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# **Generic Quality of Life versus Disease specific Quality of Life measurement following mandibular third molar removal: A patient centred evaluation**

## **Abstract**

**PURPOSE:** To evaluate the responsiveness and patient perceptions of a generic quality of life (QoL) tool following surgical removal of mandibular third molar teeth (M3M).

**PATIENTS AND METHODS:** 40 consecutive patients who met NICE guidelines for M3M removal were invited to rank items from the generic EQ5D3L and the disease specific OHIP-14 QoL tools, based on the perceived material significance of the item to the patient. The items were then assigned a numerical value dependent upon their rank and an overall score was calculated for each item. 50 consecutive patients were then invited to complete a paper based EQ5D3L QoL questionnaire, daily, for 7 days following M3M removal, returning the questionnaire in a prepaid postal envelope. Inclusion criteria were; American Association of Anaesthesiologists (ASA) Class I or II, aged 18 to 25, non-smoker, requiring surgical M3M extraction as defined by the NICE guidelines, and the procedure undertaken as an ambulatory day case procedure under general anaesthesia. All patients were treated by the same surgeon in the day surgery unit of a large district general hospital.

**RESULTS:** Most of the generic quality of life items ranked more highly than disease specific ones in terms of importance to the patients sampled. When used, the generic EQ5D3L questionnaire demonstrated a fall in QoL initially after M3M removal before improving for all participants over the subsequent 7 post-operative days. The responses to questions about “overall QoL”, “pain/discomfort” and “anxiety/depression” in the EQ5D5L tool were strongly correlated.

**CONCLUSIONS:** The EQ5D3L is a responsive tool to assess fluctuations in QoL in the early postoperative period following removal of the M3M. EQ5D3L also describes items which are perceived to be more important to patients than the disease specific OHIP-14 QoL questionnaire, and are therefore more relevant when counselling patients preoperatively. Further development of QoL and patient reported outcome measure (PROM) tools when measuring early outcomes following M3M removal, should incorporate generic items to remain relevant for patient counselling.

**Keywords:** Third molar extraction; quality of life; patient reported outcome measures

## **INTRODUCTION**

The value of patient reported outcome measures (PROMs) is increasingly recognised in quality improvement, service evaluation, research and audit (1,2). In addition to traditional surgical outcome measures, patient perception is increasingly influencing health care provision, and informed consent (3,4). PROMs also allow us to more accurately inform our patients before surgery; especially relating to choice of technique, advice about return to work and activities of daily living.

Quality of life (QoL), specifically health related QoL, is a sub-type of PROMs. It is defined as a patient's perception of the impact of their disease and/or treatment on their daily life, and their physical, psychological and social functioning or well-being (5). The emphasis of the multi-domain focus of the health-related QoL is important as it shows a fuller picture of a patient's health. QoL has been evaluated using generic QoL items where the same questionnaire has been used to measure QoL for a variety of different diseases or treatments, and disease-specific QoL tools which have been developed using items which are disease or anatomically specific.

M3M removal is the most commonly performed procedure by Oral and Maxillofacial Surgeons in the UK every year (6). The surgical procedure causes acute pain, swelling and limited mouth opening. Previous studies have measured disease specific QoL following oral surgical procedures, but with little evaluation of impact on generic QoL (7,8,9,10,11).

A systematic review in 2010 described a wide variety of validated questionnaires suitable for oral and maxillofacial surgery (1) but authors also cited a study concluding that the EQ5D3L was one of the most popular measures of health status as a whole in the evaluation of health and healthcare (12). Despite this finding, to our knowledge, the EQ5D3L has not been applied to oral surgery and there are no studies focusing on this simple and validated generic questionnaire post-operatively for M3M removal.

This study has evaluated the importance of the QoL items to patients by ranking the EQ5D3L items against items from a widely used disease specific QoL tool, the OHIP-14 questionnaire. To provide high quality evidence when counselling patients in the preoperative setting, we also measured the responsiveness of the EQ5D3L to describe changes in generic quality of life during the early convalescent period following M3M removal.

## **PATIENTS & METHODS**

After their initial assessment appointment for M3M removal, 40 consecutive patients were invited to rank randomly ordered items from a generic QoL (EQ5D3L) and the oral health specific QoL survey (OHIP-14). Patients were given 10 items to rank based on the perceived material significance of being informed about these sequelae, prior to M3M removal. Parts 1 & 2 (Figures 1 & 2) and 5 were taken from the OHIP-14. Ranked items were given a numerical score dependent on their rank, and the scores for each item were collated to give a mean overall score and rank.

