Unilateral Versus Bilateral Same-Day Surgery Outcomes for Hallux Valgus: An Eight Year Prospective Cohort Study

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Objective: To evaluate patient-reported outcomes and satisfaction 8 years following hallux valgus (HV) surgery and compare unilateral and bilateral cases.

Methods: Prospective Cohort with postal follow-up patient survey. Consecutively-recruited patients self-completed the Manchester-Oxford Foot Questionnaire (MOxFQ) ≤ 4 weeks before surgery. Of 91 patients proceeding to one-stage HV surgery (on 124 feet, 23 (18.3%) receiving further surgery), 69 (78%) of 88 eligible patients (representing 95/124, 77% feet: 43/95, 45.3% unilateral, 52/95, 54.7% bilateral) returned a follow-up questionnaire including the MOxFQ and standard satisfaction rating for surgical outcome around 8 years (range 7.4 to 8.9) later.

Results: Of 69 respondents, mean pre-operative age 49.8 (SD 12.5) years, 66 (95.7%) were female. Reporting on 95 feet, 78 (82.1%) patients were either ‘Very pleased’ (All 53/95, 55.8%; unilateral: 22/43, 51.2; bilateral 31/52, 59.6%) or ‘Fairly pleased’ (All 25/95, 26.3%; unilateral 13/43, 30.2; bilateral 12/52 23.1) with the outcome; with 17/95 (17.9%) ‘Not very pleased/very disappointed’. Change in all 3 MOxFQ scales showed a significant linear relationship with satisfaction ratings (ANOVA p<0.001). The MOxFQ pain scale showed greatest change (decrease in score) associated with being ‘Very pleased’ (mean (95% CI) reduction in score: Pain -48.0 (-42.8 to -53.2); Walking/Standing -38.4 (-32.0 to -44.8); Social-Interaction -43.1 (-36.9 to -49.4)

Conclusions: At 8 years following HV surgery, the majority of patients were pleased with the outcome. Simultaneous bilateral HV correction produced results that were no worse than unilateral correction. Change in the MOxFQ pain scale is particularly important in interpreting patients’ satisfaction with surgery.

Key Words: Foot pain, accessory bone, os supranaviculare, Pirie’s bone

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Hallux valgus (HV) is a common condition, particularly in women.∗,†,‡ HV can present unilaterally or bilaterally and is characterized by lateral deviation of the big toe and medial deviation of the first metatarsal with progressive subluxation of the first MTP joint. The condition can be painful and disabling and has been shown to have a detrimental effect on quality of life.∗
It is one of the most common indications for foot surgery, where between a quarter and a third of patients are dissatisfied with the outcome; although many factors can affect outcomes and satisfaction.

The evaluation of outcomes following HV correction tend to represent a relatively short period (i.e. 12 months or less) following surgery with few studies involving validated patient-reported outcome measures. Standardized patient-reported methods of assessing outcomes, (particularly those devised with patients’ input), reflect the patients’ rather than the clinicians’ perspective and are independent of the surgical team.

Where HV is bilateral, the question of whether patients do better to have both feet treated at the same time, or not, has received some attention, although again, outcomes evaluation has tended to be relatively short-term and not patient focused.

This paper presents patient-reported outcomes data based on a service evaluation survey conducted of consecutive patients who had received surgery for HV at one center, between 7 and 9 years previously, and who had provided baseline data prior to their surgery. Results are also broken down to compare patients who had unilateral versus bilateral HV surgery.

**Methods**

Local ethics committee approval was obtained (Applied and Qualitative Research Ethics Committee reference A02.009) for the original study; postal service evaluation survey approved by the institution’s Integrated Governance Committee (August 2011).

At baseline 100 out of 111 consecutive patients were approached and consented to take part, 38 of whom were booked for bilateral HV correction. Of these, 91 (/100) patients proceeded to surgery, of whom, 33 (/91, 36%) had bilateral surgery (total=124 operations/feet). All surgery was completed on the one day (i.e. no 2-stage operations).

Prior to conducting the postal survey, patients’ current address details were checked through the hospital information system. Questionnaires were mailed together with cover letters and a stamped addressed envelope. Where any questionnaires were returned as ‘unknown’ the patient’s last known GP practice was contacted by a member of the foot and ankle surgical team. In all other cases of non-response after 4 weeks, a reminder letter was sent out with a second copy of the survey questionnaire.

