

Novel Guide Device for Temporomandibular Joint Arthroscopy (Tel Hashomer) code: THM 2015043

Novel Guide Device for Temporomandibular Joint Arthroscopy

Dr. Waseem A. Abboud, Sheba Medical Center

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Abstract

The temporomandibular joint is the joint that connects your jaw to your skull. When this joint is injured or damaged, it can lead to a localized pain disorder called temporomandibular joint (TMJ) syndrome.

Causes of temporomandibular joint (TMJ) syndrome include injury to the <u>teeth</u> or jaw, misalignment of the teeth or jaw, <u>teeth grinding</u>, poor posture, <u>stress</u>, <u>arthritis</u>, and gum chewing.

Disorders of the temporomandibular joint (TMJ, the jaw joint) manifest with various degrees of pain, limitation of mouth opening, interference in mouth closing, joint noises, and difficulty performing daily activities such chewing and yawning. Arthroscopy of the TMJ is a minimally invasive surgical intervention aimed at diagnosis and treatment of many joint disorders. It was first described in 1974, and since then has gained great popularity and become an acceptable therapeutic modality for various joint pathologies. Arthroscopy of the TMJ is broadly divided into two types; Diagnostic & Lavage Arthroscopy, and Operative Arthroscopy. Mild and early joint disorders may benefit from Diagnostic and Lavage Arthroscopy, while advanced joint pathologies will require either Operative Arthroscopy or open surgery of the joint.

Diagnostic and Lavage Arthroscopy is a relatively simple surgical procedure, and is routinely performed in many departments of Oral and Maxillofacial surgery. It involves the introduction of an arthroscope and a needle into the joint cavity. Saline is flushed through the arthroscope into the joint cavity and escapes through the needle. Simple and repeatable surface landmarks on the face aid the surgeon while inserting the arthroscope and the needle. Operative Arthroscopy, on the other hand, is a more complicated surgical procedure that requires higher degrees of expertise. After inserting the arthroscope, a cannula is also inserted into the joint cavity, aiming to function as a portal through which surgical instruments are introduced. This working cannula should be visualized by the arthroscope upon entering the joint cavity and throughout the surgical procedure. The skin puncture of the working cannula lies at a distance ranging from 2 to 4 cm from the arthroscope, and the action of inserting it into the joint space is surgically challenging as there are no easy and repeatable surface landmarks aiding in identifying the ideal puncture site, the angulation vector, or the insertion depth.



The Need

For the working cannula to be readily visualized and functional, skin puncture site, angulation of insertion, and insertion depth must be accurate and precise. If the working cannula is improperly inserted so it becomes difficult or impossible to direct an instrument through it to be visualized by the arthroscope, it becomes necessary to remove and re-insert it, leading to greater trauma and increased surgical risks and morbidity to the patient, as well as excess leakage of saline into surrounding tissues, preventing the joint cavity from being effectively distended and dramatically shortening operation time. Generally, two or three succeeding failures to properly insert the working cannula lead to suspension of the TMJ arthroscopy.

An additional challenge is maintaining the relative orientation of the tips of the arthroscope and the working cannula in three-dimension throughout the operative procedure, so the arthroscope can have continuous and uninterrupted line of sight to the surgical instruments introduced through the working cannula. In the operation theater, much effort is made to ensure that the relative orientation is unchanged; often the main surgeon has to hold both the arthroscope and the working cannula steady with both hands, while an assistant surgeon is tasked with introducing and manipulating the surgical tools.

The Technology

We have design a guide device that enables accurate insertion of the working cannula relative to the arthroscope, and maintains this relation throughout the procedure. The device in essence is a rod that has the same length and is parallel to the arthroscope, and mounted on it. After proper insertion of the working cannula by the guide and visualizing it by the arthroscope, the working cannula is locked in this fixed orientation relative to the arthroscope, allowing the surgeon to hold the arthroscope and working cannula with one hand using the guide device, and performing the surgical instrumentation with the other hand. The guide device has multiple joints and can be configured to various positions, all of which maintain the relative orientation between the arthroscope and the working cannula.

Advantages

Facilitating proper insertion of the working cannula into the joint cavity with one single attempt, and fixating the relation of the arthroscope and the working cannula steady throughout the procedure achieves the following goals:

Minimal violation of joint capsule improved hydro-distention of joint cavity improved vision and easier surgical instrumentation.

Minimal puncturing of skin decreased surgical risks associated with facial nerve injury, ear injury, and scarring of skin.

Minimal sweeping in joint cavity looking for the working cannula prevents scuffing of joint lining and iatrogenic damage to intra-articular tissues.

More simple, predictable, and easy operation enables the novice arthroscopist of performing Operative Arthroscopy.

More simple, predictable, and easy operation allows patients with various TMJ disorders to undergo minimally invasive arthroscopic intervention instead of open surgery of the joint.

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Yeda Research & Development Co. Ltd, P.O Box 95, Rehovot 7610002, Israel, Telephone: 972-8-9470617, Fax: 972-8-9470739



Fixating the arthroscope and working cannula in 3D the main surgeon can perform the surgical instrumentation instead of merely stabilizing the relation between the cannula and arthroscope throughout the operation.

Decreased morbidity for the patient in terms of pain, swelling, and hospitalization time.

Less operative time in the surgical theatre.

More predictable procedure.

The Market

The prevalence of TMJD is between 5% and 12% of the general population. Unusual for chronic pain conditions, the prevalence rates of TMJ disorders are higher among younger persons. TMJ disorders are at least twice as prevalent in women as men, of the general population. Approximately 5% of them will benefit from a surgical intervention.

The global craniomaxillofacial devices market was valued at USD 1,018.9 million in 2014 and is expected to grow at a CAGR of 6.7% over the forecast period. Increasing demand for minimally invasive surgeries is expected to drive demand during the forecast period.

Craniomaxillofacial devices market products include temporomandibular joint (TMJ) replacement, CMF distraction, cranial flap fixation, plate and screw fixation, bone graft substitutes, and thoracic fixation. Plate and screw fixation dominated the product segment with over 70% revenue share in 2014. This dominance is attributed to its wide usage in various surgical procedures such as deformity correction, Orthognathic surgery, tumor removal and pediatric surgeries. Temporomandibular joint (TMJ) replacement devices is expected to be one of the fastest growing segment over the forecast period due to increasing incidences of road accidents and sport injuries leading to cranial and facial fractures.

Tel Hashomer Medical Research, Infrastructure and Services

Tel: +972-3-5305998 Fax: +972-3-5305944 sylvie.luria@sheba.health.gov.il