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### **TMJ Disorders**

# Quality of life, chronic pain, insomnia, and jaw malfunction in patients after alloplastic temporomandibular joint replacement: a questionnaire-based pilot study

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Abstract. Studies of patients undergoing alloplastic total temporomandibular joint replacement seldom report on quality of life (QoL) and sleep. The aim of this pilot study was to assess these factors in such a patient cohort using validated psychometric questionnaires. Data were collected via online surveys comprising the following six questionnaires: Short Form-12 Health Survey (SF-12), Patient Health Questionnaire-15, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30, Insomnia Severity Index, Graded Chronic Pain Scale, and Jaw Disability List. Pain intensity, limitation in nutrition, and treatment satisfaction were assessed using numerical rating scales. Mouth opening was measured at follow-up. The SF-12 Physical Composite Score was markedly lower than that of the age-matched general population, whereas the Mental Composite Score did not differ significantly. Participants indicated a low somatization level and low level of disability due to pain, but reduced QoL. Clinically relevant insomnia was reported by 36% of participants. In conclusion, the results of this pilot study indicate that QoL and sleep in patients with a total temporomandibular joint replacement differ from those in the general population, indicating the need for a comprehensive outcome assessment utilizing validated psychometric tools in accordance with the current biopsychosocial model of chronic disorders.

Key words: quality of life; insomnia; sleep; chronic pain; temporomandibular joint; arthroplasty; replacement; surveys.

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Symptoms resulting from temporomandibular disorders (TMD), such as pain or severe dysfunction, require treatment in 5–13% of the general population<sup>1</sup>. In patients experiencing disabling temporomandibular joint (TMJ) disease, surgical treatment should be considered when conservative measures fail to achieve acceptable mandibular function. In so-called end-stage diseases, e.g. traumatic or neoplastic destruction of the TMJ, congenital malformation (aplasia, hypoplasia), ankylosis, or idiopathic resorption, an alloplastic reconstruction may be indicated<sup>2,3</sup>.

In 2017, the American Association of Maxillofacial Oral and Surgeons (AAOMS) reformulated the guidelines for TMJ surgery and added the improvement of patient quality of life (QoL) to the general therapeutic goals<sup>4</sup>. The World Health Organization defines QoL as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broadly ranging concept affected by the person's physical health, psychological state, personal beliefs, social relationships, and their relationship to salient features of their environment. It has been shown that both chronic pain and functional impairment seriously affect QoL5-6

There is a vast body of literature on QoL in patients who have undergone knee and hip total joint replacement 9-11, yet reports on TMJ replacement are rare. Moreover, previous studies have assessed the outcomes mainly by means of Likert or visual analogue scales (VAS), or using questionnaires that have not been validated 12-15. Therefore, the aim of this study was to comprehensively investigate QoL of patients after alloplastic total TMJ replacement (TJR) using validated psychometric questionnaires.

#### Materials and methods

The study was approved by the Ethics Committee of the State of Zurich (KEK-ZH No 2014-0396).

#### Patient recruitment and data collection

Patient contact details were obtained from the clinicians who had performed the alloplastic TMJ TJR in the three participating centres: University Hospital of Zurich, University Hospital of Basel, and State Hospital of Aarau. Surgery reports from these three centres, covering the period February 2005 to February 2015, were searched in order to identify TMJ TJR

surgeries. Subsequently, the patients' contact details were extracted. Patients were contacted by telephone call and if they were interested in participating, detailed study information was provided. After informed consent was obtained, the participants received a personal link to complete the online questionnaires. Those not returning the questionnaire after 1 month were reminded by telephone.

Inclusion criteria were alloplastic TMJ TJR, time since last surgery ≥6 months, and age between 18 and 80 years. Exclusion criteria were drug or alcohol abuse, as well as the inability to follow study procedures, e.g. language problems, psychological disorders, or dementia.

Demographic data were collected from the patients' records, as well as the indication for TJR, the TJR system used, and the date of the surgery.

Psychosocial parameters were collected via an online-survey based on LimeSurvey. Data were stored automatically in an SQL database on a web server and were then exported as a csv file for further analysis in Microsoft Excel.

