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## Short-term Recovery after Orthognathic Surgery: A Medical Daily Diary Approach

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### Abstract

This study assessed the utility of a quality-of-life diary for the assessment of postoperative recovery following orthognathic surgery. A 20-item daily recovery diary was designed to assess the patients' perception of recovery in 4 domains (postoperative sequelae; pain/discomfort; oral function; daily activities) during each of the first 90 days after surgery. Fifteen of 185 patients who had agreed to participate did not return any portion of the diary. Of the remaining patients, 87% returned the full 90 days requested. Younger patients were more likely to complete the entire protocol ( $P = 0.01$ ). At 30 days, a lower percentage, in general, of patients who completed all 90 days reported recovery in oral function and general activity compared with those who did not complete all diary days. This study confirms that patients will cooperate with the completion of structured medical / health-related quality-of-life diaries during the first few months after orthognathic surgery. Information from such diaries would be valuable to patients deciding on treatment options and to the clinicians counseling them.

### Keywords

Orthognathic surgery; post-surgery recovery; medical diary

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Convalescence following surgery is a complex process. For the patient having orthognathic surgery, recovery requires the resolution of postoperative sequelae such as: nausea or swelling; the resolution of pain and discomfort; the return to comfortable oral function; and the return to their pre-surgical lifestyle and activity levels. There is little prospective systematic documentation of the patient's experience in the first few weeks or months after orthognathic surgery or the time required for postoperative recovery or the return to 'normal'.<sup>4,8,10,11</sup>

The structured medical diary is one method that has been used to document the health-related quality of life and recovery pattern following surgery. In studies with this approach, subjects typically report their pain, complications and symptom resolution at fixed intervals, usually daily. The medical diary has been used to compare postoperative recovery following tonsillectomy using different surgical devices<sup>12,25</sup> and following laparoscopic cholecystectomy in either a 23-hour or an 8-hour facility.<sup>27</sup> In dentistry, a daily diary has been

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used to study the recovery of patients who have third molars removed<sup>2,26</sup> and to assess the risk factors associated with prolonged recovery.<sup>5,14,22</sup>

One advantage of the structured diary is the timely capture of rapidly changing events and experiences without the potential bias related to the weighting subjects might give to peak levels or the most recent experience that can occur with instruments relying on retrospective recall. For example, the Oral Health Impact Profile (OHIP-14)<sup>21</sup> asks subjects to base their responses on recall over the past 14 days and the Post-surgical Perceptions (PSP)<sup>15</sup> over the past week. For research questions focused on longer-term recovery or outcomes, these potential biases may not be an issue since the within-person day-to-day variability would be expected to be small. In studies that focus on experiences or events that are expected to resolve quickly, for example in hours or days after a procedure rather than months or years, these potential recall biases could prevent valid modeling of the course of recovery and the impact of the procedure on the quality of life during recovery.

This study assessed the utility of a daily medical diary during the first 3 months following orthognathic surgery to quantify the patients' perception of their recovery in four domains: postoperative sequelae; discomfort/pain; oral function; and daily routine.

## METHODS

The Health Related Quality of Life (HRQOL) instrument developed for third molar removal<sup>20</sup> was modified for use in this study to measure the short-term outcomes of orthognathic surgery. Changes were based on interviews with 15 randomly selected patients who had had orthognathic surgery within the past 6 months. Interviewees were asked what had been the biggest problem or concern during the first 2 days of recovery, the first, second, third and fourth week of recovery. After their open ended responses, the interviewees were given the third molar diary and asked if the items listed had been a problem in the first 3 months of recovery. Modifications included increasing the time frame of completion from 14 to 90 days and requesting a rating for worst and average discomfort.

Patients who presented with a developmental facial skeletal disharmony and were scheduled for an orthognathic surgical procedure between July 2003 and April 2007 were asked to participate in a prospective clinical study approved by the Biomedical Institutional Review Board. They were excluded if they had a congenital anomaly or a history of facial trauma; had had previous facial surgery; were pregnant; had a medical condition associated with systemic neuropathy (diabetes, hypertension, kidney problems); were unable to follow written English instructions or unwilling to sign informed consent. The project was described to the patient by a research associate and written consent (assent and parental permission if the patient was under 18 years) and authorization under the Health Information Portability and Accountability act were obtained.

Demographic information (age, education level, gender, race) was collected prior to surgery. On the day of surgery, the surgical assistant recorded the surgical procedures performed. Surgery was performed by oral and maxillofacial surgery faculty and residents at UNC Memorial Hospital. All patients had rigid skeletal fixation which reduced the time frame for maxillomandibular fixation.

