Original Investigation

Optimizing Total Facial Nerve Patient Management for Effective Clinical Outcomes Research

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IMPORTANCE Assessment of outcomes in patients with facial paralysis is challenging owing to the lack of objective tools to evaluate facial function and suboptimal data collection.

OBJECTIVE To describe a methodology for prospective evaluation of patients with facial paralysis that permits optimal assessment of clinical outcomes.

DESIGN, SETTING, AND PARTICIPANTS At the Massachusetts Eye and Ear Infirmary, we have treated over 2000 patients with facial nerve injury since 2002. To better quantify and improve our outcomes, we have developed what we now believe represents a systematic method for the previsit evaluation, intake, management, and follow-up of our facial nerve patients to optimize data collection for the purposes of clinical outcome studies, as detailed in this retrospective descriptive study.

RESULTS Data collection is often poor if there is not a specific individual delegated to the task and is particularly challenging in the intraoperative setting. Retrospective acquisition of data are inherently less accurate and time consuming. A user-friendly searchable database is required to use the collected data.

CONCLUSIONS AND RELEVANCE Clinical outcomes research in the field of facial paralysis requires meticulous attention to comprehensive data collection at appropriate time points, precision photography, and the use of available quality of life and objective measurement tools. Ideally, a standardized approach for data collection would be adopted that would permit multi-institutional data analysis to improve the quality of outcomes research currently available.

LEVEL OF EVIDENCE NA.

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Over the past several decades, clinical outcomes research in facial paralysis has been hampered by a lack of objective and quantitative evaluation of facial function. Ideally, a standard and systematic model for evaluating patient outcomes would exist for patients with facial paralysis. Such a model has been generically described in a recent Outcomes Measure Framework whitepaper for the Agency for Healthcare Research and Quality and was adapted for use in facial plastic surgery and facial paralysis. The components of this model include characteristics of the patient, features of their facial paralysis, and treating health care providers. In addition, the elements of treatment, including types and intent, and their outcomes are recorded. Effective evaluation of facial outcomes following treatment requires both clinician-reported and patient-reported measures of function and well-being. Clinician-reported scales, such as the Sunnybrook Facial Grading System and the modified House-Brackmann grading scale, provide one necessary component of evaluation. Similarly, validated software tools (Facial Assessment by Computer Evaluation program [FACE-gram]) for evaluating facial movement from images also exist and play an important role in treatment planning and assessment. Finally, several relevant patient-reported outcomes measures now exist for facial paralysis such as the Facial Clinimetric Evaluation (FaCE) Scale, the NOSE Scale, and the Synkinesis Assessment Questionnaire.

Moving from model to implementation requires the development of both processes and technology to collect, manage, and interpret data. At the Massachusetts Eye and Ear Infirmary (MEEI), we have treated over 2000 patients with facial nerve injury since 2002. To better quantify and improve our outcomes, we have over the years developed what we now believe represents a systematic method for the previsit evaluation, intake, management, and follow-up of our patients with facial nerve injury to optimize data collection for the purposes of clinical studies. However, because standard and systematic data collection for many clinical entities has only recently been introduced, statistically valid conclusions will arise from analysis of data over
Methods

Institutional review board approval was not required for this study because patient information was not used to prepare the manuscript.

Before First Visit

A set of questionnaires is administered to all new patients prior to their first visit and are available electronically as well as on hard copy. Patients are required to complete these questionnaires prior to arrival at the Facial Nerve Center at MEEI. Information obtained during the preoperative visit is given in Table 1 and Table 2. Any incomplete portions of the intake data are identified and brought to the patient’s attention for completion prior to the conclusion of their visit. This acquisition of data in real time facilitates accurate data collection and avoids the challenges associated with obtaining data retrospectively.

Patient Intake and Pretreatment Evaluation

During the intake session, the medical personnel are responsible for adding the patient to the facial paralysis database and populating the appropriate preoperative data. The previsit

the next several years. Given the many subgroups of patients undergoing these treatments, studies based from a single institution lack the statistical power to perform many of the analyses that would be of the most benefit to our patients. Herein, we describe our methods for data collection for patients treated for facial nerve injury along with preliminary results. It would be ideal to standardize this approach to data collection for outcomes assessment to allow data to ultimately be shared across institutions and practices.

