

3D PRINTED COMPUTER GUIDED Vs CONVENTIONAL ARTHROCENTESIS IN THE MANAGEMENT OF TEMPOROMANDIBULAR JOINT INTERNAL DERANGEMENT

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ABSTRACT

INTRODUCTION: Temporomandibular disorder (TMD) is a general term that comprises a wide range of clinical problems involving orofacial muscles and joints with the help of patient specific guide we do arthrocentesis as a non-invasive treatment.

OBJECTIVE: The aim of this study was to evaluate the efficiency of 3D printed patient customized guides in conjugation with arthrocentesis in treatment of internal derangement of temporomandibular joint followed by PRP injection.

MATERIALS AND METHODS: A total of 20 patients were divided into two groups. In group I patients with internal derangement were managed with patient specific guide to perform arthrocentesis in comparison with the conventional technique that was used in group II. The pain intensity, maximum inter-incisal opening and range of jaw movement in lateral and protrusion movement, joint noise, number of needle relocation and duration of the procedure were assessed.

RESULTS: No needle relocation was required in the study group in contrast to the control group, with a statistically significant difference ($p=0.030$). The difference in the operation duration between both groups was statistically significant ($p=0.003$), with the study group requiring shorter time to conduct the procedure. A statistically insignificant difference was reported regarding the pain intensity, disturbance in jaw function, maximum inter-incisal opening, range in jaw movement, and joint noise.

CONCLUSION: It may be concluded from the results of this study that a computer guided patient specific arthrocentesis guide based on a preoperative CT-scan is a reliable and reproducible method for accurate and more robust conduction of the arthrocentesis procedure with minimal modifications and low complication rate.

KEYWORDS: 3D printing, Patient specific, Customized, arthrocentesis, platelet-rich plasma

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INTRODUCTION

The temporal bone, mandible, numerous associated muscles, a specialized fibrous tissue, an articular disc, and several ligaments comprise the temporomandibular joint (TMJ) (1, 2). TMJ is a synovial diarthroidal joint with four articulating surfaces and an articular disc that separates the joint into upper and lower compartments and is lubricated by synovial fluid. The lower compartment allows for hinge or rotatory motion, while the upper compartment allows for sliding or translator motion. The articular disc is a non-vascularized, non-innervated dense fibrous tissue that is strong enough to withstand pressure (3, 4).

Temporomandibular disorder (TMD) is a broad term that refers to a variety of clinical issues involving orofacial muscles and joints. It is characterized by a wide range of signs and symptoms, the most prominent of which is pain in the masticatory muscles and temporomandibular joint (TMJ) region. There may also be joint sounds and crepitus, irregular or limited mandibular

function, headache, otalgia, and mandibular locking (5).

Temporomandibular joint syndrome has several possible physical causes such as: muscle tension; this overuse in turn is often associated with psychological stress and clenching or grinding of the teeth (bruxism), also a direct blow to the jaw or the side of the head can result in bone fracture, soft tissue bruising, or dislocation of the temporomandibular joint itself. Arthritis and rheumatoid arthritis can be the first cause of TMJ syndrome (6).

Moreover, Internal derangement; is a condition in which the cartilage disk lies anterior to its proper position (6), In most cases of internal derangement, the disc moves in and out of its correct location making a clicking or popping noise as it moves. In a few cases, the disc is permanently out of position, and the patient's jaw motion range is limited. In many cases, the source of pain in the TMJ area is temporary and goes away on its own (7).

Without medications or physical treatments, approximately 80% of TMD patients will improve in six months. If the symptoms are related to muscle tension, patients may be given Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) (8). Patients who have difficulty with bruxism are usually treated with splints. A plastic splint called a night guard is given to the patient to place over the teeth before going to bed. Surgery of TMJ is ordinarily performed only to treat TMJ caused by birth deformities or certain forms of internal derangement caused by misshapen discs (9).