Each patient was given a post-surgery health diary (OSPostop) and instructed to complete the diary at bedtime each postoperative day (POD) for 90 days. The HRQOL diary was designed to assess patient perception of recovery in the following areas: postoperative sequelae; discomfort/pain; oral function; and general activity. The discomfort items were rated on Likert-like scales from no discomfort (1) to worst imaginable (7). All other items were rated from no trouble/concern (1) to lots of trouble/concern (5). Patients were also asked if any medication

had been taken to relieve pain or swelling. Completion of the diary each day took, on average, 2 min. The Flesch-Kincaid Grade level of the OSPostop is 6.8. The diaries were presented as bound monthly booklets so that all the days for a given month were together but easily portable. Dates were preprinted on each diary sheet.

Patients were seen by a research associate at each post-surgery clinical visit with the surgeon attending. These visits routinely occurred at 1, 4–6 and 12 weeks. Patients were instructed to bring their diaries to each visit. They were contacted by phone and asked to mail the diary if a visit was missed or they had neglected to bring their diary to the clinical visit. Patients were categorized according to the number of days of the diary that were returned: less than 60; less than 90 days; 90 days.

Categorical demographic and clinical characteristics were compared among the three groups of subjects, defined by the number of days of the diary returned, by Fisher's exact test. Age was compared using an exact median test. The proportion of patients in each group who reported no trouble or discomfort on POD 30 were compared using Fisher's exact test.

A telephone interview during the first postoperative months with a subset of 20 randomly selected subjects was conducted to estimate convergent validity and identify problems with the questionnaire instructions or response format. The oral responses to the diary items from the telephone contact were compared with those given on that postoperative day on the self-administered questionnaires. Agreement was defined as either the responses were the same or within 1 unit. Percent agreement was used to compare the responses for the self-administered questions and telephone queries. Disagreements were examined carefully to determine whether patients were routinely reversing items, thus indicating problems with instructions or item wording.

## RESULTS

One hundred eighty five patients consented to participate; 15 (8%) did not return the first month of diaries. Most cited repetition or 'forgetting' as the reason for withdrawal. There were no statistically significant demographic differences (gender, race, age or education level) between those who returned at least the first 30 diaries and those who did not ( $P>0.25$ ). The proportion of patients who were treated with a 1 or 2 jaw procedure was not statistically different ( $P = 0.38$ ).

The agreement between the self-administered questionnaires and the telephone interview was greater than 90% for all but three of the items. The oral and paper responses for three patients (15%) differed for average discomfort and return to recreational activities and 5 patients (25%) did not give agreement responses for talking. There were no reversals, that is, changes from 'agree' to 'disagree' or vice versa.

Of the 170 subjects who returned at least the first month of diaries, 87% completed the full 90 days requested; 5% at least 60 ; and 8% at least 30 days. Those who completed the entire protocol period were younger, on average, than those who did not (Table 1). The education level, the proportion of females, Caucasians, and those having surgery in both jaws were similar in the three groups (Table 1). In general, a lower percentage of patients who completed the protocol period reported recovery in oral function and general activity domains by 30 days compared with those who did not complete the entire protocol period (Table 2). The percent reporting recovery by 30 days for average and worst pain decreased, although not significantly, as the time of completion increased (Table 2).

## DISCUSSION

The demographic and surgical procedural characteristics of the 15 patients who withdrew did not differ significantly from those who did not withdraw. Making the diary available in an electronic format via the web or a handheld device rather than a paper and pencil format might have improved the participation rate by allowing the respondents greater freedom and flexibility in accessing and completing the daily questionnaire.<sup>3</sup>

The level of agreement between the self-administered instrument and the telephone interview and lack of reversals support the utility of a health diary approach in a more comprehensive assessment of recovery following orthognathic surgery than relying on clinical outcomes alone. The greater than 90% agreement for all but three of the items is considered adequate: some variation in response, particularly in average discomfort, talking and recreational activities, could be expected given fluctuations in activity level or time of day between the oral and paper responses. Studies targeting medical problems have validated the incorporation of health diaries for symptom reporting.<sup>17,23</sup>

Of the 170 subjects who completed at least the first month of the diary, the compliance rate for the completion of the entire 90 day protocol was 87%. The withdrawal and completion rates in this study are similar to those that have been reported for other post-surgical diary recovery studies<sup>1,19,25</sup> even though the protocol period in this study was longer. Patients who did not complete the entire diary protocol may have lost interest either because of the hassle of daily completion or the irritation of being asked to respond to items that were no longer bothersome. Younger patients were more likely to complete the protocol. The time required and repetition may have been a greater challenge for the older patients who might have more daily commitments.

For this study, a time base of 24 hours was used and all items were maintained in the daily diary for the entire 90 days. The rationale for the time-base was that a longer interval, such as 'over the past week', would have failed to differentiate recovery patterns, particularly among those items that were expected to cause problems only in the first few weeks after surgery. The rationale for the inclusion of all items throughout the entire protocol was the minimal time (about 2 min) required for completion of the diary. The repetition of items may have been an irritant to the subjects. For example, participants were expected to rate nausea at 30 and 60 days even though none of the 170 subjects reported any trouble or concern relating to nausea after day 28.