#### Onsite assessment

Maximum unassisted mouth opening was measured in millimetres with a metal ruler, always by the same dentist, during the annual follow-up visit, in accordance with the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) guidelines<sup>16</sup>. During the same visit, a 0 to 10 numerical rating scale (NRS) was used to assess the following parameters: (1) pain intensity on the operated side (0 = no pain, 10 = worst pain imaginable), (2) nutrition (0 = liquids only, 10 = able to chew any)consistency of food without difficulty), (3) overall satisfaction with TMJ TJR (0 = completely)unsatisfied. 10 = completely satisfied).

#### Questionnaires applied

Digital versions of the validated questionnaires listed below were applied to assess general health status, persisting pain, jaw function, insomnia, and QoL.

The Short Form-12 Health Survey (SF-12): this is a multipurpose generic measure of health status that consists of a subset of 12 items from the longer Short Form-36 Health Survey Questionnaire. It measures physical functioning, role limitations due to physical health or emotional problems, bodily pain, general health, vitality, social functioning, and mental health (psychological distress and psychological wellbeing). The Physical Health Composite

Score (PCS) and Mental Health Composite Score (MCS) were calculated and the data were then compared with previously published age-matched epidemiological data in order to calculate score differences <sup>17</sup>. Confidence intervals (95% CI) were calculated as  $1.96 \times$  the standard error of measurement; the 95% CI was  $\pm 6.97$  for PCS and  $\pm 6.24$  for MCS, as published previously <sup>18</sup>.

Patient Health Questionnaire-15 (PHQ-15): this evaluates the severity of somatic symptoms. The severity of 15 symptoms over the last 4 weeks is rated as 0 ('not bothered at all'), 1 ('bothered a little'), or 2 ('bothered a lot'). The total PHQ-15 score ranges from 0 to 30 and scores of  $\geq$ 5,  $\geq$ 10, and  $\geq$ 15 represent mild, moderate, and severe levels of somatization, respectively<sup>19</sup>. The data were compared with previously published epidemiological data<sup>20</sup>.

European Organisation for Research and Treatment of Cancer (EORTC) Ouality of Life Ouestionnaire Core 30 (OLO-C30)<sup>21</sup>: the summary score of the subscales function (EORTC\_F), symptom (EORTC\_S), and life quality (the total score) (EORTC\_LQ) were calculated as recommended by the EORTC Quality of Life Group<sup>22</sup>. A high score for a functional scale represents a high/healthy level of functioning and a high score for the global health status/OoL represents a high OoL, but a high score for a symptom scale/item represents a high level of symptomatology/problems. The data were compared with previously published age-matched epidemiological data<sup>23</sup>

Insomnia Severity Index (ISI): this screens for sleep disorders by measuring the severity of insomnia, sleep-related satisfaction, and interference of sleep disorders with performance during the day-time. Seven items are rated on an ordinal scale ranging from 0 to 4. The maximum score is 28. The severity of sleep disorders is determined by the following categories: 'none' (0–7), 'sub-threshold' (8–14), 'moderate' (15–21), or 'severe' (>21)<sup>24</sup>.

Graded Chronic Pain Scale Version 2.0 (GCPS v2): this consists of three pain intensity scales ranging from 'no pain' (=0) to 'pain as bad as it could be' (=10), assessing current, worst, and average pain intensity for the last 30 days. The 'disability days' reports the number of days on which pain kept the patient from performing daily activities during the last 3 months. The number of days determines a 'disability days' score ranging from 0 to 3. The interference by pain is measured for (1) daily activities, (2) recreational, social, and family activities, and (3) working ability, on scales ranging from 'no inter-

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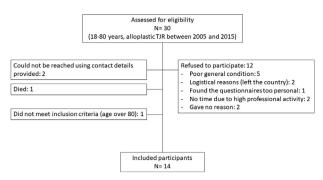


Fig. 1. Flow chart of the recruitment process including the reasons for refusal to participate in the study.

ference' (=0) to 'unable to carry on any activities' (=10) for the last 30 days. The average value of these three disability scales yields a pain activity interference score ranging from 0 to 3. The sum of this pain activity interference score and the 'disability days' score results in a sum score ranging from 0 to 6. Scores of 0-2 are considered as low disability; scores of 3 and 4 are considered as high disability, moderately limiting; and scores of 5 and 6 are considered as high disability, severely limiting<sup>2.5</sup>.

