months.
- Publication: the results of the experiment will be published in an international scientific journal.

Participant Privacy and Confidentiality of Collected Information:

- Patients diagnosed with lock-jaw who need TMJ arthroscopy will be offered the option to use the LOPO device during their surgery. They will receive an informational letter explaining the procedure and the use of the device.
- Interested patients should consult with their family doctor, presenting the explanatory letter for further advice. Regardless of their decision to participate in the trial, all patients will receive standard care in our department, including admission, hospitalization, discharge, and periodic follow-ups after surgery.
- A database containing the names of the patients (up to 10) and the experiment results (studied indices) will be maintained in an Excel sheet on a secure computer within the department.

Conditions for Halting the Medical Experiment:

- If the LOPO device does not perform as expected, based on its performance with anatomical models, its use will be halted immediately, and no further patients will be enrolled in the experiment.
- The use of the LOPO will also be immediately discontinued in the event of any known or unforeseen complications arising from the operation

Reporting Unusual Events:

- The researcher will promptly inform the Chair of the Helsinki Committee of Sheba Medical Center about any significant unusual events observed during the arthroscopy and the use of the LOPO device within one week. Additionally, any relevant new information related to these events will be communicated to the Helsinki Committee through subsequent follow-up reports.

Method of Analyzing and Processing Results:

- The data from the ten patients using the device will be compared with data from patients undergoing TMJ arthroscopy without using the LOPO device. The following parameters will be evaluated:
    - Time elapsed from insertion of the working cannula until it is clearly visible through the arthroscope.
    - Number of attempts made by the surgeon to correctly position the instruments within the joint cavity (limited to three attempts per surgery, following standard practice).
    - Number of cases where the surgeon failed to correctly insert the working cannula, despite three attempts, as observed through the arthroscope.

- Measurements of maximal mouth opening of the patients undergoing the procedure, before as compared to after arthroscopy.

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