Overall, 2 patients were known to have died and one had emigrated. Of the remaining 88 eligible patients, 69 (/88, 78%) returned a completed follow-up survey questionnaire, with no response obtained from a further 19 (/88, 22%) patients. Of the 69 respondents, 26 (38%) were bilateral cases who contributed outcome data regarding two foot (HV) operations. Thus 69 patients completed questionnaires regarding ~8 year outcomes for 95 operations/feet. Their mean pre-operative age was 49.8 (SD 12.5) years; 66 (66/69, 95.7%) were female. The mean period of follow-up (original operation date until date of survey completion) was 8.03 (SD 0.37, range 7.41 to 8.87) years.

**Assessments**

Patients completed the Manchester-Oxford Foot Questionnaire (MOxFQ) for each foot having surgery as well as the SF-36 general health survey (completed once per patient), at a pre-admission clinic, within 4 weeks prior to surgery. These measures were completed again as part of the 2011 postal survey.

The MOxFQ has previously been validated with patients undergoing HV surgery. It was subsequently revalidated in a separate study involving all patients undergoing foot or ankle surgery in a 12 month period, at one regional center. It contains 16 items, each with 5 response options, comprising 3 separate underlying dimensions: foot pain (5 items), walking/standing problems (7 items) and issues related to social interaction (4 items), including feelings of self-consciousness about foot/footwear appearance (‘cosmesis’).
Item responses are each scored from 0 to 4, with 4 representing the most severe state. The scale score representing each dimension is produced by summing the responses to each item within that dimension. Raw scale scores are then converted to a 0 to 100 point scale (100=most severe).

The SF-36 contains 36 items and is a widely used generic health status instrument. It provides scores on 8 dimensions of health: physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, mental health, energy/vitality, bodily pain and general health perceptions over the last 4 weeks. Scores for each dimension are produced by summing the responses to each item within that dimension and then converting the raw scores to a 0 to 100 point scale, (100= good health) general population norm set at 50, SD 10.

The postal survey also included a transition item, ‘How are the problems related to your foot now, compared to before your surgery?’; response options: no problems now, much better, slightly better, no change, slightly worse, much worse), and 3 questions regarding patients’ satisfaction with the outcome (‘Overall, how pleased have you been with the result of the surgery on your foot?’; ‘How pleased are you with the appearance of your foot?’; ‘How pleased are you with the range of shoes that you can wear?’); each with response options: ‘Very pleased’, ‘Fairly pleased’, ‘Not very pleased’, ‘Very disappointed’.

The transition and satisfaction items were asked in relation to each foot that had received surgery approximately 8 years previously. Additional questions asked whether the patient had received further surgery on the same foot since the original operation, and whether or not the patient currently had a problem with their other (contralateral) foot. A surgeon also checked for details of any subsequent foot surgery via the hospital patient information system.

Statistical analysis

Power calculations had determined that a sample size of 100 would give 80% power to detect, at p<0.05, a difference in proportions of 25%-30% and a medium effect size of around 0.55 between two groups of equal size. Data analysis was undertaken within SPSS release 17.0. Data are presented as mean (SD) at each assessment and mean change (SD) from pre-surgery to 8 years post surgery (post-surgical score minus pre-surgical score), with paired t-tests used to assess the statistical significance of any observed change. Statistical significance was taken at the 5% level throughout.

Some analyses (e.g. patient characteristics and SF-36 outcomes) have been conducted at the level of the patient (n=91 who had surgery, n=69 questionnaire respondents), while analyses of foot-specific outcomes and satisfaction with surgery have been conducted at the level of the foot (n=124 foot operations, involving n=95 completed questionnaires). Since 26 patients had bilateral operations, (which threatened the independence of patients’ observations on their two individual feet), baseline analyses were repeated three times: on the data for left feet only (n=61/124, 49.2%), right feet only (n=63/124, 50.8%), and for both feet (n=124; with 52 patients contributing data for both left and right feet). The results were, in fact, very similar for all analyses, and thus only the analyses that combined data for left and right feet are presented here.

The effect size (ES) statistic has been used to demonstrate the magnitude of change detected by the different outcome measures. This is calculated by dividing the mean change in scores (post-surgical score minus pre-surgical score) by the pre-surgical SD, this standardization by the SD allowing direct comparison to be made between instruments with different scales.