Jaw Disability List (JDL): this is a checklist of 12 jaw-related functions and is included in the RDC/TMD diagnostic recommendations<sup>26</sup>. Participants checked their perceived limited functions in everyday activity at the time of the assessment. The total number of activities was summed

#### Statistical analysis

Descriptive statistics and correlations were calculated with IBM SPSS Statistics

version 25.0 (IBM Corp., Armonk, NY, USA). Due to the ordinal data type, non-parametric procedures were applied.

#### Results

Thirty patients were assessed for study eligibility. Two of them could not be reached with the contact details provided, one had died, one did not fulfil the inclusion criteria, and 12 refused to participate (for details please see Fig. 1). Thus 14 TMJ TJR patients participated in this study. These 14 participants (11 female) had a mean age 45 years 2 months (standard deviation (SD) 15 years 4 months) at the time of surgery, and the mean follow-up since the last surgery was 4 years 7 months (SD 2 years 6 months).

The indications for TJR surgery were as follows: severe degenerative joint disease with compromised TMJ function (n = 5), failed primary therapy after trauma (n = 1), ankylosis (n = 3), condylar resorption (n = 1), pigmented villonodular syno-

vitis (n = 1), lymphangiomatosis (n = 1), extensive jaw resection due to squamous cell carcinoma (n = 1), and mandibular keratocyst extending to the TMJ (n = 1). Six patients had undergone unilateral joint replacement and eight had undergone bilateral joint replacement. The TMJ prostheses used were from different manufacturers: Rotec, Weisendorf, Germany (n = 3); TMJ Concepts, Inc., Ventura, CA, USA (n = 7); Biomet, Jacksonville, FL, USA (n = 4). Five patients received a stock replacement and nine a custom-fitted one.

Detailed descriptive statistics for the function-related and psychosocial measures are given in Supplementary Material Table S1, available online. Average pain intensity was 2.2 (SD 2.6), nutrition 6.2 (SD 3.1), and satisfaction 7.6 (SD 2.3). Average mouth opening was 34.3 mm (SD 9.3 mm).

On the SF-12, the physical and mental health composite scores (PCS and MCS) were 40.1 (SD 7.6) and 50.5 (SD 10.8), respectively. When compared to a previously published age-matched population examined in Germany, the difference in mean scores was -8.9 (SD 8.6) for SF-12 PCS and 0.1 (SD 11.2) for SF-12 MCS, indicating that physical health was worse than in the general population, whereas mental health did not differ significantly (Fig. 2).

The mean PHQ-15 score was 8.1 (SD 6.1), showing a low somatization level. However, it was still twice as high as in a general population, with a mean of 3.8 (SD 4.1), and this difference was statistically significant (P = 0.001).

The EORTC QLQ-C30 summary score was 72.3 (SD 25.8) (Fig. 3).

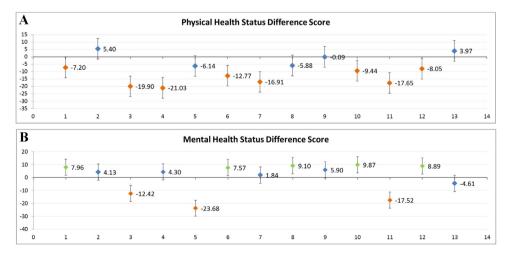
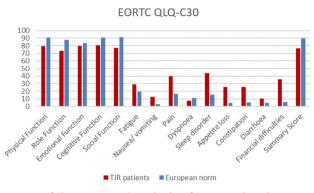


Fig. 2. Difference scores for the Short Form-12 Health Survey composite scores: (a) physical health (PCS), (b) mental health (MCS). PCS 95% CI  $\pm$  6.97, MCS 95% CI  $\pm$  6.24. Each point represents one patient. Green points represent significantly better health status (difference score >95% CI), while orange points represent significantly worse health status (difference score <95% CI).

