**A potential new oral mapping (OM) method in the clinical evaluation and documentation of oral submucous fibrosis**

* **A prospective clinical crossover study**

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**ABSTRACT:**

**Background:** Despite much research, there is a lack of a definite protocol or method for documenting oral submucous fibrosis (OSMF) site presentation. In this study we propose a new potential oral mapping (OM) method and evaluated its use in recording OSMF affected mucosal sites.

**Methods:** 50 OSMF patients were evaluated by 15 primary care dental practitioners using both, a conventional subjective recording method and a new OM method, to document the degree of involvement of affected oral mucosa with a crossover study design. Mann-Whitney test (Non-parametric test) was used to make comparison between groups to determine any significant differences between the two identification methods. Wilcoxon tests were used to evaluate any significant differences in the difficulty in identification of two methods.

**Results: There was** a low agreement between the two methods used to detect OSMF in affected mucosal surfaces (p-value <0.0001). More lesions were identified using the proposed OM method and less discrepancy was found among dental practitioners. A difference in difficulty of OSMF documentation was found (Wilcoxon z = 3.615, p-value <0.001), with the proposed OM method found to be easier.

**Conclusion:** The proposed OM method appears to be useful for documentation, can easily be adapted in clinical practice and effectively administered in clinical research. Additionally, it could be a useful tool to helping to maintain an OSMF database.

***Key Words*:** Oral Submucous fibrosis, oral mapping method, OSMF documentation, OSMF database

**INTRODUCTION:**

Oral submucous fibrosis (OSMF) is a debilitating condition of the oral mucosa causing progressive scarring.1 Over recent years, there has been growing interest in the concept of the classification and staging of OSMF.2,3 Although there are no current standardized systematic OSMF data documenting schemes or instruments, several classification schemes have been described in the literature.4-10 Existing schemes are essentially staging or OSMF grading systems rather than true data recording instruments.11 Therefore the way in which the OSMF patients are evaluated and classified needs to be revisited.

Recently, we proposed a systematic staging scheme for OSMF taking into account the potential changes in the whole oral cavity instead of the most prominent lesions (TFM staging).11 Based on the same rationale, the requirement for a comprehensive documenting system for OSMF cannot be underestimated. In this study we evaluated a new method which incorporates details of morphological features of all affected OSMF surfaces, such that the significance of mucosal lesions is meaningfully conveyed to colleagues involved in the care of these patients. We have also tested the validity of the method using a prospective clinical study on an OSMF affected population.

**METHODS:**

This study was approved by Institutional Research Ethical Committee (Human) Navodaya Medical College and Hospital (IEC/NMCH/NDC/12E/2018) and from the institutional review board of King Fahad Medical City, Riyadh. A total of 50 patients with clinically diagnosed OSMF were randomly recruited. Informed consent was obtained from all patients before inclusion in the study. 15 general dental practitioners agreed to take part in this study after being contacted by one of the authors.

Oral mapping (OM) method

A new documentation method (**Figure 1**) representing the different mucosal surfaces of the oral cavity and oesophagus (if this was visualised by an oesophagoscope) was used for this study. Each area on the recording method had an abbreviation indicating the nature of mucosal fibrosis and any structural changes signifying malignant transformation.

All 50 recruited patients were randomly categorized as Group ‘A’ and Group ‘B’ with 25 patients in each group. The investigating dental practitioners were also randomly grouped as Team ‘A’ (n=8) and Team ‘B’ (n=7). A crossover study was designed in order to avoid any possible learning effect from the two examination and recording experiences. The study was carried out in two stages, as follows.

***Stage 1:***

Group ‘A’ patients were assessed by Team ‘A’ using a conventional subjective method of OSMF documentation. Group ‘B’ patients were assessed by Team ‘B’ practitioners using the new OM proposed method. Each team clinically assessed and recorded the affected surfaces. After completing the documentation, Group ‘A’ patients were assessed by Team ‘B’ and vice versa.

***Stage 2:***

After 1 week, the recruited patients were seen again and the same practitioners reassessed and documented the affected surfaces but with group ‘A’ patients assessed by Team ‘A’ dental practitioners using the new OM method firstand Group ‘B’ assessed by Team ‘B’ using conventional subjective methods. After the first documentation, both the teams were switched as before.

All practitioners were asked to score the level of difficulty for using both documenting methods at the end of the stage 2, on a Likert scale graded from 1 to 5, in which 1=Very difficult, 2= Difficult, 3= Neutral, 4=Easy, 5=Very easy.

The clinical findings recorded using conventional subjective method were re-arranged systematically to the 18 categories of the new OM method (**Figure 1**) to ease data comparison.

