CHAPTER 16

# BUNION SURGERY: A Prospective Clinical Outcomes Study

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Hallux abducto valgus is one of the most common structural deformities seen in the practice of podiatric medicine with over 150,000 bunion surgeries performed annually. 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] There is not one simple solution for the correction of this complex deformity. This has lead to the development of over one hundred procedures for the surgical correction of bunion deformities. The success rates of these procedures are often judged on the surgeon's and/or patient's subjective impression. There have been many retrospective studies in the orthopaedic and podiatric literature that have evaluated the efficacy of bunion surgery.[2-22] Several studies were performed prospectively[22,23] but only one used a validated clinical outcomes measurement scales.[24]

There is an increased emphasis on validated measurement scales for assessment of clinical outcomes. Medicare's National Committee for Quality Assurance (NCQA) has adopted the SF-36 in their Medicare Health Outcomes Survey. The Medical Outcomes Trust (MOT), based in Massachusetts, was formed to develop and adopt universal outcomes assessment tools. They have also adopted the SF-36 as a generic measurement tool for health assessment. The SF-36 questionnaire has been integrated into the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) developed by the American Academy of Orthopaedic Surgeons (AAOS). 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 provide the national norms for outcomes.

These tools have been used to evaluate bunion surgery by the AOFAS. This latter study involved 311 bunion patients 195 of which completed a self reported questionnaire at 12 months. The authors concluded that, "significant improvement in pain, function, and satisfaction after bunion surgery performed by members of the American Orthopaedic Foot and Ankle Society."

The future of clinical research includes patient based validated outcomes scales. Medicare is leading the way and assisting other third party payers in developing medical outcomes based medicine. Our outcomes are being measured by other agencies. Other health care professions are assuming a proactive stance and developing their clinical outcomes databases to establish the standard of care. As a profession we must recognize this and contribute to this cause. Ultimately, the patients benefit.

## MATERIALS AND METHODS

The study design is a prospective clinical outcomes study. However, a control group was not incorporated. Most bunion patients that undergo surgery report that the pain is getting progressively worse. It is not practical or ethical to withhold surgery from this group, hence the lack of a control group. It could be argued that filling out forms on different dates may affect the reliability of the patient reported data. However, the self-reporting forms we have included are validated as repeatable measures of pain and health outcomes. The statistical model is a repeated measures design where each subject serves as the control. This model eliminates subject variability and increases the power of the statistical analysis.

Data was collected from patients who have consented to and have had surgical bunion correction. The clinicians that have participated in the study are Podiatry Institute faculty who have all completed the same residency program. The questionnaire used in this is based on several validated clinical outcomes measurement tools. The McGill Pain Questionnaire, and SF-36 score were included in this version of the questionnaire. Other parameters included radiographic analysis, clinical measures and demographic data. The clinical data includes relevant information such as chief complaint, associated deformities, range of motion, co-morbidities and activity level. The demographic questionnaire was based on questions found in the General Social Survey developed by the University of Michigan and questions found in the US Census Bureau survey. The questionnaire includes a total of twenty-five pages for the first year of the study. Each following year will require an additional four pages.

The SF-36 was developed by Q-Metric and consists of thirty-six questions with a multi-item scale measurement for eight health parameters. 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 since it has become the standard for health measurements in many medical fields. The SF-36 allows comparisons to be made with over 750 other studies that have researched the effect of many different medical interventions and healthcare delivery systems. This study is registered with Q-Metric with permission to use their SF-36 scale.

The McGill Pain Questionnaire is a validated scale that more precisely measures bodily pain. It includes a visual analog scale. The McGill pain questionnaire expands on bodily pain health concept included in the SF-36. We elected to include it in our study since pain is the leading health parameter we generally address with bunion surgery. This information allows for comparison with the orthopedic literature as well as other studies for functional outcomes.

Radiographic parameters are measured using the X-PODite 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 landmarks. 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 forwarded copies of the radiographs to have them measured. This procedure eliminates inter-rater variability and increases accuracy and repeatability.

Surgical data includes the procedure, the details of the steps performed, the method of fixation, whether a tourniquet, epinephrine, or dexamethasone was used, and the type of anesthesia used. The first postoperative evaluation form includes information regarding medications and dosing, weightbearing status and six clinical signs. The clinical signs are scaled from one to four and include edema, erythema, ecchymosis, bleeding, dehiscence, and infection. Similar forms are filled out at three months, six months and twelve months that also include range of motion. Data was also collected with regards to complications. Whether the complication is symptomatic is recorded. The type of complication is divided into two broad categories either soft tissue or bone each with multiple subcategories. The result of the complication and any revision surgery is recorded and a space is provided for elaboration.