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*Fig. 3.* Mean scores of the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Core 30 (QLQ-C30). Red indicates patients after alloplastic total TMJ replacement and blue indicates the European normative data, as published by Hinz et al.<sup>23</sup>. A high score for a functional scale represents a high/healthy level of functioning and a high score for the global health status/quality of life (QoL) represents a high QoL, but a high score for a symptom scale/item represents a high level of symptomatology/problems.

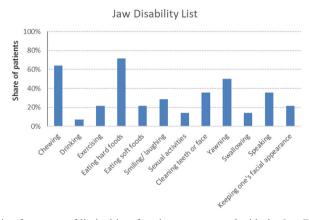


Fig. 4. Relative frequency of limited jaw functions as measured with the Jaw Disability List.

The mean ISI score was 10.0 (SD 5.4). Thirty-six percent of participants presented clinically relevant insomnia and 28% presented subthreshold insomnia. The remaining 36% reported no symptoms of insomnia.

Regarding the JDL, the participants reported an average limitation in four out of the 12 jaw function types. The most frequently reported limitations were 'eating hard food' (71%), 'chewing' (64%), 'yawning' (50%), 'cleaning teeth or face' (36%), and 'speaking' (36%) (Fig. 4).

The average GCPS disability score was 2.2 (SD 2.4), indicating low disability.

In order to understand the deviations in physical functioning and sleep in this sample from those in the general population or comparable samples, the participants were divided into a low disability group (GCPS <3) and a high disability group (GCPS  $\ge$ 3). Mann—Whitney U-tests were performed to in-

vestigate group differences (see Table 1). The two groups were comparable regarding age and age at surgical intervention. Significant differences were found for pain, physical functioning (SF-12 PCS), and sleep.

Significant and strong correlation effects were found between pain and SF-12 MCS, PHQ-15, EORTC\_S, EORTC\_LQ, ISI, and GCPS; between nutrition and satisfaction, mouth opening, SF-12 PCS, PHQ-15, EORTC\_S, EORTC\_LQ, ISI, and GCPS; between satisfaction and mouth opening; between SF-12 PCS and PHO-15, EORTC\_F, EORTC\_S, EORTC\_LQ, ISI, and GCPS; between PHQ-15 and EORTC\_F, EORTC\_S, EORTC\_LQ, ISI, and GCPS; between EORTC\_F and EORTC\_S, EORTC\_LQ, ISI, and GCPS; between EORTC\_S and EORTC\_LQ, ISI, and GCPS; between EORTC\_LQ and ISI and GCPS; and between ISI and GCPS. No significant correlations were found between JDL and the other measures (Table 2).

#### **Discussion**

This small sample pilot study showed reduced physical functioning in patients after TMJ TJR compared to the general population. Indeed, the SF-12 PCS (Short Form-12 Health Survey Physical Composite Score) was markedly lower in these patients than in the age-matched general population<sup>17</sup>, whereas the MCS (Mental Composite Score) did not differ from the epidemiological data. The results are comparable to previously reported postoperative PCS and MCS in patients after lumbar fusion for degenerative spondylolisthesis, as well as total knee or hip replacement<sup>27</sup>. Reduced physical functioning was also found in the corresponding EORTC QLQC30 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30) physical function subscale. Since approximately 60% of patients with a painful TMD suffer from two or more comorbid pains, it is possible that the participants experienced concomitant bodily pain, which was not specifically assessed in this study<sup>28,29</sup>

The PHQ-15 (Patient Health Question-naire-15) score of 8.1 (SD 6.1) indicated a low somatization level; however, it was still significantly higher than in the general population<sup>20</sup>.

The mean EORTC QLQ-C30 summary score of 72.3 was considerably lower than the European norm of 89.5<sup>23</sup>. This result is similar to that of patients with stage III–IV cancer, i.e. 73.0 (SD 18.3)<sup>30</sup>.