Arthrocentesis is a simplified alternative to the most common arthroscopic surgical procedure. It is minimally invasive and may be performed in the office with comparable success and diminished morbidity (10). It is commonly defined as a lavage of the joint and is traditionally accomplished without viewing the joint space. It may be completed under local anesthesia as an office procedure, with or without the addition of sedation. The primary purpose is to clear the joint of tissue debris, blood and pain mediators that are believed to be by products of intra-articular inflammation (11).

PRP is used as a treatment option for specialties including orthopedics, sports medicine, dentistry, otolaryngology, neurosurgery, ophthalmology, urology, wound healing, cosmetic, cardiothoracic and maxillofacial surgery. Platelets Rich Plasma (PRP) is a natural concentrate of blood growth factors and is thought to deliver activated platelets when injected thus may reduce inflammation, provide pain relief, improve function and stimulate possible cartilage regeneration at the site of injury (12).

Several possible complications are considered during arthrocentesis if there is wrong entry such as bleeding, instrument breakage, laceration of external auditory canal, injury to facial nerve, paralysis of facial nerve and alternation of visual accuracy (13).

Recently, surgeons have begun to adopt Computer-Aided Design and Computer Aided Manufacturing (CAD/CAM) software initially engineered for applications in neurosurgery and radiation therapy to assist in the planning and implementation of complex Cranio-Maxillofacial (CMF) procedures (14, 15). CAD/CAM software enables the clinician to import 2D computed tomography (CT) data in DICOM format (Digital Imaging and Communications in Medicine) to a computer work station and generate an accurate 3D representation of the skeletal and soft tissue anatomy(16, 17), The data set can then be used to additively manufacture a 3D printed model (15).

Henceforth; the purpose of this study is to evaluate the efficiency of 3D printed patient customized guides to direct the passage of inlet and outlet needles into superior joint spaces of

temporomandibular joint (TMJ) and conventional arthrocentesis in treatment of internal derangement of temporomandibular joint.

PATIENTS AND METHODS

Study design

This study was a Randomized Control Clinical Trial with a 1:1 allocation ratio. It was performed up and reported according to the CONSORT guidelines. Sample size was calculated based on assuming 95% confidence level and 80% study power to be 10 patients per group, with respect to loss to follow up cases. Participants in this study were selected from those admitted to the Outpatient Clinic of Alexandria University Teaching Hospital and operated in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. enrolled patients were randomly allocated into two groups group I (Arthrocentesis using patient specific guide) and group II conventional Arthrocentesis procedure

Inclusion criteria

Patients suffering from pain located in the affected TMJ, especially during opening, joint noises, limited mouth opening (less than 35 mm), impeded lateral movement toward the unaffected side, deviation toward the affected side in opening and protrusion movements were included in the study. All patients had proved refractory to conservative treatment and were instructed to wear acrylic splint four weeks before any procedures.

Materials

For arthrocentesis we use standard sterile normal saline, 18-gauge needle, Elastic bandage and for PRP preparation we need Centrifugal machine (Mini Laboratory Centrifuge Lab Medical Practice 4000 rpm.). Stereo-lithography 3D Printer with its post-curing unit was utilized to print accurate 3D-models using Ultraviolet (UV)-curable photopolymer resin (Sony SCS 8100. Sony, Taipei 114, Taiwan)

Methods

Preoperative assessment

The diagnosis of cases was performed by a questionnaire and clinical examination. All patients were informed preoperatively about the procedure. All details were recorded in a questionnaire by the examiner including the personal data, past history, previous treatments and chief complain. Pain level was determined by patient's self-assessment using a Numerical Pain Scale (NPS I) (18) from zero to 10. The level of disturbance in jaw function was assessed using another Numerical Pain Scale (NPS II) (18) where "0" indicates excellent ability to talk, chew and yawn while "10" refers to inability of doing such functions. Observation of deviation on mouth opening was also monitored.

Clinical Examination (18)

A caliper will be used to measure the following ranges of pain free joint movements:

Maximal inter-incisal opening, jaw movement toward the contra-lateral unaffected side, and protrusive movement. The muscle of mastication and the joint were palpated, and joint auscultation was performed to note the presence of any joint sounds.

