Author’s response to reviews

Title: Template-based temporomandibular joint puncturing and access in minimally invasive TMJ surgery (MITMJS) – a technical note and first clinical results

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Note: a version using highlighting and different styles was uploaded as "complementary material"

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Template-based temporomandibular joint access in minimally invasive TMJ surgery (MITMJS) – a technical note and first clinical results

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Head & Face Medicine

Please include a point-by-point response within the 'Response to Reviewers' box in the submission system and highlight (with 'tracked changes'/coloured/underlines/highlighted text) all changes made when revising the manuscript. Please ensure you describe additional experiments that were carried out and include a detailed rebuttal of any criticisms or requested revisions that you disagreed with. Please also ensure that your revised manuscript conforms to the journal style, which can be found in the Submission Guidelines on the journal homepage.
The authors thank the reviewers for their concise important remarks. All will be dealt with, changes in the manuscript due to Reviewer 1 will be marked light blue, due to Reviewer 2 yellow. Regarding Reviewer 3 some changes were made. As these had been already marked in other colours, no additional markings were used.

Reviewer reports:

Reviewer #1: First of all I would like to thank for the opportunity to review the manuscript “Template-based temporomandibular joint access in minimally invasive TMJ surgery (MITMJS) – a technical note and first clinical results

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The topic of the manuscript is of sufficient interest as minimal invasive surgery of the TMJ will be the future of surgical treatment of TMD related to morphologic alterations of the TMJ.

Originality

The technical note is sufficiently novel, important and also interesting. A sufficient present literature search in this field showed no other current study with the same scope.

Structure

All in all, the article is clearly laid out. All key elements are present. The title exactly describes the content of the article.

Introduction

The introduction describes accurately, what the authors tried to achieve. The introduction is relatively long, but the topic is complex and the information given in the introduction summarizes the relevant clinical experience up to now rather well.
Results

This section is short but fitting the requirement of a technical note. The describes results support the claims of the discussion part rather good.

In the discussion I miss one fact that should be added: the use of CBCT/CT with radiation closed to the orbit in relatively young patients (on the image is a young patient). This is always a little bit critical as MRI is the imaging modality of choice in TMJ-problems. The authors should discuss if this template related procedure can also be applicated based on MRI?

The authors thank Reviewer 1 for the remarks concerning radiation exposure. The patient shown, was 53 ys old. The reviewer is right in insisting that the least amount of radiation exposure should be used especially if orbit scans had been acquired. In Fig. 2 the full midface CBCT was included. The case shown in figure 2 was indeed treated before the one shown in figure 1 were the orbits were not included and in all subsequent cases the orbits were not included, too. Here the optical scan served as a radiation-free mode to show the required surface data. As the scans have to be registered, acquisition of the TMJ only by way of CBCT can be difficult, thus some area below the orbits is helpful. The reviewer is right that MRI data could be used either, avoiding radiation exposure.

Therefore the manuscript was changed as follows:

M&M, page 3:

..It is used for TMJ diagnosis and provides volumetric images of the anatomic structures of the patients´ craniofacial skeleton. Alternatively CT or MRI data could be used. If CT or CBCT was to be used, the orbits should be not included due to unnecessary radiation exposure. The…

Further in the result- and discussion section I saw some language problems that should be reviewed by a native speaker prior to publication.

Some changes were made, hopefully being the ones seen by the reviewer.

Tables

The imaging material and graphs illustrate the required information from the text. The imaging quality of the displayed example could be better.
Figs 1-3 are screenshots taken from the planning software and alas cannot be improved.

References

The reference list is up to date and covers a long time frame.

The reviewer suggests that the paper should be accepted in the overworked version after minor revision.

Reviewer #2: With "Template-based temporomandibular joint access in minimally invasive TMJ surgery (MITMJS) - a technical note and first clinical results" the authors describe a new technique transferring CAD-CAM-techniques to TMJ minimally invasive surgery (or more exactly TMJ puncturing). The article is written in apparently good English and is written both fluently and concisely and well structured.