A high proportion of the study population reported clinically relevant insomnia (36%). This compares to 5.8% of general practice patients, 15.8% of care seekers at an orofacial pain unit, and 26.5% of chronic pain sufferers <sup>31,32</sup>. The high prevalence of sleep disorders in the present study is astonishing, as the average pain intensity was low. ISI (Insomnia Severity Index) scores correlated positively with the impairment by pain and negatively with QoL and the physical health status. This observation may be of high relevance, since a good sleep quality strengthens physiological and psychological resilience <sup>33</sup>.

The deviations described above are potentially attributable to a subgroup of patients with high disability scores on the GCPS (Graded Chronic Pain Scale); this subgroup showed markedly altered scores in most of the assessments compared with the low disability subgroup. The present study design does not allow a statement regarding possible causes of the high disability scores to be made. It remains unclear whether the reduced physical function, sleep problems, lower

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*Table 1.* Differences in mean score and standard deviation between patients with low and high disability scores (GCPS).

Variable		n	Mean	SD	$Z^{\mathrm{a}}$
Age	GCPS <3	8	50.64	17.93	-0.39 NS
	GCSP $\geq 3$	6	48.70	15.01	
Age at surgery	GCPS <3	8	45.36	17.30	-0.13  NS
	GCSP $\geq 3$	6	44.96	13.79	
Pain	GCPS <3	8	0.88	1.25	-2.16*
	GCSP $\geq 3$	6	4.00	2.90	
Nutrition	GCPS <3	8	7.13	3.23	-1.52  NS
	GCSP $\geq 3$	6	5.00	2.76	
Satisfaction	GCPS <3	8	7.88	2.59	-0.72  NS
	GCSP $\geq 3$	6	7.33	2.16	
Max opening <sup>b</sup>	GCPS < 3	8	37.00	8.32	-1.37  NS
	GCSP $\geq 3$	4	28.75	9.71	
SF-12 PCS	GCPS < 3	8	43.91	6.69	-2.35*
	GCSP $\geq 3$	5	34.04	4.63	
SF-12 MCS	GCPS < 3	8	56.11	3.91	-1.76  NS
	GCSP $\geq 3$	5	41.66	12.84	
PHQ-15	GCPS < 3	8	5.63	3.96	-1.49  NS
	GCSP >3	6	11.33	7.34	
EORTC_F	GCPS < 3	8	90.56	7.68	-1.55 NS
	GCSP $\geq 3$	6	55.93	31.63	
EORTC_S	GCPS < 3	8	82.37	16.92	-1.49  NS
	GCSP >3	6	56.84	30.66	
EORTC_LQ	GCPS < 3	8	85.83	11.83	-1.94 NS
_ `	GCSP >3	6	54.35	29.26	
ISI	$\frac{-}{\text{GCPS}} < 3$	8	6.88	4.29	-2.52**
	GCSP >3	6	14.17	3.76	
JDL	$\frac{-}{\text{GCPS}} < 3$	8	3.38	3.78	-0.66  NS
	GCSP >3	6	4.50	3.62	

EORTC\_F/S/LQ, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 Function/Symptom/Life Quality; GCPS, Graded Chronic Pain Scale; ISI, Insomnia Severity Index; JDL, Jaw Disability List; PHQ-15, Patient Health Questionnaire-15; NS, not significant; SD, standard deviation; SF-12 PCS, Short Form-12 Health Survey Physical Health Composite Score; SF-12 MCS, Short Form-12 Health Survey Mental Health Composite Score.

QoL, and higher pain levels are due to the intervention or to pre-existing conditions.

There is no international consensus regarding whether pain relief should be a primary outcome of TMJ TJR. Recent guidance from the National Institute for Health and Care Excellence (NICE) indicates re-establishment of function and pain relief as equally relevant aims<sup>34</sup>. However, some researchers have argued that TMJ reconstruction is aimed primarily at restoration of mandibular form and function and that any pain relief is only a secondary benefit<sup>2,35</sup>. This issue highlights the importance of managing patient expectations, rather than the absolute level of functioning<sup>36</sup>.