Dental evaluation was performed to eliminate any odontogenic sources of pain, detect any missing molars, and to find evidence of bruxism, nail biting, deep bite, or presence of occlusal abnormalities.

Radiographic Examination (19)

Panoramic radiograph was taken to exclude dental cause of pain. Magnetic Resonance Image (MRI) was used preoperatively to confirm the clinical diagnosis and determine the stage of internal derangement. A Computed Tomography Scan (CT) was obtained in order to prepare the patient specific guide. The scan was obtained with patient in maximum mouth opening with a bite-block utilized to maintain this maximum opening.

Occlusal adjustments were performed and a mandibular hard, clear, silicon, full vacuum splint 2 ml in thickness was constructed for all patients. Each patient was instructed to wear the occlusal splint during day time and at night during sleep.

Surgical guide stent design and fabrication (20, 21)

A 3D printed guide was designed for each patient of study group to lead the inlet and outlet needles in superior joint space of T.M.J. Planning was accomplished using the Digital Imaging and Communication in medicine (DICOM) data from the preoperative CT. Segmentation and planning software package (Materialise innovation suite (Mimics and 3Matic): Materialise, leuven, Belgium, mimics@materialise.be) with surface based rendering for surgical planning and simulation was utilized to produce a mask for the entire area of interest. This will be followed by the creation of two different three-dimensional models; a skull bone mask and a soft tissue profile mask (Figure 1). The optimal positions, angulations, and penetration depth for the inlet and outlet needles were determined and virtually checked based on the created bone and soft tissue masks. This will be followed by the creation of two virtual hollowed tubes, with internal diameter identical to that of a 20-gauge needles (1.4 mm). The cantho-tragal line was drawn on the soft tissue mask, where reference points were selected to mark as points of entry for needle through the skin. Point A was marked 10 mm anterior and 2 mm beneath the tragus point and on the cantho-tragal line, while Point B was marked 20 mm anterior and 10 mm beneath the tragus point and on the cantho-tragal line.

The created tubes acted as a sleeves drawn at the suggested pathways to allow for guided passage of the needles intraoperatively. The main bulk of the patient specific guide was formed fitting

on the soft tissue mask. To achieve stability and to ensure replication of the virtual position intraoperatively, the body of the guide was anchored in the tragus undercut. The designed guide was exported as an (Standard Tessellation Language) STL format file to a specialized software (NETFAB, Autodesk Inc; McInnis Parkway San Rafael, CA) on a 3D printing machine (Sony SCS 8100). The printed guide was chemically sterilized in glutaraldehyde (Cidex®: Advanced sterilization products (ASP): Gubelstrasse, Switzerland) solution for 24 hours prior to surgery.

Operative phase

Surgical field was painted with povidone-iodine (Betadine: Povidone-iodine, 7.5% (0.75% available iodine), Purdue Products L.P.) and draped. External auditory canal was protected using a cotton pledge. Few drops of local anesthesia were injected subcutaneously to block auriculo-temporal nerve.

Platelets Rich Plasma (PRP) Preparation

PRP was prepared by collecting 10ml blood from the ulnar vein of the patient in a glass centrifuge tube with sodium citrate (3.2%) as an anticoagulant under sterile aseptic condition. The collected blood was mixed with the citrate using rotational movements; an even number of tubes was placed in a centrifuge machine.

Centrifugation parameters was set at 3,200 rpm for 12 minutes. After separation of the erythrocytes, the platelet poor plasma and PRP layered directly above the erythrocytes, the platelet rich plasma was aspirated with caution into a separate syringe.

For Activation of PRP, after the soft spin the upper layer (buffy coat) was transferred in a new sterile tube (without anticoagulant). To obtain a platelet concentrate, centrifuge the tube at a higher speed (a strong spin) and for longer time. The lower 1/3 is platelet-rich plasma, while the upper 2/3 is platelet-poor plasma (PPP).

