CHAPTER 11

BUNION SURGERY: A Prospective Clinical Outcomes Study

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INTRODUCTION

Podiatric surgeons perform the majority of over 150,000 bunion procedures in the United States each year in an effort to eliminate pain and restore function of the first metatarsophalangeal joint. Experience tells us that patients do well with bunion surgery, but the profession has not comprehensively quantified this in the literature. There are many retrospective studies addressing the efficacy of a particular procedure, relying on chart review, radiographic measurements and patient interviews or questionnaires. The gold standard is the prospective study design using validated measurement scales, and there are no such studies in the podiatric literature. The podiatric profession needs to scientifically prove and quantify the benefits provided by surgical bunion correction. The goal of this study is to provide long-term prospective clinical outcomes data evaluating the efficacy for the surgical treatment of hallux abducto valgus. We will show that surgical correction of bunions increases patient quality of life through an increase in function and reduction in pain.

LITERATURE REVIEW

Hallux abducto valgus is one of the most common structural deformities seen in the practice of podiatric medicine. The etiology of hallux abducto valgus is multi-factorial. Faulty biomechanics including a hypermobile first ray, improper shoe gear, arthritic conditions, neuromuscular disorders genetic disorders and a genetic predisposition have all been implicated in the development of bunions.[1] Due to the complexity of the deformity there is not one solution for its surgical correction.

There have been many retrospective studies in the orthopaedic and podiatric literature that have evaluated the efficacy of bunion surgery.[2-22] In the orthopaedic literature there are multiple prospective studies but none of these studies address clinical outcomes using validated tools.[23, 24] One study, yet to be published, presented 305 bunion patients addressing the efficacy of bunion surgery (American Orthopaedic Foot and Ankle Society Winter Meeting, February 7, 1999, in Anaheim, California). The study found "that bunion surgery is highly effective when performed by an orthopaedic surgeon." Another study did use the American Orthopaedic Foot and Ankle Society's Hallux Metatarsophalangeal-Interphalangeal Scale.[23] There are no published studies incorporating the McGill pain questionnaire, SF-36 or any other validated health measurement scale in assessment of bunion surgery.

The SF-36 developed by John Ware, Ph.D. of Quality Metric consists of thirty-six questions with a multi-term scale measurement for eight health parameters.[25] These include: 1) physical functioning; 2) role limitations due to physical health problems; 3) bodily pain; 4) general health; 5) vitality; 6) social functioning; 7) role limitations due to emotional problems; and 8) mental health. This scale was selected because it is the gold standard for health measurements in many medical fields. The SF-36 allows comparisons with over 2000 other studies that have researched the effect of many different medical interventions and health care delivery systems. This bunion study is registered with Q-Metric with permission to use their SF-36 scale.

The McGill Pain Questionnaire (MPQ) is a validated scale that precisely measures bodily pain.[26, 27] It includes a visual analog scale. The McGill pain questionnaire expands on bodily pain health concepts included in the SF-36. The MPQ has been used to evaluate arthritis,[28-32] cancer,[29,33-37] postoperative pain[38-43] as well as experimental pain in the laboratory.[26,44]

There is an increased emphasis on validated measurement scales for clinical outcomes. Medicare's National Committee for Quality Assurance (NCQA) has adopted the SF-36 in their Medicare Health Outcomes Survey. The results of this survey will be sent to health care plans and Health Care Financing Administration (HCFA). The Medical Outcomes Trust (MOT), based in Masschusetts, was formed to develop and adopt universal outcomes assessments tools. They have also adopted SF-36 as a generic mea-

surement tool for health assessment. The SF-36 questionnaire has become part of the Musculoskeletal Outcomes Data Evaluation and Management Systems (MODEMS) developed by the American Academy of Orthopaedic Surgeons (AAOS) and two of its component societies. MODEMS is a program that provides orthopaedic surgeons with assistance in completing the medical outcomes instruments and data analysis. The surgeons in turn provide their clinical outcomes data to a national database whose purpose is to eventually provide the national "norms" for outcomes.

In a presentation "Hallux Abducto Valgus Update" made by the principal investigator (Podiatry Institute Update '99 Seminar, Atlanta Georgia, May, 1999), the following pilot study data were introduced. In this prospective outcomes pilot study, 32 patients underwent 33 bunion procedures with an average follow-up of 6.7 months.[3-11] The only health measurement scale in this study was the McGill pain questionnaire. The present pain index improved from 3.00 to 0.18. The pain descriptors were reduced from an average value of 17.0 to 1.2 and visual analog scale from 84.7% pain to 6.0% following bunion surgery. All McGill and radiographic parameters were statistically significant ($p<0.001$). No conclusions could be drawn from the four complications presented. This pilot study was established to develop the data acquisition system and to demonstrate some expected trends in the data. This study did not include the SF-36 or the AOFAS Hallux Metatarsophalangeal-Interphalangeal Scale. This pilot study did support the use of bunion surgery as a tool to restore quality of life by eliminating pain and restoring function.