It has been suggested that in order to improve treatment outcomes, not only should the prevention of residual pain, stiffness, and swelling be addressed, but also the patient's preoperative expectations of the likely outcome. Also, meeting preoperative expectations has been shown to be an equally important factor for the prediction of a patient's overall satisfac-

tion with the treatment as achieving satisfactory pain relief postoperatively<sup>37</sup>. Additionally, three baseline factors have been identified as influencing patientreported outcomes: expectations, mental health, and other joints problems (the first two being modifiable)<sup>38</sup>. Furthermore, the most significant pre-intervention predictors were found to be (1) the baseline scores of the same domains, (2) the presence of social support, (3) absence of lower back pain or comorbidities, and (4) baseline mental health<sup>39</sup>.

Along this line of reasoning, the preoperative function and the number of comorbid conditions appeared to be important predictive factors for function at 6 months after total knee arthroplasty (TKA)<sup>40</sup>. Patients with greater dysfunction prior to surgery were less prone to attain satisfactory functional outcomes and could require additional rehabilitation. Older age, years of follow-up, greater number of comorbidities, and a poorer mental health state were deemed prognostic factors negatively influencing a sustained

functional outcome after TKA<sup>41</sup>. Consequently, appropriate counselling prior to surgery was highly recommended to ensure realistic expectations. Based on these results, an accurate biopsychosocial presurgical assessment by means of validated tools is strongly advisable.

In patients suffering from TMD, catastrophizing and depression contribute to the progression of chronic pain and disability<sup>42</sup>. However, in this study, the SF-12 mental composite scores did not differ significantly from those of the general population and were not associated with other parameters except pain.

An association between dysregulation in multiple system domains, particularly in the sensory and the psychological domains, and an increased risk of painful TMD has also been suggested<sup>43</sup>. This finding is in line with the current multidimensional, biopsychosocial model of chronic pain<sup>44</sup>.

On the other hand, patients with isolated myofascial TMD without concomitant comorbid conditions have been reported to show a widespread pressure hypersensitivity, implicating an involvement of censensitization<sup>45</sup>. Furthermore, experimental studies have shown reduced descending noxious inhibitory control (DNIC) in patients with severely painful knee osteoarthritis<sup>46</sup>. A systematic review on sex differences in pain modulation revealed a more efficient DNIC in male patients than in female patients<sup>47</sup>. The same study showed no correlation of radiological findings with clinical or experimental pain parameters. Genetic factors, in particular the oestrogen-related receptor beta gene (ESRRB), are associated with TMD and TMD with comorbid rotator cuff disease<sup>48</sup>. The present study results may therefore have been influenced by the fact that most participants were female. However, due to the small sample size (only three male participants), the effects of sex were not assessed.

A retrospective study showed improvements in QoL, mood, social interactions, pain, facial aesthetics, and jaw function following a TMJ TJR<sup>49</sup>. Development of a validated QoL questionnaire for patients undergoing TMJ TJR would enable multicentre studies and thus allow optimization of treatment strategies and consequently improvements in outcomes. The improvement of QoL after TMJ TJR has recently been assessed in a prospective study of 36 patients<sup>50</sup>. The study revealed that the QoL of most of the patients (33/36) improved considerably, with significant changes in pain, diet, mood, anxiety, and recreation. The authors strongly ad-

<sup>&</sup>lt;sup>a</sup> Mann–Whitney *U*-test: P > 0.05 NS, \*P < 0.05, \*\*P < 0.01.

<sup>&</sup>lt;sup>b</sup> Maximum unassisted mouth opening.

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Table 2. Correlations between function-related and psychosocial measures; Spearman's rho (ρ).

