CHAPTER **25**

SURROGATE MARKERS FOR PATIENT SATISFACTION AFTER HALLUX VALGUS SURGERY

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INTRODUCTION

Correction of hallux abducto valgus (HAV) is commonly performed by foot surgeons throughout the world, and every year approximately 171,000 bunionectomies are performed in the US (1). Multiple variables have been theorized to influence patient outcomes following bunionectomy, and it is thought that patient satisfaction following HAV repair varies with the severity of deformity, comorbidities, operative interventions, the postoperative course, as well as the degree of structural realignment achieved intra-operatively. Unfortunately, the association of structural realignment of the first ray with postoperative patient satisfaction remains unclear, even though restoration of the radiographic appearance of the first ray is generally thought to correlate with satisfaction (2, 3). The prevalence of this deformity and its unresponsiveness to conservative therapy leads clinicians and patients to proceed with attempts at surgical intervention, thereby necessitating identification of early postoperative surrogate endpoints to aid clinicians in predicting successful surgical outcomes. Identification of early postoperative surrogate markers, such as radiographic measurements, for long-term patient satisfaction following HAV repair would be a useful tool for surgeons, and could be used to predict the long-term outcome at an early stage following the surgery.

To date, there have been no published peer-reviewed studies that show a statistically or clinically significant correlation between long-term postoperative patient satisfaction and the radiographic realignment of the first ray following hallux valgus correction. Numerous published works describe normal radiographic values for the first intermetatarsal angle, metatarsal protrusion distance, tibial sesamoid position, hallux abductus angle, and first metatarsophalangeal joint dorsiflexion (4-7). However, none of these studies correlates alteration of any of these independent variables with long-term patient satisfaction with the surgery.

The primary aim of this preliminary investigation was to measure the association of skeletal realignment, along with other variables, with long-term patient satisfaction following surgical repair of HAV deformity. The secondary aim was to explain the outcome in clinical terms. By design, this pilot investigation was intended to provide insight into the relationship of the clinical variables with patient satisfaction, in preparation for the development of a well-designed prospective cohort study.

PATIENTS AND METHODS

We analyzed data that were obtained in a prospective fashion, and pertained to a series of 27 consecutive patients who had undergone unilateral HAV correction with and without adjunct hammertoe or lesser metatarsal surgery. All of the operations were performed by the senior author (DSM), and the operations took place during the period extending from March 2008 to December 2008. Furthermore, to be included in the series, patients had to have at least 6 months of postoperative follow-up. Single-staged hallux valgus repairs, including proximal and distal osteotomies and first metatarsocuneiform fusions, with adductor hallucis tendon transfer, and with or without hammertoe or lesser metatarsal surgery, were included. The choice of osteotomy fixation and postoperative care was determined at the discretion of the surgeon. The primary outcome of interest was subjective patient satisfaction (yes or no) at the time of the latest postoperative follow-up visit. Secondary outcomes included the ability to wear the desired shoes, as well as the change in pain, foot-related quality of life, and the radiographic measurements. Pain was measured using the 100-mm visual analog scale (VAS) score, and foot-related quality of life was measured using the Bristol Foot Score (BFS) (8). The following independent variables were ascertained and recorded: age and age category (years), sex, body mass index (BMI), and BMI category, adjunct procedures, tourniquet time, the presence of a crossover second toe, weeks to radiographic evidence of bone healing, duration of postoperative nonweight bearing, and months of follow-up. The following preoperative and postoperative radiographic measurements were also recorded: first

Table 1

STATISTICAL DESCRIPTION OF DEMOGRAPHIC AND OUTCOME VARIABLES (EXCLUDING RADIOGRAPHIC FINDINGS) (N = 27 PATIENTS THAT UNDERWENT UNILATERAL BUNIONECTOMY)