The reviewer, however, had already got the opportunity to serve as a reviewer for a first version of the article when submitted to a different journal. The authors by now slightly modified their submission and duly integrated/addressed some of the major criticisms according to the first review into the revised version of the article.

Basically, the article thus has been significantly improved compared to the previous version mentioned above. Nevertheless some points still need to be considered as critical and/or need to be clarified or stressed more profoundly in the present version.

Accordingly, the article is now correctly declared as a technical note regarding the removable guide, which is basically a clever design. Nevertheless, the article still does not offer any advanced clinical data, e.g. comparing the new technique to the conventional puncturing techniques. Declaring the paper a technical note, however, now helps to heal this drawback.

In the following comments, the Reviewer alludes to the previous major criticisms and comments on the solutions provided by the authors according to the present submission:
Regarding 1st major point of previous criticism:

As criticised before, the relevant clinical problem in MITMJS is less the puncturing technique itself (as primarily addressed in the paper), but first of all navigation/orientation during triangulation and most of all manipulation (!) within the joint, i.e. to visualize all important structures without losing the correct position of the trocar/endoscope during intraoperative manipulation (!) (please note: the trocar should be re-inserted as few times as possible).

This is absolutely true and reinsertion of the trocar during the procedure is not suggested in the manuscript (only repositioning of the guide to pivot the trocar if required)

The puncturing aid will not help to solve this problem, which is much more addressed by intraoperative changes of mandibular position (which cannot be reasonably simulated preoperatively, even less so in most clinical conditions requiring arthroscopy and MITMJS)

So the article still (!) needs to get a different and better fitting title: e.g "A surgical template to facilitate TMJ puncturing technique etc", as already proposed in the first review.

The title was therefore changed to:

Template-based temporomandibular joint puncturing and access in minimally invasive TMJ surgery (MITMJS) – a technical note and first clinical results

As already pointed out there, advanced MITMJS (i.e. intraoperative surgery via double puncturing technique) is a much more challenging procedure than the mere puncturing alone and requires a full three-dimensional manoeuvre within the joint cavity, which again requires continuous intraoperative changes of mandibular position (cf. above) usually performed by the assisting surgeon/nurse.

So the article really should focus on being a puncturing aid and frankly stress the limitations of the procedure (so it may be a help rather for novices and for selected cases for experienced surgeons)

The authors agree with reviewer 2, therefore this argument was stressed in the discussion, second paragraph:
Regarding TMJ procedures, this novel approach allows the exact planning of the endoscope and manipulation instruments position which might make TMJ procedures easier and safer for novices in the field…

2nd point of previous major criticism:

The reviewer already remarked in the first version of the now revised paper that the puncturing technique is usually recommend to be done in different jaw positions during first and second puncture (mouth open in protrusion/laterotrusion for the first puncture for the superior-posterior joint space, second anterior puncture in mouth closed position, however both of them are performed under some form of intraoperative distraction).

As already pointed out before - except for arthrocentesis in needle or small canula technique - this is usually done and often even only possible under muscle relaxation viz. under general anesthesia, so a sufficient simulation via preoperative splint during CBCT/CT is often not yet (!) possible at the time of the pre-op CBCT scan.

The authors now mention the possibility to simulate these different jaw position preoperatively via splints to answer to this criticism of the first review.

This sound basically logical at first glance, but will not withstand a critical analysis: if done so as described now in the paper, this would mean:

a) at least twice CBCT/CT with then double irradiation dose (highly questionable for a primarily puncturing aid, then)

Again, the authors agree with reviewer 2, and therefore included the following statement in the discussion chapter which should have been made before:

…surgery. In these cases MRI scans should be used to prevent undue radiation exposure. Furthermore…

b) does not warrant a successful atraumatic puncture, as the second puncture should deliberately be performed under direct visualization of the entry site via the first Portal scope, at least according to state of the art!

So the described technique requires two (basically preventable!) CBCTS/CTs, and may allow for putting the first and second scope in, but still mostly not in the recommended optimum position
(that's why the second puncture should be done under direct visualization and not according to any CT planning, cf. recent respective publications, no improvement of puncturing e.g. by ultrasound etc.)