For patients in group I (study group):

The body part of the patient specific guide was applied and adapted around the ear and beneath the tragus. Two needles were inserted in each sleeve and the arthrocentesis procedure was conducted in the usual manner. The anterior needle acted as an outlet for the outflow for the solution which was collected in a kidney dish. Both needles were inserted to a depth of about 1.5 cm (Figure 2)

For patients in group II (control group):

The standard Two points were marked over the articular fossa and eminence and along the cantho-tragus line. and the arthrocentesis procedure was conducted in the usual manner. Both utilized needles were inserted to a depth of about 1.5 cm (Figure 3).

In both groups, the PRP was injected into the upper joint space; the point of injection was located along the cantho-tragal line, 10 mm from

the middle of the tragus and 2 mm below the line. After injection, the patient was asked to open and close the mouth several times for a minute to ensure equal distribution of PRP before it converts into gel. Early postoperative care

All patients were instructed to apply ice pack extra-orally starting immediately postoperatively for 12 hours. The patients were also instructed to follow oral soft diet for 3 days and gradually resume to normal diet after 3 days. Paracetamol 500mg tablets every eight hours for 5 days and Amoxicillin + clavulanate 1 gm twice daily for 5 days were prescribed.

Clinical follow-up phase

Follow up was done at 1 week, 3 months and 6 month intervals. Postoperative evaluation included the following parameters: Pain Intensity Level, Disturbance in Jaw Function Level. Maximum Inter-Incisal Opening, Range of Jaw Movement to the Contra-Lateral Side, Range of Protrusive Movements, joint noise at Opening and Closing, and Muscle Tenderness on Palpation.

Evaluation of Computer Guided Arthrocentesis Accuracy

Needle Relocation

The need to relocate the needle after first puncture of both needles was used to compare between the efficacy of the computer guided arthrocentesis guide and the conventional free hand arthrocentesis.

Arthrocentesis Duration

The duration of the arthrocentesis operation was used to compare between the efficacy of the computer guided arthrocentesis guide and the conventional free hand arthrocentesis. The time was recorded from the start of the first needle puncture till the end of the lavage procedure, excluding the period required to administrate the local anesthetic nerve block.

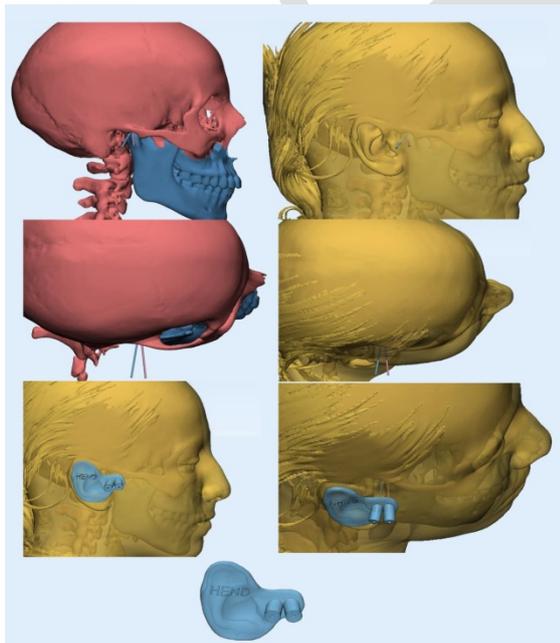


Figure (1): Three-dimensional view of the virtual design of the guide adapted to the soft tissue component of the computed tomography scan.

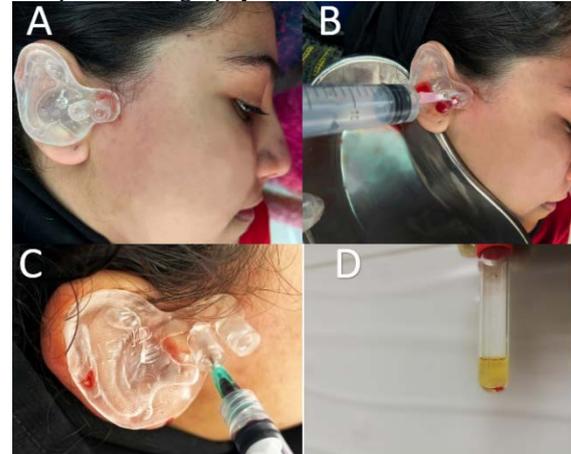


Figure (2): Arthrocentesis procedure for the Study group. A) patient specific guide in site. B) lavage of the joint through the guide. C) injection of PRP D) activated PrP.