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An ES of 1.0 (or -1.0 for scales in which improvement is associated with a decrease in score) is equivalent to a change of one SD in the sample. Values of 0.2, 0.5 and 0.8 are typically regarded as indicating small, medium and large degrees of change, respectively.\textsuperscript{15,16}

The relationship between MOxFQ change scores and four levels of response on the satisfaction with surgery rating have been explored using analysis of variance (ANOVA) test for linearity and Tukey post-hoc tests.

Results

Survey respondents versus non-respondents

Survey non-respondents were somewhat more likely to be male, younger, and employed, than respondents (no differences were statistically significant), but were no more likely to have received bilateral surgery on the original operation date. Respondents and non-respondents did not differ significantly with regard to the type of surgery that they received (Foot level analysis/ Respondents: Scarf procedure, with or without Akin 57/68, 83.8%; chevron 8/68, 11.8%; ‘another form of surgery’ 3/68, 4.4% versus Non-respondents: Scarf procedure, with or without Akin 17/21, 81.0%; chevron 4/21, 19.0%; ’another form of surgery’ 0/21, 0%); or with regard to the need to have subsequent surgery (including revision) to the same foot (Foot level analysis/ Respondents 17/95, 17.9% versus non-respondents 6/29, 20.7%). Respondents’ pre-operative MOxFQ scores were all somewhat higher (worse) than those of non-respondents, particularly for the Walking/standing scale, although they did not differ significantly [MOxFQ Walking/standing (W/S), Pain and Social-Interaction (SI) scores: Respondents’ mean (SD) scores: W/S 47.3 (25.5); Pain 55.3 (17.8); SI 47.7 (22.5) versus Non-respondents’ mean (SD) scores: W/S 38.5 (21.2); Pain 49.8 (22.6); SI 43.8 (22.2).]

Unilateral versus Bilateral patient characteristics

There were no significant differences in the characteristics of patients who received unilateral versus bilateral surgery in relation to age, sex, qualifications or work status. Unsurprisingly, while 15 of the 43 patients having unilateral surgery reported having a problem affecting the contralateral foot (at baseline), all patients having bilateral surgery reported this (15/43, 34.9% versus 26/26, 100.0%; p<0.001).

Outcomes

Person-level analyses

Table 1 shows pre-, post-operative and change scores, plus effect sizes (ESs), for the generic SF-36, for all patients, and separately for patients having unilateral and bilateral surgery.

Overall, with the exception of the Pain domain (ES 0.7), most of the SF-36 domains showed small to moderate (in terms of ES) increases in score (i.e., improvement) compared with patients’ pre-operative baseline measures ~8 years previously. The largest improvements in health status (i.e. ES ≥ 0.4) were all highly significant (P≥0.001).

SF-36 pre-operative scores were mostly slightly higher (better) in patients having unilateral, compared with those having bilateral surgery, although none of these differences were statistically significant (p value range 0.21 to 0.79). SF-36 scores were even more similar for unilateral and bilateral surgical groups when analyses were repeated after excluding patients who only had a unilateral foot problem at baseline (results not shown). Conversely, SF-36 post-operative scores were mostly lower (worse) in patients having unilateral, rather than bilateral surgery, although again, none of these differences were statistically significant (p value range 0.10 to 0.70).
Table 1 Mean pre-operative, 8 year post-operative and change values, plus effect sizes for SF-36 patient-reported sub-scales in all patients, and comparing those who received unilateral versus bilateral surgery to correct hallux valgus. [Patient-level analysis]
### Table 2

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*Number of feet represented in the analysis, where a pre- and ~8 year post-operative MOxFQ had been completed concerning a foot that received surgery.

Paired t-test calculates the statistical significance of any difference between the pre-operative domain score and the equivalent 8 year post-operative score within the unilateral versus bilateral surgical groups.

*p<0.05, **p<0.01, ***p<0.001: Statistical significance (t-tests) of changes between unilateral versus bilateral surgical groups. High absolute scores=most severe

Table 2. Mean pre-operative, 8 year post-operative and change values, plus effect sizes for MOxFQ patient-reported domains/sub-scales, representing all feet that received bunion surgery and comparing outcomes of operations that represented a unilateral versus bilateral procedures [Foot-level analysis].
The magnitude of the differences between the pre- and post-operative SF-36 scores, within the unilateral and bilateral groups, are shown most clearly by the ESs. (Table 1) Amongst those who had unilateral surgery, ESs for the SF-36 domains were all small (≤ 0.3) with the exception of the Pain domain, which was moderate (ES 0.6); while amongst those who had bilateral surgery, most of the SF-36 domains achieved moderate ESs (ES 0.5 to <0.8); although the ES for the Pain domain was large (ES 0.8).