	Nutritio	nSatisfact	ionMouth ope	eningSF-12 PC	CSSF-12 MC	SPHQ-15	EORTC_	FEORTC_	SEORTC_L	QISI	GCPS	JDL
Pain	-0.33	-0.28	0.04	-0.28	-0.80**	0.57*	-0.50	-0.58*	-0.59*	0.61*	0.63*	-0.29
	n14	14	12	13	13	14	14	14	14	14	14	14
Nutrition		0.67**	0.65*	0.61*	0.31	-0.56*	0.50	0.57*	0.56*	-0.59*	-0.61*	0.08
	n	14	12	13	13	14	14	14	14	14	14	14
Satisfaction			0.65*	0.19	0.20	-0.27	0.15	0.21	0.22	-0.31	-0.36	-0.17
	n		12	13	13	14	14	14	14	14	14	14
Mouth openir	ng			0.42	0.25	-0.52	0.38	0.50	0.48	-0.47	-0.49	0.14
	n			12	12	12	12	12	12	12	12	12
SF-12 PCS					0.36	-0.72*		0.65	0.77**		*-0.67*	
	n				13	13	13	13	13	13	13	13
SF-12 MCS						-0.42	0.43	0.40	0.47	-0.41	-0.49	0.22
	n					13	13	13	13	13	13	13
PHQ-15							-0.90**	-0.98**	-0.97**	0.80**		0.08
	n						14	14	14	14	14	14
EORTC_F								0.94**	0.96**		*-0.66*	
	n							14	14	14	14	14
EORTC_S									0.97**		*-0.61*	
	n								14	14	14	14
EORTC_LQ											*-0.71*	
101	n									14	14	14
ISI											0.85**	0.19
CCDC	n										14	14
GCPS												0.10
	n											14

EORTC\_F/S/LQ, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 Function/Symptom/Life Quality; GCPS, Graded Chronic Pain Scale; ISI, Insomnia Severity Index; JDL, Jaw Disability List; PHQ-15, Patient Health Questionnaire-15; SF-12 PCS, Short Form-12 Health Survey Physical Health Composite Score; SF-12 MCS, Short Form-12 Health Survey Mental Health Composite Score.

vocate using patient-reported outcome measures (PROMs) for the assessment of the impact that the procedure has on patients. Findings of this study are consistent with the results of another longitudinal, prospective study<sup>51</sup>, which found significant improvement only for psychological discomfort at 12 months after TMJ TJR. Other domains of oral health-related QoL (OHRQoL) such as functional limitation, physical pain, physical disability, psychological disability, social disability, and handicap showed some reduction, but these were not statistically significant. In general, the OHROoL improved, but it still differed from that of the general population, similarly to the results of the present study. The authors concluded that severely degenerated TMJs will not function as normal joints, even after alloplastic TMJ TJR.

In a 20-year follow-up study of patients undergoing TMJ TJR, an increased number of previous surgeries was identified as a factor negatively influencing pain and functional improvement<sup>52</sup>. On the other hand, a high complication rate has been reported in the literature, ranging from 27% to 56% <sup>12,53</sup>. Since TJR is a highly invasive irreversible treatment, discussing objectives and realistic outcome options with patients requires caution by the clinician. An extensive discussion of the

various risks and benefits is an important element of a shared decision process<sup>54</sup>.

The results of this study are of a preliminary nature and must be interpreted with caution due to the limited sample size and high rate of refusals to participate in the study. The most frequent reason for refusal (five out of 12) was poor general health condition. These patients presumably had reduced QoL and high disability levels. Their inclusion would possibly have shifted the scores further away from those of the general population. Two further patients refused to participate due to high work-loads, which indicates a high level of everyday life activity. Nevertheless, their jaw function could not be determined. Another limitation is the lack of baseline preoperative data. In the available literature on preoperative QoL, the data were obtained simultaneously with postoperative data, which inevitably leads to bias in data collection as the responders are asked about a past health state<sup>49,55</sup>.

In conclusion, this study showed that, with the exception of the SF-12 Mental Composite Score, all patient scores deviated from the values found in the general population. They showed high levels of impairment by chronic pain as well as insomnia, and their jaw function was limited. These deviations are potentially attributable to a subgroup of patients with

high disability scores. We recommend discussing these aspects carefully with patients prior to surgery in order to avoid unrealistic expectations. Future studies should evaluate whether disability measures have predictive value for the post-operative outcome. A further prospective study on a larger sample should reveal if patient QoL changes postoperatively compared to the preoperative state.

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#### Ethical approval

The Ethics Committee of the State of Zurich approved this study (KEK-ZH-No 2014-0396).

#### **Competing interests**

The authors declare no conflicts of interest.

#### Patient consent

Not required.

<sup>\*</sup>P < 0.05; \*\*P < 0.01; all others not significant.

Quality of life after alloplastic TMJ replacement

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#### Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijom.2020.09.022.

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