Table 1. Timing of Outcomes Assessment for Patients With Flaccid Paralysis

<table>
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<tr>
<th>Intervention</th>
<th>Assessment at Initial Visit</th>
<th>Outcomes Assessment</th>
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Abbreviations: Botox, onabotulinum toxin-A; eval, evaluation; FACE-gram, Facial Assessment by Computer Evaluation program; FaCE, Facial Clinimetric Evaluation Scale; FGS, Sunnybrook Facial Grading Scale; NA, not applicable;
questionnaires are stored in the patient’s medical record. Pre-operative photographs are obtained in standard fashion by the medical staff during the following expressions: at repose, eyebrow raise, gentle eye closure, strong eye closure, gentle smile, strong smile, pursing lips, and depression of lower lip. Meticulous attention is paid to head position during photography to permit accurate data acquisition from photograph analysis software (Box 1). A digital single-lens reflex cropped-frame camera (Nikon D90; Nikon Inc) with a fixed focal length lens is used and on aperture priority mode at standardized settings. A studio with a solid background and professional flash are used to optimize contrast. Standardized video recordings of each patient are also taken at this stage.

**Examination**

During the visit with the medical staff, the standard history is taken and physical examination is performed and dictated into the electronic medical record. Clinician-graded scales are also addressed at this point, including the Sunnybrook Facial Grading System (Table 1 and Table 2). Various laboratory tests may be ordered as indicated (Box 2).

**Interventions**

Initial management guidelines are shown in the Figure. During the initial visit and in the ensuing workup, a diagnosis is established and the patient is treated on the basis of current treatment paradigms. For instance, patients with acute onset Bell palsy and favorable electrophysiological profiles have a high likelihood of rapid recovery and are therefore treated more conservatively with interventions including eyelid stretch exercises, moisturization, and tapping the eye shut at night. The patient is evaluated 30 days following initial presentation, and if eye closure remains incomplete and/or there is a poor Bell phenomenon, depending on clinical circumstances, a thin-profile platinum eyelid weight placement is recommended. The patient is then reevaluated after 4 months, and if the face remains completely flaccid, a magnetic resonance imaging scan with gadolinium of the cerebellopontine angle and parotid gland is considered to investigate for presence of occult neoplasm.

The patient management model used in our clinic is displayed in the Figure. If a patient undergoes surgery, several intraoperative measurements are made (Box 3) depending on the type of intervention performed. We make every effort to record data in real time; in our experience, although data collection is minimally time consuming, the retrospective acquisition of data from patients is much more costly with regard to time and is less accurate.

**Postintervention Management**

Patients are characterized by the type of treatment they receive, as described in the previous “Interventions” subsection. Patients are administered the postoperative questionnaires at set intervals (Table 1 and Table 2), and data are entered into our database.

**Results**

Specific problems identified during retrospective data analysis and their solutions are described in the following subsections.

**Photography**

Although the quality of our photography was sufficient for subjective analysis and reviewing with the patient, attempts at quantitative analysis from photographs revealed that several frontal view photographs were not always taken in a perfectly frontal plane (ie, the patient’s coronal plane was not parallel to the image sensor of the camera). In these cases, the FACE-gram software is unable to accurately measure smile information because the eyes are not in the same plane. The software depends on equal circumferences for each iris; if the eyes are in different planes relative to the image sensor of the camera, they will not be the same size, thereby confounding measurements. Meticulous patient positioning during photography with an appreciation that these photographs will be used to obtain objective measurements for analysis is paramount.
Several patients continued to improve outside of the expected recovery period. For instance, though we typically expect a free gracilis muscle transfer driven by the ipsilateral trigeminal nerve to stabilize recovery by 1 year postoperatively, we identified a patient who developed increased excursion of the oral commissure outside the expected recovery period. Thus, we now obtain postoperative photographs from dynamic reconstructions at multiple visits, even up to 3 years following the intervention.

### Preoperative Patient-Reported Outcomes Measures and Clinician-Graded Scales

Several patients were missing patient-reported outcomes measures, such as the FaCE Scale score, and clinician-graded scales, such as the Sunnybrook Facial Grading System. Absence of preoperative information makes outcomes assessment impossible. We addressed these issues by administering questionnaires to patients as soon as they have established care in our center and requiring them to complete this information at repeated visits. At the preoperative visit, materials are reviewed for completeness.

### Intraoperative Data Recording

Intraoperative data acquisition is a unique challenge. The surgeon remains focused on the care of the patient, and the nursing staff is frequently completely occupied, particularly during complex cases. Nonetheless, recording data are fundamental to quality improvement, and reliable systems to acquire these data are critical in the changing health care climate. In the early years of the Facial Nerve Center, data collection was suboptimal because no staff member was given the responsibility for recording data. To address this issue, we developed a checklist and designated a single individual to be responsible for data collection. During a free gracilis muscle transfer, the clinical fellow obtains measurements of the muscle as listed in Box 3 and calls them out to the nursing staff. These measurements are recorded on the checklist, and collected by the fellow postoperatively to transfer to the database.