At any rate, the authors should stress these still presenting as major (!) drawbacks in the discussion. As long as the technique is declared as a puncturing aid for novices (and not for advanced MITMJS) this would be OK, then

As reviewer 2 is surely an expert in the field of TMJ surgery, his criticism that a template would not be helpful for him is fully understandable (which could be true regarding many template suggestions ranging from implantology to orthognathics for the particular experts).

As pointed out and stated in the manuscript 2 x, the authors see the advantages for novices and less for experts.

3rd point of major previous criticism:

According to the previous review, for a more advanced practitioner in arthroscopy the device appears to be of less help/unnecessary, but may be useful in selected cases, however at high costs for planning. The authors now basically addressed the cost problem (still very high planning time), but so far did not address the irradiation hygiene aspects.

The underlying problem is, that experience (which can and should be trained in a cadaver lab first!) will allow to avoid irradiation, so the indication for CBCT/CT in different mandibular positions is clearly problematic under both irradiation hygiene and immanent cost aspects

This at least needs to be self-critically discussed!

Regarding costs 3 aspects have to be discussed:

1. The costs of template generation/resin material: this has been addressed in the text (discussion) and ranges between 5 – 6 €/template which the authors consider quite reasonable.

2. time for planning. Here the authors stated, that experience lead to a marked reduction in planning time. In the discussion it was pointed out that using our software solution, a reduction from 3 hrs to 1 hr seems realistic. In case of a (probable) future software improvement, even a more marked time reduction should be achieved.
Thus the following text was added in the discussion:

…1 hour seems realistic using our software workflow. Furthermore, software improvements should allow additional time gain. As the template…

Judging from software development progress in other fields of CMF, this attitude is not unreasonable.

3. costs for data acquisition and radiation exposure. The authors agree with reviewer 2 that the acquisition of multiple CT/CBCT data sets for different jaw positions would lead to an undue X-rax exposure. Here MRI scans would be appropriate and MRI DICOM data could have been utilized instead of CBCT in our patients if they had been available.

Thus

…However, dental splints (e.g. to distract – protrude the mandible) could be inserted during scanning and repositioned at surgery. In these cases MRI scans should be used to prevent undue radiation exposure. Furthermore,…

was added in the discussion. Costs regarding data acquisition are 0 € (if an optical scanner is present) regarding optical scanning and the costs for CT/CBCT/MRI scanning. As this will vary from country to country no values are stated (in Germany 130.– 500.– € could be appropriate)

The following statement was added.

…gain. Finally the costs regarding data acquisition have to be considered, but as in our patients the data used for TMJ diagnostics could be used, no additional costs were necessary. As…

Recommendation to simplify the publication process:

To sum up, the guiding device needs to be declared (and critically discussed) as a basically/potentially helpful solution for beginners in the field (however affected with irradiation as a major drawback to be self-critically discussed).

Though puncturing itself is a minor or less relevant problem at least for more experienced surgeons, nevertheless this technique may be of interest even for more experienced surgeons in selected cases (e.g. after reconstructive or ablative surgery etc.), with a potential capacity to improve orientation, which then will justify the irradiation dose. So this should be (and then deserves to be) communicated as a technical note, then.

The authors are pleased that reviewer 2 sees at least some potential benefit of our workflow.
The following sentence was added in discussion:

…questionable. Although this technical note focuses on minimally invasive TMJ procedures, the workflow regarding dismountable puncturing or guiding templates may be used for further applications in TMJ, CMF, or neurosurgery.

Personal comment cf previous review: whether it is beneficial for learners, also remains to be evaluated via a prospective randomized controlled or a matched pair series (nevertheless highly problematic due to the irradiation doses, cf. above and cf. ethical vote).

Reviewer #3: It is an interesting Approach to make TMJ-Arthroscopy less misterious, as the device allows for a clearly defined Position when starting to push in the arthroscope into the Joint. The English needs checking as some of the Grammar is not correct.

Some mistakes were found and corrected in the text.