## RESULTS

Two hundred and ninety five patients have been included in the study to date and are in different phases along the time line. The left foot underwent surgery 50% of the time and vice versa. The female to male ratio was 7 to 1. Mean weight and height were 153 lbs and 65 inches respectively. Demographic data including race, ethnicity, education, job description, and household income and class are shown in that order Tables 1 through 6. Tobacco use was present in 14% of the patients.

The mean duration of symptoms was 52 months with a range from 2 to 480 months. Sixty five percent had prior treatment with shoe gear modification, NSAID therapy, custom or over the counter orthotics and prior surgical intervention in that order of prevalence. Twenty-one percent had undergone prior foot surgery. Hammertoe syndrome of the second digit was present in 28.2%, metatarsalgia in 32.1% and an intractable plantar keratosis or tyloma in 14.0% of the patient population.

The majority of the patients underwent an Austin (51%) or Kalish (9%) modification representing over 60% of the procedures performed. Utilizing a step-wise approach to bunion correction results in ancillary maneuvers for correction of the deformity. Twenty five percent of the patients underwent adjunctive hammertoe correction of a lesser digit and an additional 3% underwent an additional procedure other than hammertoe correction.

Radiographic measurements were taken for inter-metatarsal angle, hallux abductus angle, tibial sesamoid position, hallux abductus interphalangeus, first metatarsal declination angle, proximal articular set angle, and first metatarsal protrusion distance, tibial sesamoid second metatarsal distance preoperatively, at 3 months, six months, and twelve months. Observing the Bonferroni equality for multiple comparisons with six comparisons for each parameter statistical significance was positive at $P < 0.0083$ (0.05/6). This method for determining statistical significance in pair-wise comparisons is conservative. Therefore, if there is statistical significance found it is unlikely an error.

The McGill results for the pain descriptors, pain index and visual analog score were reported. Since there were ten comparisons made for each parameter the p level to achieve statistical significance for the McGill parameters was $P < 0.005$ (0.05/10). With ten comparisons the Bonferroni equality may be regarded as over conservative. When statistical differences exist between ten comparisons using this test it is extremely rare that it would be due to chance.

The SF-36 score means for bodily pain, physical function, role physical, social function, general health,

vitality, role emotional and mental health were reported and the statistical significance level was the same as for the radiographic parameters.

## DISCUSSION

A significant majority of the patients undergoing bunion correction are female. This is consistent with studies including the AOFAS study.[24] A majority of the patients treated in this study were white and European-American. The education level demonstrated a fairly even distribution from less than high school to graduate professional degree. The job description with the highest representation was professional/technical (e.g., doctor, teacher, engineer, artist, accountant). A majority of the patients (51.8%) undergoing surgery had household income in excess of $75,000 with 20.5% above $100,000. The self reported social class most represented was the middle class with 64.3% of the population with and additional 13% listing upper class.

A majority of the patients had light duty, sedentary or desk jobs. However, one third have jobs requiring them to stand and another 7% have heavy-duty positions. A significant majority of the patients participated in some level of exercise with almost half of all patients exercising at least three times per week. For the patients in this study function is critical since work duties require standing and walking and exercise is of major importance.

The most frequent chief complaint was bump pain reported in almost 80% of the patients questioned. A distant second was joint pain with less than 20%. As a secondary complaint 40% listed joint pain and 36% did not have a secondary complaint. Thirteen percent listed symptoms consistent with limitus as their secondary complaint.

Combining the Austin and the Kalish modification captured 60% of the procedures performed. The only other procedure with over 10% of the population was the modified McBride. The remaining patients had a base wedge, Silver, Reverdin or one of its modifications, fusion, implant or Lapidus. Rarely are these procedures performed in isolation without ancillary soft tissue and osseous procedures. There is typically a step-wise approach to the procedure combining ancillary steps. Adductor tendon release, fibular sesamoidal ligament release, lateral capsular release and medial capsulorraphy are all perofmred in a majority of the procedures. It must be kept in mind that these ancillary procedures may not be required or are excluded in the definition of some of the primary procedures. The remaining ancillary steps including fibular sesamoid excision, flexor hallucis brevis tenotomy, adductor tendon transfer, subchondral drilling, externsor hallucis tenotomy and extensor hallucis longus lengthening were all performed less than fifty percent of the time. Absorbable fixation was the most common type of fixation used in this study to date. Screws and K-wire fixation were next in that order of prevalence. It is likely that this will be reversed over time as more of the surgeons in this study use traditional screws or k-wires but had to date enrolled fewer patients. Over 75% of the patients did not undergo any adjunctive procedure. Of those that had an adjunct procedure, hammertoe surgery was the most common procedure with 25%. The method of anesthesia was most often monitored anesthesia care. General anesthesia, spinal and simple local were also used to a much lesser degree. Postoperatively about a third received an injection of dexamethasone and another third ketorolac, and the last third did not receive an injection.