Data analysis was performed using SPSS Statistics for Windows (version 25.0, IBM Corp, Armonk, USA). Exploratory data analysis revealed that some areas of the oral cavity produced non-normal distribution of the number of identifications. Given the small sample size and the lack of evidence of consistency of distribution, summary statistics are reported as median and range. Mann-Whitney test (Non-parametric test) was used to make comparison between groups to determine any significant differences between the two identification methods. Wilcoxon tests were used to evaluate any significant differences in the difficulty in identification of two methods. Data were analyzed using SPSS Statistics. A p-value of p<0.05 was taken as statistically significant.

**RESULTS:**

Data patterns for both methods were first inspected visually. No outliers were found for the data for OM method, although the spread was one of the largest for identifications with the OM method (**Table 1**). Total numbers of identification of affected surfaces were 2,276 with conventional subjective method and 4,380 with oral mapping method. **Table 1** shows that for all, except the buccal mucosal surface, more lesions were identified using the proposed OM method. There was a significant difference (Z -4, p<0.000; significant) between the two identification methods for all the surfaces accept for buccal surfaces (Z=-0.6, p=0.547; NS, Z=-0.265, p=1.12; NS). There was a significant difference found in the difficulty (Wilcoxon z = 3.615, p <0.001) of OSMF documentation with the OM method registered as easier (**Table 2**).

**DISCUSSION:**

In our previous study we noted the incidence of malignant transformation in non-predominant (non-chewing) mucosal surfaces. 13 An Indian study 14 reported 13% of squamous cell carcinoma and 23% of epithelial dysplasia in OSMF were due to chronic mucosal trauma. In such instances, missing the documentation of these non-predominant lesions could result in loss of follow up data for effective diagnosis and prevention of malignant transformation. Existing OSMF medical therapy that is based on clinical trials and studies does not currently utilize any reproducible way of recording and documenting potential changes in the mucosa such as blanching, fibrous bands (**Figure 2**) so that drug response can be checked effectively. Furthermore, conventional methods of subjective documentation have an inherent risk of losing or missing the data about oral lesions and consequently any effective changes. Therefore, documentation of the entire oral cavity in a systematic approach seems reasonable.11

The new OM proposed method assesses the entire oral cavity and produces a standardized clinical documentation protocol and map that can be readily reproduced each time. We found less detection of OSMF in affected surfaces with the conventional subjective method (2,276) while documentation using the OM method yielded more number of surface (4,380) identification.

It is important to note that the data patterns for both methods were first inspected visually and showed a less discrepancy and closure agreement among all practitioners in documentation using the OM instrument when compared to the conventional subjective method. Therefore, the new proposed OM method can be considered as a reliable and reproducible instrument by the limited number of practitioners who used it. Among the oral mucosal surfaces, we found that by the conventional subjective examination method, the most missed affected areas were the pterygomandibular raphe, tonsillar pillar, tongue, and floor of the mouth. One explanation for this could be due to overlooking all the affected surfaces and focusing on the predominant OSMF areas in a way akin to tunnel vision. In these instances, the OM method of documentation provides a systematic way to examine and record the oral mucosa and therefore helps to document the disease extent more accurately.

The Wilcoxon’s test results showed a significant difference (z = 3.615, p <0.001) in difficulty with the conventional subjective method found to be a more difficult procedure compared to proposed OM method. The ease may be due to the systematic charting of the all components of the oral cavity which successfully assist to examine and record the data.

Additionally, the suggested proposal accommodates other necessary details such as nature of the assessment (for example NA-Not assessed in cases of trismus), suspicious lesions (lesion in question Mq), and presence of any concomitant potential malignant disorders (Mp), if available -details of the malignant transformation (M1, M2). The proposed method allows the addition of personalized details including the fibrosis severity of each surface, presence of any physical irritation sources.

There is a lack of standardized protocols to monitor the treatment progress in the clinical practice and for clinical trials.11,15 OSMF databases are still not effectively standardised due to the absence of a standard global method which can be reproduced for examination and to assess potential changes.

Conventional existing subjective assessment methods tend to focus mainly on the prominent lesion and hence the treatment effect or disease progress or more subtle lesions can be overlooked.

The proposed new OM method provides a focused, systematic and comprehensive evaluation of the oral cavity, which can be reproduced every time enabling treatment progress of each affected surfaces to be effectively monitored.

**CONCLUSION**:

A new proposed method for documenting the entire representation of the oral cavity along with any extension into the oesophagus is proposed, which is easy to use and the data can be effectively reproduced. Its use in both, clinical practice and research, might help to better categorizes information, the recording of data, more effective communication, and therefore help guide treatment plans. Additionally, a reproducible recording method would be an effective tool to maintain OSMF databases and hence other potential malignant disorders of the oral cavity. Further research is required to evaluate the efficacy of this proposed method more fully.

**ETHICS STATEMENT**

Approval granted by the Institutional research ethical committee (Human) of Navodaya Dental College and Hospital, Raichur and IRB King Fahad Medical City Riyadh

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**Legends:**

**Figure 1**. Oral mapping (OM) method

**Figure 2**, A patient with oral submucous fibrosis affecting the right tonsillar fossa and pterygopalatine areas.

**Table 1**. Comparison of median (range and interquartile range) of documented affected surfaces with conventional and oral mapping (OM) method.