Risk factor or outcome variable		Median (range), or count (%)
Age (years)		46 (19,71)
Age category (years)	<45	13 (48.15)
	45-54	5 (18.52)
	55-64	7 (25.93)
	≥65	2 (7.41)
Body mass index		26.1 (18.6, 31.2)
Body mass index category	Normal	7 (25.93)
	Overweight	17 (62.96)
	Obese	3 (11.11)
Sex	Female	17 (62.97)
	Male	10 (37.03)
Procedure (muscle-tendon balance +)	Distal osteotomy	20 (74.07)
	Proximal osteotomy	4 (14.81)
	Lapidus	3 (11.11)
Adjunct procedure	None	6 (22.22)
	Any hammertoe	15 (55.56)
	Any metatarsal	2 (7.41)
	Any hammertoe or metatarsal	4 (14.81)
Tourniquet time (minutes)		40 (33, 61)
Satisfied with shoe	Preoperative	12 (44.44)
	Postoperative	22 (81.48)
Nonweight bearing (weeks)	0	20 (74.07)
	5	3 (11.11)
	6	4 (14.81)
Bone healed (weeks)		6 (6, 9)
Bone healed category (weeks)	6	24 (88.89)
	7	1 (3.7)
	8	1 (3.7)
	9	1 (3.7)
Duration of follow up (months)		16 (11, 22)
Complication (one involved the first ray)		3 (11.11)
Satisfied		25 (92.59)†
Preoperative VAS pain		84 (39, 100)
Postoperative VAS pain		33 (0, 51)
Change VAS pain*		49 (4, 94)
Preoperative BFS		59 (49, 69)
Postoperative BFS		17 (0, 47)
Change BFS*		41 (18, 59)

*Change was statistically significant ($P < 0.0001$)

†The incidence of long-term postoperative satisfaction was 92.59% (25 of 27 patients)

intermetatarsal angle (IMA), hallux abductus angle (HAA), tibial sesamoid position (TSP), first metatarsal protrusion distance, and the Seiberg index (9).

The data were analyzed with attention paid to type and distribution. A statistical description of the case series was undertaken, along with tests of the null hypothesis to determine whether or not significant differences existed between outcomes based on risk factors. Spearman's rank correlation coefficients were also computed for the independent and outcome variables. Statistical significance was defined at the 5% ($P \leq 0.05$) level.

RESULTS

Table 1 depicts demographic and outcome variables describing the entire series of patients. The overall median age of the participants was 46 years (19-71) years, and 17 (62.96%) were female and 10 (37.03%) were male. The median duration of follow-up was 16 (11-22) months. The overall median BMI was 26.1 (18.6-31.2), and 20 (74.07%) were either overweight or obese. Twenty (74.07%) of the patients underwent bunionectomy with the use of a distal first metatarsal osteotomy, whereas 7 (25.93%) underwent either a proximal metatarsal base osteotomy or a Lapidus fusion.

With regard to adjunct procedures performed along with bunionectomy, only 6 (22.22%) of the operations did not include an adjunct surgical procedure, and 15 (55.56%) of the patients underwent adjunct hammertoe repair. Overall, the median tourniquet time was 40 minutes (33-61 minutes). Prior to the operation, 12 (44.44%) of the patients were satisfied with their shoe gear, whereas following the surgery 22 (81.48%) of the patients were satisfied with their shoes. Twenty (74.07%) of the patients were managed with immediate postoperative weight bearing, and these were the same patients that had been treated with the use of a distal first metatarsal osteotomy. The overall median time to bone healing was 6 weeks (6-9 weeks), and in 24 (88.89%) of the patients the bone was deemed healed by 6 weeks.

Three (11.11) patients experienced complications, all of which were minor, and only 1 (3.7%), a delayed union, involved the first ray. Following the operation, 25 (92.59%) of the patients were subjectively satisfied with the results of the bunionectomy. The VAS pain score improved by 49 mm (4-94 mm), and the difference between the preoperative and postoperative pain scores was statistically significant ($P < 0.0001$). Similarly, the BFS improved by 41 points (18-59 points), and this difference was also statistically significant ($P < 0.0001$).

Table 2 depicts the radiographic findings, which revealed statistically significant differences for all of the parameters when the preoperative and postoperative measurements were compared. Overall, the first IMA reduced by 10° (7°-18°), and this change was statistically sig-

Table 2

STATISTICAL DESCRIPTION OF THE RADIOGRAPHIC FINDINGS (N = 27 PATIENTS THAT UNDERWENT UNILATERAL BUNIONECTOMY)