### Discussion

Despite massive breakthroughs in medical information exchange over the past several decades, patients with the same disease process are often treated differently in different medical centers across the United States and around the globe. Variability in treatment is perhaps even more amplified in surgery, where quality of care is dependent not only on the type of care prescribed, but also on the technical skill of the surgeon delivering the care. With the current state of the economy...
and the high costs of health care, analysis of the effects of our interventions on our patients is essential to optimize outcomes and minimize costs.

In facial plastic and reconstructive surgery, conducting high-quality outcomes studies for evaluating treatment effectiveness represents a challenging task; even ongoing outcomes assessment for quality improvement (and eventually accountable care reporting) is difficult. The highly regarded double-blinded randomized clinical trial is not an option for these types of interventions and randomization to “sham” procedures would not be ethical. For rigorous evaluation of specific procedures, more real-world approaches such as cluster-randomized trials (randomizing by institution or practice) may be more appropriate, and such studies will require common infrastructure in many institutions. Similarly, as practice-based outcomes assessment becomes a more common part of all care delivery, standardized approaches will be required to permit data to be aggregated and compared.

For conditions like facial paralysis, the relatively low volume of cases will make both clinical research and clinical outcomes assessment an ongoing challenge unless institutions and practices adopt integrated frameworks for collecting and analyzing data. Without this integration, studies will be underpowered to detect clinically (or even statistically) significant differences between groups. New technologies and treatment methods that might represent true improvements could be abandoned because under current practices “no statistically significant difference was found between the novel method and the status quo.” For example, although facial paralysis is not uncommon, with an incidence rate of 80 cases per 100,000 individuals annually,10 the number of patients who require FGMT is much smaller. Because of the limited treatment group, sample size is inherently low, restricting our power to detect differences that may be clinically and/or statistically significant. By comparison, the incidence rate of myocardial infarction is approximately 600 cases per 100,000 annually, providing investigations with a much more robust sample from which to analyze data. Improving the evidence base requires larger cohorts of affected patients. At present, patient care decisions in facial plastic and reconstructive surgery are often made based on anecdotal data presented from an author’s “series of 10 patients” or even case reports.

Because of the current shortcomings in facial plastic and reconstructive surgery outcomes research, we aimed to standardize the intake, management, and postoperative care of our patients with facial paralysis in an effort to optimize data collection for future outcomes studies, which continues to be a work in progress. When the Facial Nerve Center was first established, our focus was to provide excellent clinical care for our patients, perhaps at the expense of meticulous data collection. This lack of data collection is a pitfall for many when embarking on innovative management strategies focusing on the present without a long-term view with respect to quality improvement.

Our early attempts at data collection were insufficient, particularly with our free gracilis muscle transfer cases. Intraoperatively, we consistently recorded only inset weight, presence or absence of preoperative Tinel sign, number of sutures placed during neurorrhaphy, and suture size. Although our postoperative photography was reliably consistent, our recording of FaCE Scale scores was inconsistent.

Clinicians face many challenges in a busy office setting, and data collection can easily be neglected. Pressure from insurance companies has forced many clinicians to see many more patients to fulfill their financial responsibilities, decreasing the amount of time we spend with each individual. In addition, third party payers also demand justification for our treatment decisions. Justification for our clinical decisions is dependent on clinical outcomes research, which in turn is de-
pendent on high-quality data collection. Fortunately, technology and the use of checklists dramatically improved our ability to record information.

Technology has substantially facilitated our efforts to communicate across geographic distances between patient and health care provider. Our referral base extends throughout the United States and internationally. Patients living at a distance must travel to visit us, precluding consistent in-person acquisition of postoperative outcomes data. Nonetheless, it is essential to obtain data from these patients to increase power and avoid selection bias. We have addressed this issue by using electronic methods to obtain data. For questionnaires such as the FaCE Scale, we were often able to administer the survey via the telephone. When photographic data were required, we asked patients to submit photographs to a secure MEEI account. In addition, the use of Skype (Skype Communications SARL) and Face Time (Apple Inc) has facilitated postoperative assessment of our patients.

Conclusions

Outcomes research in facial plastic surgery is challenging and time consuming but critical to quality improvement. For treatment of patients with facial nerve injury, we have refined a clinical workflow to optimize data collection not only for clinical care but also for clinical outcomes research in the future. It is essential for facial plastic surgeons to adopt these proposed or similar data collection methods to permit the execution of high-quality, sufficiently powered multicenter studies. Without standardized and regular data collection, we will continue to rely on low-level evidence from anecdotal reports or underpowered studies.

ARTICLE INFORMATION

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REFERENCES