In the second part of the study we recorded patients' QoL using the EQ5D3L Parts 1 & 2 daily, for up to 7 days following M3M removal (permission granted for use by EuroQol Group Foundation on this patient number on 16/01/2014). Inclusion criteria were; Class I or II by the American Society of Anesthesiologists (ASA), aged 18 to 25 and non-smoker. They were listed to have at least one horizontal, or mesio-angular impacted M3M to be removed and requiring a surgical approach defined by the raising of a muco-periosteal flap, bone removal and tooth sectioning. Exclusion criteria were; immunosuppressant diseases or drugs, chronic pain syndromes, and known illicit drug use. All patients were treated under a general anaesthetic by the same surgeon in the day surgery unit of a large district general hospital. As part of service evaluation 50 consecutive patients who met the inclusion criteria were invited to complete the EQ5D3L QoL survey. The questionnaire was printed onto seven sheets of A4 paper (one for each day), and patients were given a prepaid envelope to return the completed questionnaire.

For each questionnaire returned, the responses were collated in an anonymized database. The response to questions 1-5 was coded following published guidance (euroqol.org) as follows; no complaint - score of 1, some problems - score of 2, a lot of problems - score of 3. For each participant, five summary scores were created from the sum of all responses to a particular question across the week. Higher scores indicate greater impact on quality of life in a given domain. Question 6 of EQ5D3L (Figure 2) was calculated for a 20cm vertical VAS. This is a score of general well-being which was recorded each day post-operatively, and scored out of 100. The response to this question was recorded as a numerical value lying close to where the line drawn by the patient crossed the scale. The results for all respondents were collated and a mean score of responses to question 6 with confidence intervals was calculated for each day. The lower scores indicate greater impact on overall quality of life. For days 2-7, difference scores were derived as the change in VAS between the first post-operative VAS response (day one) and the VAS response at each day of follow up. A one-way repeated measure ANOVA test with 6 degrees of freedom was performed to

assess for difference in mean VAS between different days. A post-hoc test to detect difference in mean VAS between different days was implemented as a pairwise comparison of predictive margins. Linear regression of individual participant VAS scores against days since surgery was performed to assess for a trend of VAS over time, with participant ID included as an indicator variable. Pairwise correlation of total scores for questions 1-6 was performed with a Bonferroni correction for multiple testing. All statistical analysis was undertaken using the statistical package STATA (StataCorp 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP).

On discussion with our local institutional research and development review board they granted an exception from the requirement of ethical approval for the 2 part prospective study and accepted it as a service evaluation project.

## **RESULTS**

Results 1: Mean overall ranking of the EQ5D3L vs OHIP-14.

All 40 patients completed the ranking request for the 10 questions. EQ5D3L questions generally ranked as more important than the OHIP-14 for the consultation group. Results are shown in overall rank order in Table 1. A score of 10 was given to a rank of "1" and a score of 1 was given to a rank of "10". Scores were then collated and a mean taken to give an overall rank score. Rank of 1 is high. EQ5D3L items are highlighted in bold text.

Results 2: Generic QoL following M3M removal

Of 50 patients invited to take part, 36 returned surveys anonymously (a response rate of 72%). Of those who participated, the completion rate for the EQ5D3L QoL tool was 100%.

Results 2.1. The ANOVA test indicated a difference in VAS between different days of follow up ( $P < 0.0001$ , F ratio 345.25). The post hoc test indicated mean VAS improved on every day compared to the previous day ( $P$  all  $< 0.001$ , smallest T stat 4.43 for day 4 vs 3, largest T stat 11.48 for day 7 vs 6). The test for trend indicated improvement in mean VAS over time at a rate of approximately 6 units of the VAS scale per day ( $P < 0.001$ , T stat 41.42, beta coefficient 6.15, 95% CI for coefficient 5.85-6.44) The mean VAS for each day and the trend over time are shown in table 2 and Figure 3. The mean change from baseline score is shown for each day in table 2.

Results 2.2: Collated responses of questions 1 – 5 of EQ5D3L Part 1 (Figure 1).

In all 5 items, quality of life was impaired and then improved during the early post-operative period. By day seven, no individuals reported severe impairment for any item. The greatest impairment on every day was in the pain or discomfort item, and a large proportion of individuals continued to report some pain or discomfort even at day seven (see Figure 4.1, 4.2, 4.3, 4.4, 4.5).

Results 2.3: Correlation between elements of EQ5D3L.