One way to increase compliance without changing the time base of 24 hours may be to alter the structure of the daily diary such that some items are asked every day for the first few weeks but only occasionally throughout the remainder of the protocol period. This consideration may be important since compliance with the completion of the full protocol diary length appeared to be related to the patient's perception of their recovery. Variation in the structure format of the diary requires sufficient preliminary data to characterize the recovery pattern and to estimate a reasonable frequency of inclusion for each item.

Increasing the frequency of telephone or email contact by research staff might also increase compliance and adherence. Such contact can serve as a reminder of the importance of completing the entire protocol even if the patient is no longer troubled by one or all items and of accurate reporting based on the time specified. Adherence to the fixed schedule of completion by the patient is a potential concern: was the diary actually completed each day or did the patient wait until the diary was due and then complete all the preceding days?<sup>24</sup> Transient subjective feelings such as feeling trapped or anxious are more susceptible to recall bias than concrete objective events such as food trapped in teeth.<sup>18</sup> Requesting return of the daily logs on a frequent schedule, perhaps weekly, may decrease possible completion bias.

Allowing participants to choose the time of day for completion that best suited their lifestyle, rather than giving instructions to complete at bedtime might also improve adherence.<sup>7</sup>

Some studies have implemented diaries on handheld electronic devices that automatically time stamp the entry<sup>1</sup> so that adherence and completion rates can be calculated accurately. Handheld electronic diaries are more expensive than paper and pencil.<sup>16</sup> If adherence is critical, it is possible to augment paper diaries with electronic prompts by phone, watch or pager, but such prompts may be disruptive to the participant's life and may increase the number who withdraw from the study. The debate<sup>9</sup> over the use of paper and pencil or electronic diaries continues, although Green et al<sup>6</sup> reported that both provided equivalent psychometric and response patterns.

Completion of health diaries requires a level of participant commitment that is different from that of most other research participation, and careful consideration of the possible barriers to compliance and schedule adherence is critical. Educational level did not appear to influence compliance. The educational level of the participants was sufficient to follow and comply with the instructions. All of the respondents who were 18 years or less were in high school or had completed high school. Of those older than 18, all had completed high school and 84% had at least some college education. Health diaries, both paper and electronic, have been used with children as young as 8 years.<sup>13</sup>

Health diaries can provide a day-by-day characterization of recovery that is important for informed consent and for the patient's understanding of treatment options and the impact each treatment option is likely to have on the preparation and time estimated for recovery. Incorporating a health diary such as the OSPostop, is potentially useful in research targeted at improving the management of the immediate post-surgery recovery: for example, comparisons of anesthetic or pre/post surgery medication regimes or comparisons of procedures, such as orthognathic surgery and temporary skeletal anchorage, for the treatment of specific dentofacial disharmonies.

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**Table 1**

A comparison of the demographic and surgical procedural characteristics of the patients I the study.

	Less than 60 days (n=13) (8%) %	Less than 90 days (n=9) (5%) %	All 90 days (n=148) (87%) %	P-value
Gender-Female	61.5	66.7	64.9	0.94
Male	38.5	33.3	35.1	
Race-Caucasian	84.6	77.8	84.5	0.80
Other	15.4	22.2	15.5	
Education – High School	18.0	62.0	54.0	0.06
College	81.0	38.0	46.0	
Sgtype-2 Jaw	46.1	55.6	38.3	0.64
Mand	15.4	11.1	29.5	
Max	38.5	33.3	32.2	
Median Age	22.5	17.8	18.4	0.01



**Table 2**

A comparison of the patients who completed the entire 90 day diary and those who did not with respect to the percentage of patients who reported recovery (no trouble/concern) at 30 days after surgery.

	Less than 60 Days %	Less than 90 Days %	All 90 days %	P value
<b>Postoperative sequelae</b>				
Bruising	100.0	100.0	98.7	1.0
Nausea	100.0	100.0	99.3	1.0
Sleeping	100.0	100.0	88.4	0.41
Bad Taste/Breath	92.3	77.8	87.3	0.58
Bleeding	100.0	100.0	100.0	1.0
Swelling	84.6	77.8	83.8	0.89
<b>Food Collection</b>				
In Teeth	76.9	88.9	67.0	0.58
Soft Tissue Incision	92.3	100.0	88.5	0.85
<b>Emotional</b>				
Feeling Trapped	92.3	100.0	96.0	0.63
Anxious	92.3	88.9	92.0	0.82
<b>General Activity</b>				
Talking	100.0	88.9	77.0	0.30
Routine	100.0	77.8	73.7	0.08
Social	100.0	66.7	68.9	0.03
Recreation	61.5	44.4	42.6	0.45
<b>Oral Function</b>				
Opening	69.2	55.6	39.9	0.05
Eating	53.9	22.2	28.4	0.15
Chewing	55.2	22.2	12.9	0.01
<b>Discomfort</b>				
Average Pain	100.0	88.9	87.2	0.47
Worst Pain	92.3	77.8	73.7	0.43
No Medication for Pain/Discomfort	76.9	88.9	80.4	0.82