### **Table 2**. Wilcoxon test results

Table 1. Comparison of median (range and interquartile range) of documented affected surfaces with conventional and oral mapping (OM) method

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Upper lip | Lower lip | Oral  commisure | Buccal surface | Pterygomandibular raphe | Faucial pillar |
| Right side | Conventional method | 5 (12.7) | 13 (24.10) | 1 (12.4) | 38 (6.4) | 4 (11.5) | 3 (11.4) |
|  | OM method | 13 (3.3) | 27 (4.1) | 28 (6.2) | 39 (6.2) | 21 (4.1) | 17 (15.1) |
|  | z-value | -4.61 | -4.41 | -4.75 | -0.60 | -4.72 | -4.71 |
|  | p-value | <0.0001 | <0.0001 | <0.0001 | 0.547 | <0.0001 | <0.0001 |
|  | Inference | Significant | Significant | Significant | NS | Significant | Significant |
| Left side | Conventional method | 5 (12.7) | 13 (24.10) | 1 (12.3) | 18 (4.3) | 5 (16.6) | 3 (11.5) |
|  | OM method | 13 (3.3) | 27 (4.1) | 16 (5.5) | 19 (4.1) | 20 (1.1) | 8 (11.2) |
|  | z-value | -4.61 | -4.41 | -4.64 | -1.12 | -4.75 | -2.41 |
|  | p-value | <0.0001 | <0.0001 | <0.0001 | -0.265 | <0.0001 | 0.016 |
|  | Inference | Significant | Significant | Significant | NS | Significant | Significant |
| Tongue | Conventional method | 0.5 (2.1) |  |  |  |  |  |
|  | OM method | 2 (2.0) |  |  |  |  |  |
|  | z-value | -3.97 |  |  |  |  |  |
|  | p-value | <0.0001 |  |  |  |  |  |
|  | Inference | Significant |  |  |  |  |  |
| Hard palate | Conventional method | 5 (7.3) |  |  |  |  |  |
|  | OM method | 13 (3.2) |  |  |  |  |  |
|  | z-value | -4.70 |  |  |  |  |  |
|  | p-value | <0.0001 |  |  |  |  |  |
|  | Inference | Significant |  |  |  |  |  |
| Soft palate | Conventional method | 12 (7.4) |  |  |  |  |  |
|  | OM method | 17 (5.3) |  |  |  |  |  |
|  | z-value | -3.73 |  |  |  |  |  |
|  | p-value | <0.0001 |  |  |  |  |  |
|  | Inference | Significant |  |  |  |  |  |
| Uvula | Conventional method | 12 (7.4) |  |  |  |  |  |
|  | OM method | 17 (7.2) |  |  |  |  |  |
|  | z-value | -3.63 |  |  |  |  |  |
|  | p-value | <0.0001 |  |  |  |  |  |
|  | Inference | Significant |  |  |  |  |  |
| FOM(Floor of the mouth) | Conventional method | 1 (1.1) |  |  |  |  |  |
|  | OM method | 2 (1.0) |  |  |  |  |  |
|  | z-value | -4.46 |  |  |  |  |  |
|  | p-value | <0.0001 |  |  |  |  |  |
|  | Inference | Significant |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Right side | | | Left side | | |
| Surface | Standardised test statistic (z) | P-value |  | Standardised test statistic (z) | P-value |  |
| Upper lip | 3.411 | .001 | OM method counted many more and less variability | 3.411 | .001 | More counts in OM method, less variability |
| Lower lip | 3.409 | .001 | OM method counted many more and less variability | 3.409 | .001 | More counts in OM method, but less variability |
| Oral commisure | 3.424 | .001 | OM method counted many more and less variability | 3.306 | .001 | More counts in OM method, less variability |
| Buccal surface | 1.342 | .180 | Most counts the same both times | 1.633 | .102 | Most counts the same both times |
| Pterygomandibular raphe | 3.425 | .001 | OM method counted many more and less variability | 3.412 | .001 | OM method counted many more and less variability |
| Faucial pillars | 3.412 | .001 | OM method counted many more, but same variability | 2.809 | .005 | More counts in OM method, but not as big a difference as with other surfaces |
| Tongue | 3.017 | .003 | More incidences identified in OM method but numbers very low compared to other surfaces | | | |
| Hard palate | 3.413 | .001 | More incidences identified in OM method but less variability | | | |
| Soft palate | 3.167 | .002 | Values similar between weeks, but the numbers identified by individual doctors were slightly more in OM method | | | |
| Uvula | 3.074 | .002 | Values similar between weeks, but the numbers identified by individual doctors were slightly more in OM method | | | |
| Floor of mouth | 3.416 | .001 | More counts in OM method, but incidences very low throughout only 0-2 lesions identified using either method | | | |