Radiographic variable	Median (range), or count (%)
Preoperative first intermetatarsal angle (°)	14 (11, 21)
Postoperative first intermetatarsal angle (°)	3 (1, 7)
Change first intermetatarsal angle (°)*	10 (7, 18)
Preoperative hallux abductus angle (°)	24 (18, 36)
Postoperative hallux abductus angle (°)	5 (2, 12)
Change hallux abductus angle (°)*	20 (13, 33)
Preoperative tibial sesamoid position	6 (5, 7)
Postoperative tibial sesamoid position	2 (1, 4)
Change tibial sesamoid position*	4 (2, 5)
Preoperative first metatarsal protrusion (mm)	0 (-2, 2)
Postoperative first metatarsal protrusion (mm)	0 (-2, 1)
Change first metatarsal protrusion (mm)†	1 (-1, 3)
Preoperative Seiberg index (mm)	1 (0, 3)
Postoperative Seiberg index (mm)	1 (0, 2)
Change Seiberg index (mm)‡	0 (-1, 2)

* Wilcoxon signed ranks test, $P < 0.0001$
† Wilcoxon signed ranks test, $P = 0.0151$
‡ Wilcoxon signed ranks test, $P = 0.0039$

nificant ($P < 0.0001$). The HAA reduced by 20° (13° to 33°), and the tibial sesamoid position reduced by 4 (2-5), and these differences were also statistically significant ($P < 0.0001$). Comparison of the preoperative to postoperative first metatarsal protrusion distance revealed an overall 1 (-1 to 3) mm change ($P = 0.0151$), and the Seiberg's index changed 0 (-1 to 2; $P = 0.0039$).

Table 3 depicts the prevalence of the risk factors and outcomes, stratified by whether or not the patient was subjectively satisfied at the long-term follow-up visit. Inspection of these results showed that only age <45 years, and the preoperative presence of a crossover second toe, were statistically significant. In fact, 52% of the satisfied patients were <45 years of age, and none of the dissatisfied patients were <45 years of age. Moreover, 2 (100%) of the dissatisfied patients displayed a crossover second toe deformity prior to the bunionectomy procedure, whereas on 4 (16%) of those that were satisfied displayed a crossover second toe before the bunionectomy was performed.

We also performed correlation analyses in an effort to determine the linear relationship between important clinical variables and long-term outcomes. To this end, we used Spearman's rank correlation coefficient (ρ) because it measures the strength of the linear dependence between variables, and ranges from $1 \geq \rho \geq -1$. A correlation coefficient of 1 indicates perfect positive correlation, whereas -1 indicates perfect negative (inverse) correlation, and 0 indicates no linear association. By convention, a correlation coefficient >0 to ≤4 indicates a weak linear association, whereas a value of 5 indicates a moderate association, and a value ≥6 indicates a strong linear association.

Correlation of the immediate postoperative radiographic measurements to long-term patient satisfaction revealed weak to moderate inverse relationships for realignment of the first IMA, HAA, and first metatarsal protrusion distance, and a weak positive correlation with the Seiberg's index; however,

Table 3

PREVALENCE OF RISK FACTORS BY OUTCOME (N = 27 PATIENTS THAT UNDERWENT UNILATERAL BUNIONECTOMY)

Risk factor variable	Not satisfied (n = 2)	Satisfied (n = 25)	*P**
Age (years)	57.5 (49, 66)	44 (19, 71)	0.1947
Age <45 years	0	13 (52)	0.045
Age 45-54 years	1 (50)	4 (16)	
Age 55-64 years	0	7 (28)	
Age ≥65 years	1 (50)	1 (4)	
Male sex	1 (50)	9 (36)	0.693
BMI	26.95 (26, 27.9)	26.1 (18.6, 31.2)	0.853
Normal (BMI 18.5-24.9)	0 7 (28)	0.53	
Overweight (BMI 25-29.9)	2 (100)	15 (60)	
Obese (BMI ≥30)	0	3 (12)	
MTB + distal osteotomy	1 (50)	19 (76)	0.18
MTB + proximal osteotomy	0	4 (16)	
MTB + Lapidus	1 (50)	2 (8)	
No adjunct procedure	0	6 (24)	0.631
Adjunct hammertoe	2 (100)	13 (52)	
Adjunct lesser metatarsal	0	2 (8)	
Adjunct hammertoe + lesser metatarsal	0	4 (16)	
Crossover second toe preoperative	2 (100)	4 (16)	0.006
Tourniquet time (minutes)	43.5 (36, 51)	40 (33, 61)	0.8529
Nonweight bearing (weeks)	2.5 (0, 5)	0 (0, 6)	0.5875
Bone healed (weeks)	7 (6, 8)	6 (6, 9)	0.0749
Follow up (months)	15 (12, 18)	16 (11, 22)	0.9257