A comparison of the SF-36 change score differences between the unilateral and bilateral surgical groups revealed differences to be statistically significant in 3 domains: Role Physical (Uni/Bi mean change, SD: 1.4, 30.5/ 20.7,30.7; p=0.02), Social Functioning (Uni/Bi mean change, SD: 3.6, 28.6/15.6, 21.6; p=0.03) and Mental Health (Uni/Bi mean change, SD: 3.6, 15.3/ 10.0, 12.4 p=0.004), with bilateral cases registering greater change on these scales than unilateral cases.
Foot level analyses

Within the period (~8 years) following the original operation, further surgery had been conducted on the same foot in 23 cases (23/124, 18.5%). Overall, each MOxFQ scale/domain registered a very large ES (WS -1.1, Pain -1.8, SI -1.3), representing decreases (i.e., improvement) from the pre-surgery baseline scores 8 years previously, with all related change scores highly significant (p<0.001). (Table 2) The magnitude of the differences/changes between the pre- and 8 year post-operative MOxFQ scores within the unilateral and bilateral subgroups, are shown by the ESs. Amongst those who had unilateral surgery, ESs for all 3 MOxFQ scale domains were large (≥ -0.8); while ESs amongst those who had bilateral surgery, were slightly larger (ES ≥ -1.1). These changes over time were all highly significant.

A comparison of the change score differences between the unilateral and bilateral groups revealed very similar (and statistically insignificant) mean change scores for the differences in W/S and Pain scales, but the change scores did differ significantly for the SI domain, (which assesses aspects of work and social participation, footwear and ‘cosmesis’), with bilateral cases registering greater change on this scale than unilateral cases (Uni/Bilateral mean change, SD: -19.8, 29.4 versus -36.9, 25.5; p<0.01). The difference between these change scores (of 17.1 score points) was greater than the Standard Error of Measurement (SEM) (11.92 score points) that has previously been estimated for this scale10.

Patient satisfaction [per foot]

Table 3 reports patients’ responses to the transition and satisfaction items asked in relation to each foot that received surgery. Comparisons are made between responses that relate to a unilateral operation versus those relating to each foot comprising a bilateral (same day) procedure. Overall, more than half of the foot operations (53, 55.8%) were associated with patients being ‘Very pleased’ with the outcome of their surgery and a high proportion (78, 82.1%) were rated as either ‘Very pleased’ or ‘Fairly pleased’.

Three-quarters (72, 75.8%) of pre-operative foot problems were now reported as non-existent (‘No problems now’) or ‘ Much better’. Poorer satisfaction ratings were given specifically in relation to the range of shoes patients could now wear (35, 36.8% ‘Very pleased’) and with the appearance of the foot (45, 47.4% ‘Very pleased’). Bilateral operations attracted the highest proportion of extremely positive satisfaction ratings across all 4 items, compared with unilateral operations, although none of these differences were statistically significant.

Relationship between patient satisfaction and foot outcome measures (MOxFQ)
[foot-level analysis]

Figures 1A and 1B show the mean 8 year post-operative MOxFQ W/S, Pain and SI scale scores and change scores respectively, together with 95% confidence intervals (CIs), broken down according to patients’ responses [‘Very pleased’, ‘Fairly pleased’, ‘Not very pleased’, Very disappointed] to the satisfaction item: ‘How pleased are you now with the result of your foot surgery?’

Regarding post-operative MOxFQ scale scores (figure 1a), mean scores for all 3 MOxFQ scales that were associated with the most positive (‘Very pleased’) satisfaction rating (Mean, 95% CIs: W/S 8.8, 4.4 to -13.1; Pain 8.9, 5.1 to -12.8; SI 4.6, 1.9 to -7.3) were distinctly lower/better than scores associated with other responses to the satisfaction item with all patients who were ‘Very pleased’ with the outcome scoring <14 on each MOxFQ scale. Thus, there was also no overlap between 95% CIs for mean scores related to this response and those related to any other response. However, most of the 95% CIs associated with all other (less positive) ratings on the transition item overlapped.