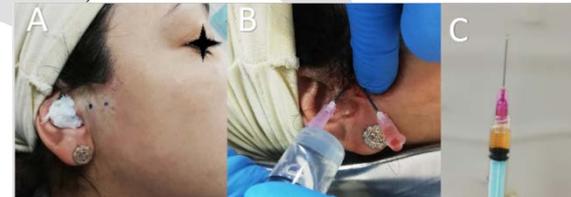


Figure (3): Arthrocentesis procedure for the Control group. A) Landmark for insertion the needle for arthrocentesis and PRP injection. B) Inlet and outlet of needle. C) activated PrP.

RESULTS

Clinical Parameters Evaluation

Intergroup comparison regarding the clinical parameters' reported a statistically insignificant difference across the follow-up period.

Regarding the clinical parameters, all of the enrolled patients in this study (n=20) reported a statistically significant decrease in pain intensity levels across the follow up period ($p < 0.001$). Across the follow up period, all of the enrolled patients in this study (n=20) reported a statistically significant decrease in pain intensity levels and decrease in the level of functional disturbance ($p < 0.001$) (Table 1).

Regarding the Maximum inter-incisal distance, Range of pain free jaw movement toward the contra-lateral unaffected side, and protrusive movement all of the enrolled patients in this study showed a statistically significant increase in the pain free maximum inter-incisal mouth opening ($p < 0.001$). By the end of the follow up period twelve patients have recovered from joint noises with a statistically significant improvement in the observed jaw noises during function ($P < 0.001$) (Figure 4).

Evaluation of Computer Guided Arthrocentesis Accuracy Needle Relocation

In the study group, no need for needle relocation was reported for both the first and the second needle. However, in the control group, five patients did not require needle re-puncture for the first needle and three patients in the second needle. Regarding the first needle location, the comparison between the computer guided group and the free hand group was statistically significant (p=0.003) (Table 2).

Arthrocentesis Duration

In the study group, the mean recorded duration of the arthrocentesis operation was 8.40 ± 1.07 min. However, in the control group, the mean recorded duration to execute the arthrocentesis procedure was 10.30 ± 1.16 min. The difference between the computer guided arthrocentesis and the free hand technique regarding the duration needed to execute the procedure was statistically significant (p=0.001) (Table 3).

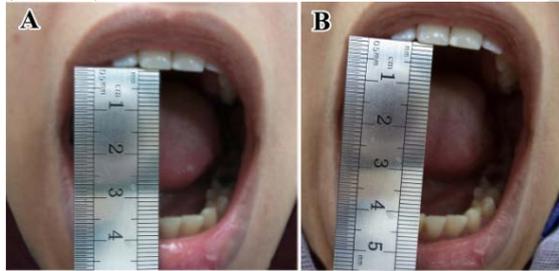


Figure (4): Comparative photographic picture between the preoperative (A), and postoperative (B) Maximum interincisal in the study group.

Table (1): Comparison between the different studied periods regarding the clinical parameters (n = 20).

Clinical Paramters (n=20)/ Mean ± SD.	Preop	1 W	3 M	6 M	p
Disturbance in function	6.60 ± 1.70	3.60 ± 1.57	0.85 ± 1.14	0.15 ± 0.37	<0.001*
Pain intensity	7.35 ± 1.23	4.70 ± 1.26	1.35 ± 1.23	0.05 ± 0.22	<0.001*
Maximal interincisal opening	31.48 ± 6.43	36.56 ± 4.17	40.03 ± 3.13	41.73 ± 2.74	<0.001*
Contra lateral	6.91 ± 0.78	8.55 ± 0.92	9.93 ± 1.18	10.80 ± 1.12	<0.001*
Protrusive movement	5.86 ± 0.57	7.44 ± 1.06	8.52 ± 1.27	9.54 ± 1.78	<0.001*

SD: Standard deviation

F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using Post Hoc Test (adjusted Bonferroni)

p: p value for comparing between the different studied periods

*: Statistically significant at p ≤ 0.05

Table (2): Comparison between the two studied groups according to number of relocation of first and second needle.