*Chi- square test for trend across ordered groups, Wilcoxon's rank sum (Mann-Whitney U) test for continuous data.
BMI = body mass index; MTB = muscle-tendon balance

none of these correlations was statistically significant. When a number of clinically important variables were correlated with clinically important outcomes (Table 4), the following statistically significant correlations were identified: postoperative first IMA ≤6° and ≥40% pain reduction (r = 0.4703; *P* = 0.0133) (Figure 1), postoperative ability to wear the desired shoe and long-term subjective satisfaction (r = 0.5933; *P* = 0.0011) (Figure 2), preoperative crossover second toe and long-term subjective satisfaction (r = -0.5292; *P* = 0.0045) (Figure 3), and postoperative ability to wear the desired shoe and ≥ 30% improvement in the BFS (r = 0.4114; *P* = 0.0330) (Figure 4).

Table 4

CORRELATION BETWEEN RADIOGRAPHIC AND CLINICAL FINDINGS AND LONG-TERM OUTCOMES

Correlations	Spearman's ρ	*P*
Postoperative first IMA ≤6° and ≥40% pain reduction	0.4703	0.0133
Postoperative ability to wear desired shoe and satisfaction	0.5933	0.0011
Preoperative crossover second toe and postoperative satisfaction	-0.5292	0.0045
Postoperative ability to wear desired shoe and ≥30% improved BFS	0.4114	0.0330

*Correlation by Spearman's rank correlation coefficient (ρ)

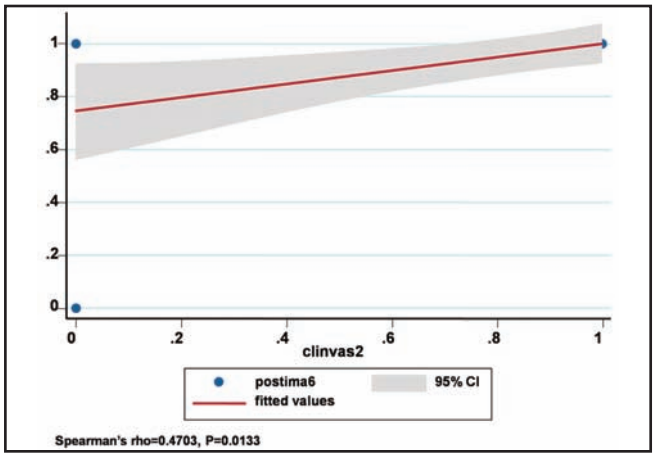

Figure 1. Correlation of postoperative first IMA ≤6° with ≥40% long-term pain reduction.

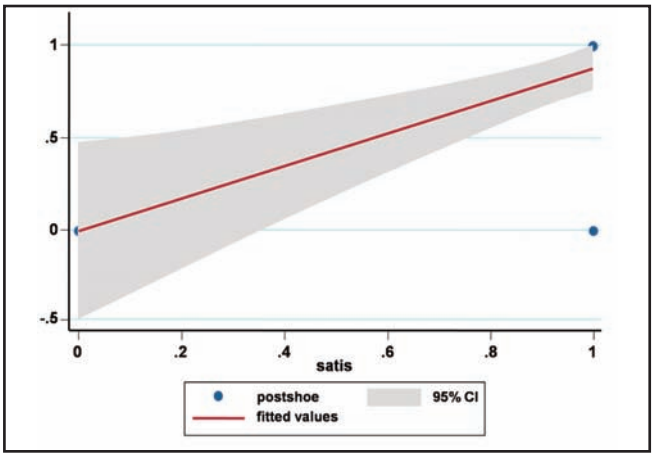

Figure 2. Correlation of postoperative ability to wear desired shoe with long-term subjective satisfaction.

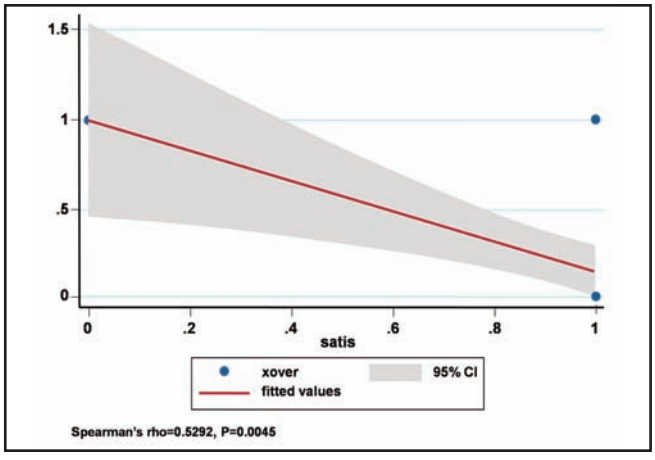

Figure 3. Correlation of preoperative crossover second toe with long-term postoperative satisfaction.