RESEARCH DESIGN AND METHODOLOGY

The study design is a prospective clinical outcomes study. It does not however, contain a control group, namely a patient population with painful bunions that do not undergo surgery. Most patients who opt for surgery report that the pain is long-standing and getting progressively worse. It is not practical and may be considered unethical to withhold surgery from these patients. It could be argued that filling out forms on different dates may alter the patient reported data. The forms we have included are validated as repeatable measures of pain and health measurements allowing us to repeat the measurements at different points along the treatment. This study is a repeated measures study where each subject serves as the control. This model eliminates between subject variability, greatly increasing the power of the statistical analysis.

Data is obtained from patients who have consented to and will undergo surgical bunion correction. The clinicians participating in the study are Podiatry Institute faculty members that have completed the same residency program. Thirty-six members have agreed to participate in the bunion trial. There were multiple reasons for selecting this group of podiatric physicians. Since everyone will have completed the same residency program, we have controlled the type and level of training. The faculty attends annual meetings and works closely together on multiple projects. Therefore, the infrastructure is in place to conduct the study. The faculty is accustomed to donating time to such endeavors and can be trained at national meetings to participate in clinical outcomes studies. This endeavor has started a paradigm shift for clinicians to view each patient as a person in need of their care as well as a subject for clinical outcomes research.

The questionnaire is based on several validated clinical outcomes measurement tools and input from the Podiatry Institute faculty. The questionnaire includes a total of twenty-five pages for the first year of study. Each following year will require an additional four pages. Included in the questionnaire are data encompassing demographics, range of motion, radiographic parameters, SF-36, McGill Pain Questionnaire, AOFAS Hallux Metatarsophalangeal-Interphalangeal Scale, surgical procedure, postoperative course and complications. Much of the data is measured repeatedly throughout the treatment including a preoperative evaluation, first postoperative visit at three, six and twelve months and annually thereafter.

Although there are twenty-five pages to the questionnaire, the surgeon is only required to fill out five pages over the course of the first year for each patient. In the design of the study, we attempted to make the surgeon contribution to the questionnaire as simple as possible. The intent was to provide a form that could be filled out quickly and unobtrusively during each patient visit. The surgeon is also required to fill out the complications form when they exist. A third party will perform the four pages of radiographic measurements and this process will be discussed later in this section. The patient will be responsible for filling out fourteen pages of the questionnaire for the

first year in the study. The intent of this study is to follow patients in a longitudinal study until patient is lost to follow-up. Patients will be contacted once a year after the first year.

The SF-36 and McGill Pain Questionnaire and their application were described previously. The AOFAS Hallux Metatarsophalangeal-Interphalangeal Scale was included for completeness. This scale has not been psychometrically tested for validity; however, it has been used in other studies. The demographic questionnaire is based on questions found in the General Social Survey developed by the University of Michigan and those in the U.S. Census bureau survey. The objective was to ask sufficient questions to classify race, ethnicity and socioeconomic class. This information will be instrumental in determining trends in the population and to eliminate these variables when evaluating the data.

The radiographic parameters are measured using the X-PO Dite system that includes a Digital Radiograph Analyzer. This device is a backlit-digitizing tablet with a resolution of 2000 lines per inch. The radiographs are placed on the digitizer and the user selects anatomic marks. The software calculates the radiographic parameters and outputs data in the file format used for data collection in our study. The accuracy and repeatability of this device is less than one degree for angular measurements and less than one millimeter for linear measurements. The faculty are required to forward copies of the radiographs to be measured. This reduces acquisition time of the radiographic parameters by eighty-five percent and entirely eliminates data entry. Most importantly, the XPO Dite minimizes inter-rater variability and increases accuracy and repeatability.

The surgical data form records which procedure was performed, details of the steps performed, the method of fixation, whether a tourniquet, epinephrine, or dexamethasone was used, the type of anesthesia used and the range of motion following closure. Complications data is divided into two broad categories, either soft tissue or bone, each with multiple subcategories. The result of the complication and any surgical revision is recorded and a space is provided for elaboration. This data may ultimately prove to be the most important in the study when correlated with the remaining data.

A software program is currently being written for data entry of the questionnaire forms into a database and for data export into the SAS Institute statistical analysis software. Repeated measures analysis of variance with between and within parameters will be used to detect significant changes among the categoricl variables. Otherwise, appropriate pair-wise comparisons will be made to determine the statistical significance of each hypothesis.

SUMMARY

The medical community is in the information age where medical outcomes will be utilized to optimize patient care and health. Decisions about type of care and future allocation of health care dollars will require proof of efficacy. This study aims to provide this information with regard to bunion surgery. We will show that bunion surgery improves patient health by decreasing pain and improving function. This study will provide information about optimization of care by comparing factors such as procedure selection, postoperative care and preoperative pain level. We will also provide the information needed to compare bunion surgery to other medical interventions by securing its place in the health care delivery system.

The future of clinical research is in the direction of patient-based validated outcomes scales. Medicare is leading the way and helping other third-party payers develop medical outcomes. Other health care professions are assuming a proactive stance and developing their clinical outcomes databases to establish the standard of care. The lack of prospective clincial outcomes in the podiatric literature may place the profession in a compromised position when competing for health care dollars in the future. To secure the profession's position in the health care market, we must provide health care organizations, especially third-party payers, with data that supports the surgical treatment of hallux abducto valgus, as well as other surgical and conservative procedures. The podiatric profession must recognize this and contribute to this literature or it will have difficulty obtaining recognition and health care dollars.

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