Negative post-operative experience presented as a cluster of impairment in “overall QoL” (VAS), “pain/ discomfort” and “anxiety/ depression” (correlation coefficients within this cluster all  $>0.7$  or  $<-0.7$ ,  $p$  value for correlations within this cluster all  $< 1.5e-06$ ).

## **DISCUSSION**

Previous studies have looked at disease specific, oral health related QoL (7,8,9,13) most commonly using the Oral Health Impact Profile (OHIP-14) or the UK Oral Health related Quality of Life measure questionnaire (OHQOLUK-16). However, the results of this service evaluation suggest that the generic EQ5D3L QoL questionnaire is a responsive tool, which records items which are of more material significance to our patients when recording PROMs following M3M removal, in the convalescent period.

The EQ5D3L tool records generic QoL giving us data on return to work and estimated time to an improvement in pain and swelling. Using this tool we have demonstrated the impact on social, physical and psychological aspects of life for our patients in the convalescent period. We had a high return rate of 72% and 100% completion rate of the returned surveys in our study, with no errors, and no negative feedback from patients. This suggests that the EQ5D3L is easy to complete and was well received by our patients.

Previously studies have used disease specific QoL tools to measure the impact of pain, swelling (14) and mild pericoronitis (15,16) of the presence of an impacted M3M on QoL. However we are not aware of generic QoL studies which have measured the acute effects of surgery following M3M removal.

The data from this generic EQ5D3L has clearly illustrated the reduction in QoL in the immediate post-operative period, and the improvement over the subsequent 7 days. Measuring generic QoL in the convalescent period allows surgeons to provide patients with evidence based and materially significant data to compare the acute effects of different treatment modalities, and for consent and counselling in the preoperative consultation.

Authors favour the EQ5D3L over a disease specific questionnaire because questions about the convalescent period and also the average time to return to work are questions that we are most commonly asked as clinicians. We find it a simple, but effective, tool to gain significant information. We found, in particular, the use of the VAS element of the questionnaire (EQ5D3L Part 2) demonstrated information very clearly and daily changes were shown easily even at a glance.

The correlation between responses suggests that the domains measured by the EQ5D3L are not truly independent, but represent related facets of the social, physical and psychological process of convalescence. We speculate that addressing a patient's "pain/ discomfort" post-operatively might have a direct impact on "anxiety/ depression" and "overall QoL" and hence improve patient experience. It could also inform future areas of research to reduce pain and post-operative sequelae in M3M surgery e.g. analgesic management, surgical technique, or facial cooling studies.

This study also illustrates the emotional impact of surgery on patients following M3M removal. In the EQ5D3L, emotional aspects are measured by the "anxiety/ worry" item which was seen to strongly correlate with overall QoL. This suggests that the management of emotional outcomes is another area for research which might lead to improvements in PROMs.

QoL was not recorded on an EQ5D3L survey directly pre-operatively which is a limitation of this study. Whilst a comparison to pre-operative state would have been interesting for comparison, it does not diminish the findings of the study. Another drawback is that the study did not include objective measurement of pain or swelling for each patient, however since this study focused on patient perception, and experience, this aspect is not considered a significant weakness.

## **CONCLUSION**

The EQ5D3L is a simple, and responsive instrument for recording quality of life following surgical removal of M3M, which captures information that patients feel is significant.

The QoL gradually improved in the early post-operative period (7 days). Strong correlation was found between "overall QoL", "pain/ discomfort" and "anxiety/ depression", and the EQ5D3L tool was found easy to use by our patients.

As the importance of PROMs increases, measuring of QoL has become a priority in health service provision. The impact of surgery for M3M on generic QoL in the convalescent period has not been evaluated in the recent literature. This study provides useful data on patient experience immediately following surgery, allowing clinicians to counsel patients accurately prior to surgery, compare different treatment modalities, and informs further research to improve QoL during the convalescent period.

### **Conflict of Interest**

None

### **Ethics statement/confirmation of patient permission**

No patient permission has been obtained as there are no clinical details or identifying information has been recorded or disclosed. No ethical approval has been sought due to the project being a service evaluation not clinical research

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### **Table legends**

**Table 1:** overall rank of answers from EQ-5D-5L and OHIP-14

**Table 2:** Change in Mean visual analogue scale (VAS) over time

### **Figure legends**

**Figure 1:** EQ5D5L Survey Part 1

**Figure 2:** EQ5D5L Part 2 visual analogue scale (VAS)

**Figure 3:** Change in mean VAS over time

**Figure 4:** EQ5D5L Survey Part 1 collated responses

X axis - Time after surgery (days)

Y axis – proportion of participants

Key to answers:

Blue – a lot of problems

Red – some problems

Yellow – No complaint