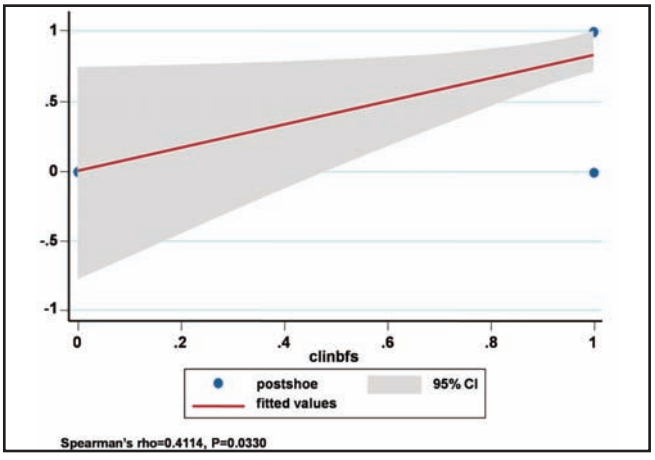

Figure 4. Correlation of postoperative ability to wear desired shoe with ≥30% improvement in long-term BFS.

DISCUSSION

In this case series, the incidence of long-term subjective satisfaction following unilateral bunionectomy was 92.59%. And, based on the results of this preliminary investigation, immediate postoperative first ray radiographic measurements are, at best, moderate surrogates for patient satisfaction, pain reduction, and foot related quality of life following HAV surgery. These findings, however, did not meet statistical significance, and we feel that this may have been due to the fact that only 27 patients were involved in the analyses (a type 2 statistical error, where we did not have enough statistical power to detect a significant difference). Despite our inability to identify immediate postoperative, isolated surrogate radiographic markers for long-term satisfaction following bunion surgery, we were able to identify several clinically and statistically significant results, namely: 1) patients <45 years of age were more likely than older patients to be satisfied at the long-term follow-up visit, 2) a positive correlation between an immediate postoperative first IMA ≤6° and ≥40% pain reduction, 3) a positive correlation between the postoperative ability to wear the desired shoe and long-term subjective satisfaction, 4) an inverse correlation between the preoperative presence of a crossover second toe and long-term postoperative subjective satisfaction, and 5) a positive correlation between the postoperative ability to wear the desired shoe and ≥30% improvement of the BFS. The strongest correlation that we observed was the ability to wear the desired shoe following bunionectomy with long-term patient subjective satisfaction.

Like most case series, a number of methodological limitations threatened the validity of our findings. We have already noted our concerns related to the small sample size, which may have imparted a type 2 statistical error (failure to identify a statistically significant differences when, in fact, one existed). Furthermore, in this preliminary study, the surgeons who performed the operations also measured the radiographic variables and abstracted the data from the medical records, which they also created, and this probably imparted a number of biases. Still further, we did not undertake explanatory analyses beyond correlation, and therefore cannot make any statement as to the potential influence that confounding or effect modification may have had on our results. Finally, we did not undertake a sensitivity analysis that would be required in order to determine the potential influence of unmeasured variables on the outcomes that we observed.

In conclusion, in this pilot investigation, we were not able to identify any statistically significant immediate, isolated postoperative radiographic surrogate markers for long-term patient satisfaction following bunionectomy. It appears, however, that patients <45 years of age are more likely to be satisfied, that reduction of the immediate post-operative first IMA to ≤6° correlates with ≥40% long-term pain reduction, the postoperative ability to wear the desired shoe also correlates with ≥30% improvement in the BFS, the preoperative presence of a crossover second toe inversely correlates with long-term subjective satisfaction, and the postoperative ability to wear the desired shoe strongly correlates with long-term subjective satisfaction following bunionectomy. Based on these results, we recommend that further investigation be performed on a larger sample of patients, in order to allow for more definitive delineation of the risks that are more likely to influence patient satisfaction after hallux valgus surgery. We also believe that the results of this investigation can be used in the development of prospective cohort studies, and randomized controlled trials, that focus on patient satisfaction following HAV surgery.

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