Number of Needle Relocation	Group A (n = 10)		Group B (n = 10)		Test of Sig.	p
	No.	%	No.	%		
First needle					$\chi^2=5.785^*$	MC p=0.030*
0	10	100.0	5	50.0		
1	0	0.0	2	20.0		
2	0	0.0	1	10.0		
3	0	0.0	2	20.0		
Second needle					$\chi^2=9.938^*$	MC p=0.003*
0	10	100.0	3	30.0		
1	0	0.0	2	20.0		
2	0	0.0	4	40.0		
3	0	0.0	1	10.0		

SD: Standard deviation

χ^2 : Chi square test

MC: Monte Carlo

p: p value for comparing between the two studied groups

*: Statistically significant at p ≤ 0.05

Group A: Treated by using computer guided arthrocentesis

Group B: Treated by using free hand conventional arthrocentesis

Table (3): Comparison between the two studied groups according to the duration of the operation.

Duration of the operation / min	Group A (n = 10)		Group B (n = 10)		Test of Sig.	p
	No.	%	No.	%		
Mean ± SD.	8.40 ± 1.07		10.30 ± 1.16		t=3.800*	0.001*
Min. – Max.	7.0 – 10.0		9.0 – 12.0			

SD: Standard deviation t: Student t-test

p: p value for comparing between the two studied groups

*: Statistically significant at $p \leq 0.05$

Group A: Treated by using computer guided arthrocentesis

Group B: Treated by using free hand conventional arthrocentesis

DISCUSSION

Arthrocentesis is a simplified lavage of the joint which is traditionally accomplished without viewing the joint space and primary purpose to clear the joint of tissue debris, blood and pain mediators that are believed to be by products of intra-articular inflammation (11).

Arthrocentesis procedure is usually followed by a TMJ capsule injection. Platelets Rich Plasm provides a promising inexpensive option that stimulate the repair or replacement of the joint damaged tissues. PRP is a natural concentrate of blood growth factors and is thought to deliver activated platelets when injected thus may reduce inflammation, provide pain relief, improve function and stimulate possible cartilage regeneration at the site of injury (12).

A contemporary modification to the well-established arthrocentesis procedure is the implementation of Computer-Aided Design and Computer Aided Manufacturing (CAD/CAM) to virtually plan and generate a surgical guide for accurate replication of the superior joint cavity anatomy (15, 22).

Henceforth; the primary purpose of this study was to compare the accuracy of the patient specific 3D-printed TMJ arthrocentesis guides versus the conventional free hand method. Furthermore; the secondary purpose of this study was to evaluation of the efficacy of post-arthrocentesis PRP joint injection in the management of internal derangement of temporomandibular joint.

Regarding the subjective patient symptomatic parameters, all of the enrolled patients in this study showed a statistically significant improvement across the follow up period. All of the enrolled patients showed alleviated symptoms at the end of the follow up period when recorded with VAS I, pain intensity level, and VAS II disturbance in Jaw Function Level. The results of this study falls in line with the reports where PRP was used as intra-articular injection (12, 23, 24).

Objective appraisal regarding the success of the arthrocentesis procedure and the intra-articular joint PRP injection was evaluated by determining the maximum pain free mouth opening, jaw movement to the contra-lateral side, range of protrusive movements, joint noise, and muscle tenderness on palpation. In all of the studied objective variables, all of the enrolled patients in

this study reported a statistically significant improvement across the follow up period.