The radiographic parameters that would be affected by bunion correction namely, intermetatarsal angle, hallux abductus angle, tibial sesamoid position, hallux interphalangeus angle, proximal articular set angle, and metatarsal protrusion distance all had significant changes between the preoperative and the three month assessments. Without exception there were no significant differences detected between three, six and twelve month radiographic measurements. In all cases but one there was a significant difference between the preoperative evaluation and all three different postoperative measurements. The one exception was for the first metatarsal protrusion distance. There was no statistically significant difference between the preoperative and twelve-month evaluation, although there was between the preoperative and three and six month evaluations. There were no differences found between any of the measurements for first metatarsal declination and the tibial sesamoid second metatarsal distance. There was not a return of the deformity over the twelve months following surgery.

There were three parameters calculated for the McGill questionnaire, pain descriptors, pain index and visual analog scale for pain. The descriptors were fifteen in number with a range in values from zero to three. The values shown are a percentage based on a normalized score over a range from zero to forty-five subtracted from one hundred. The higher the score the lower the pain level. A score of one hundred would be no pain. We did not anticipate reduced pain at the first post-operative evaluation, performed within a week of the procedure. There were significant reductions in the pain descriptors between pre-operative, post-operative and three-month evaluations. Beyond three-months there were no significant changes with the pain descriptor scores.

Evaluating the pain index a score from zero to five with five being the highest level of pain, we see continuous reduction in this score at each time interval. The reductions in the pain index score between each time interval with the exception of between six and twelve months were statistically significant, although the trend did continue into the twelfth month. The visual analog scale followed the same trend as seen with the pain index with statistical significance up until the twelve month.

The bodily pain index from the SF-36 questionnaire showed a continuous trend of decreased pain at each of the time intervals. Statistically significant differences were seen between pre-operative, three month and six month time intervals. Although there was a trend at each time interval towards improved physical function, it was not until between three and six months before a significant difference was detected. Role physical and social function decreased between the pre-operative value and the third month. This difference was not statistically significant in either case. Between three and six months both scores improved significantly. Further improvement was seen at twelve months without statistical significance. Both vitality and general health had trends of modest increases between pre-operative and the first two time intervals. However at twelve months they had small decreases in these two parameters. There were no statistically significant differences seen with general health, but vitality was significantly different between three and six months. Role emotional and mental health showed no appreciable trends or statistical significance.

The only published data on the patient outcomes for bunion surgery were produced by Thordarson et al.[24] They used two questionnaires to evaluate patients preoperatively and at six and twelve months following surgery. One of their questionnaires included the SF-36. Although the paper references two tables, they are not included in the article. They found increases of five or more points for physical function, role-physical, bodily pain, and role emotional at six months. The only score not to maintain this increase was role emotional. For physical function, role-physical and bodily pain we saw increases of greater than ten points at six months with values of 11.1, 14.2 and 15.6 respectively. In all three cases we saw further improvement in the scores from six to twelve months. Our data shows that social function, vitality and general health would also meet the five-point delta criteria at six months. Although general health and vitality had decreases at twelve months they maintained a five-point differential compared to preoperative levels. Social function improved slightly during this last time interval.

Range of motion decreased just over 4 degrees from preoperative to three months but then improved eight degrees to go beyond the preoperative value at six months. Statistically the differences between three-month values and all other values were significant. However, the improvement seen at six and twelve months was not statistically significant compared to the pre-operative value. Approximately eight degrees of plantarflexion was lost following surgery. This was significant and no changes were seen after three months.

## CONCLUSION

Radiographic measurements showed significant reductions in the intermetatarsal, hallux abductus, proximal articular set, hallux interphalangeus angles and tibial sesamoid position. Over the twelve month period there was no significant reversal of the changes made following surgery. The improvement in pain at the first post-operative visit following surgery as seen with the McGill parameters was counterintuitive. We anticipated a short-term increase in pain. We included the McGill immediately after surgery to measure this. We did not measure function with the SF-36 at this time since we were asking patient to restrict their activity level. Further decrease in pain was seen at three and six months in all three McGill parameters and the SF-36 bodily pain score. However, functional outcomes including physical function, role physical, social function and vitality did not improve until six months. In fact between three and six months there were decreases seen in role physical and social function. It may not be coincidental that dorsiflexion range of motion decreased slightly at three months and improved six months. It is not possible to discern if the decrease in motion or the decrease in activity is causal.

This study is unique in its approach to obtain both objective measures and clinical outcomes in a prospective study involving bunion surgery. We are currently enrolling additional patients and plan to present further data annually. The data presented here is a pilot study of a continuing effort funded by the American Podiatric Medical Association.

As the database grows we plan to evaluate the data for confounding factors. Stratification of the health outcomes by demographic data, surgical procedure and objective measures, such as the radiographic data, should provide additional insight to optimize surgical care. Additional studies will be designed to answer new questions based on the data analyzed in this database. The goal is optimization of clinical outcomes and improved quality of life following bunion surgery and other treatments of the foot.

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