Kaneyama et al described the success criteria for arthrocentesis procedure as mild or total disappearance of arthralgia, mouth opening measurement of ≥ 38 mm, and lateral and protrusive movements of ≥ 6 mm (25). Kaneyama et al reported a 88% 3-month short-term success rate (25). Al-Belasy and Dolwick (2007) conducted a systematic review which includes 19 arthrocentesis studies. They reported an overall success rate of 83.2% (26).

The results of this study demonstrates the considerable surgical accuracy of the patient specific arthrocentesis guide when compared to the free hand technique. This is clearly apparent in the statistically significant difference between the guided study group and the conventional free-hand group regarding the number of both needles relocation. Using the patient specific arthrocentesis guide, the operator of this study did report no need for needle relocation for either the first or the second needle. Similar outcome was reported by Mahmoud et al (2020), where they documented a precise piercing of the superior joint cavity in 50 of 52 patients. They further visualized the location of the needle in the superior joint cavity using an arthroscope (22).

The report by Mahmoud et al (2020) was the first to introduce the fabrication of a surgical guide to transfer the virtual arthrocentesis procedure intraoperatively. This was made possible with the use of Computed Tomography (CT) scan DICOM data and the utilization of Virtual Surgical Planning principles in order to replicate the virtual scenario into the clinical situation. Despite their use of CBCT scan, Matsumoto et al (2011) relied on a plastic semicircular protractor to replicate the CBCT image-measured angles, and a rubber stopper to replicate the determined depth of insertion (18).

CAD/CAM technology provided several opportunities in the dental and medical field in order to achieve a more predictable outcome with minimal complication rate. In the study group, none of the patient reported postoperative complication, hematoma formation or facial nerve affection from the procedure. This outcome is in accordance with the outcome reached by Mahmoud et al., (2020) (22) The outcome of this study verified the accuracy of the virtual arthrocentesis procedure, where in all of the fabricated guides no need to re-puncture the patient were reported, no modification in the fabricated sleeves was needed and the procedure was performed in the least possible time with great patient satisfaction when correlated with the improvement in clinical symptoms.

The free-hand arthrocentesis procedure is well-established in the literature with the use of slandered references points that are commonly

believed to be invariable and slandered for application in majority of the patients (26). However due to the great anatomical variability, Sembronio et al (2021) reported the utilization of careful joint palpation is more reliable than the commonly utilized reference points (27). The variability in the procedure is affected by the degree of training and the operator expertise in performing the arthrocentesis procedure (27).

Recording the duration of the arthrocentesis operation, from the start of the first needle puncture till the end of the lavage procedure, was one of the examined parameters in this study. The mean recorded duration in the study group was 8.40 ± 1.07 min, with a statistically significant difference between the guided and the conventional groups ($p=0.001$).

This study is limited by the added financial burden on the patient required to create the patient specific guide. Despite yielding an improved outcome regarding the need to needle relocate and the duration of the procedure, added cost burdens the patient in the form of unjustified computed tomography scan, designing software, and the 3D printed guide cost. The utilization of CT-scan is solely for the purpose of guide fabrication and does not add diagnostic value for internal derangement patients, along with the added radiation exposure. Although, guided arthrocentesis yielded a decrease in the operative time, the designing process of the guide is time consuming preoperatively. The utilization of the MRI scan DICOM data to perform a virtual arthrocentesis procedure may be a point of future investigation and an amendment to the current technique.

It may be concluded from the collective results of this study that a computer guided patient specific arthrocentesis guide based on a preoperative CT-scan is a reliable and reproducible method for accurate and more robust conduction of the arthrocentesis procedure with minimal modifications and low complication rate. The implantation of this technique may be a guiding path for the less experienced surgeons to gain confidence in the procedure and by the implementation of this technique the learning curve will flatten. Furthermore; the utilization of PRP as inter-articular injection following the arthrocentesis procedure yielded an outstanding clinical performance with high success rate in alleviating subjective symptoms and improving of the objective signs for patients burdened with internal derangement.

CONFLICT OF INTEREST

The authors deny any conflicts of interest.

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