Further analyses (ANOVA with testing for linear trend and Tukey post-hoc comparisons) confirmed significant linear trends in MOxFQ domain score across categories of response (p<0.001).
In particular, however, post-operative MOxFQ scores associated with the ‘Very pleased’ response were significantly different ($p<0.001$) from scores associated with other ‘less pleased’ responses, while scores associated with these less pleased responses were generally not significantly different from each other.

Regarding MOxFQ scale change scores (figure 1b), mean change in the MOxFQ scales associated with the most positive rating (‘Very pleased’) to the satisfaction item was greatest in the Pain domain (Mean, 95% CIs: Pain -48.0, -42.8 to -53.2; W/S -38.4, -32.0 to -44.8; SI -43.1; -36.9 to 49.4). This change in the Pain domain was considerably greater than pain change scores associated with all other responses to the satisfaction item, with the 95% CIs not overlapping with those of any other category of response. This was not the case in relation to MOxFQ W/S and SI scales, where overlap of mean change score 95% CIs occurred across most levels of response to the satisfaction item. The response options ‘not very pleased’ or ‘Very disappointed’ represented small numbers of operations/feet and therefore associated mean MOxFQ change scores generally had wide 95% CIs which tended to overlap with 95% CIs for most of the MOxFQ change scores associated with other patient responses.

Further analyses (ANOVA, with Tukey post-hoc comparisons) confirmed that the change in the MOxFQ pain scale that was associated with the ‘Very pleased’ response was significantly different from pain changes associated with other ‘less pleased’ responses; while change scores associated with the less pleased responses were generally not significantly different from each other. Associations between changes in the MOxFQ W/S and SI scales and responses to the satisfaction item were found to be not so clear-cut, with change scores associated with the ‘very pleased’ response not significantly different from other responses, although change on the MOxFQ SI scale that was associated with the ‘very disappointed’ response was significantly different from changes associated with any other responses ($p<0.001$).
Discussion

This paper has presented standard patient-reported outcomes at around eight years following one-stage surgery for HV, based on a response rate of 78% to a postal survey and compared with patients’ pre-operative data. This is the first time that a validated foot-specific measure (the MOxFQ) has been used to evaluate and benchmark long-term outcomes following surgery for HV.

Just over a third of patients who received unilateral foot surgery reported having a problem (unspecified) with the contralateral foot at baseline, but otherwise the characteristics of these patients, which included their pre-operative general health status (SF-36) scores, did not differ significantly from those of patients having bilateral surgery. This suggested that ill health was not a likely explanation for patients with bilateral foot problems having unilateral, rather than bilateral, surgery.

An examination of pre-operative versus 8 year post-operative changes in patients’ health status showed that the 3 foot-specific domains of the MOxFQ detected changes that were much greater and more consistent than was the case for those detected by the generic SF-36 domains. This was unsurprising, as generic measures detect perturbations in health-related quality of life that can be due to any condition affecting any part of the body. Over time, the likelihood increases that symptoms related to a different condition (‘noise’) will arise that ‘drown out’ changes that are specific to the condition of interest. Nonetheless, in the current study, when comparisons were made between bilateral and unilateral cases, significant differences in changes between the two groups were detected by the SF-36, albeit by the Social Functioning, Role Physical and (in particular) Mental Health domains, and not by the more obviously relevant domains (i.e. Physical function or Pain).

Interestingly, when changes in MOxFQ scores were compared for bilateral and unilateral operations, it was the Social-Interaction scale, rather than the Pain or Walking-Standing scales that detected a large and significant difference between the two groups. The Social-Interaction scale addresses work/everyday and social/recreational activities, patients’ attitude to their foot appearance (‘cosmesis’) and wearable range of shoes, which overall construct chimes with aspects of the more Social-Psychological oriented SF-36 scales. The magnitude of the difference (in the S-I scale) observed between the two groups was greater than the SEM previously estimated for this scale. Changes greater than the SEM of a PROM are considered to be a real (i.e. beyond the measurement error of the scale) and likely clinically relevant magnitude of change/difference when comparing outcomes between patient groups.17

A high proportion of the foot operations (over 80%) were associated with respondents being at least ‘Fairly pleased’ with the outcome of surgery. Bilateral operations attracted the highest proportion of extremely positive satisfaction ratings. Limitations in the range of shoes respondents could now wear (which could, of course, be influenced by either or both feet) and with their attitude to the appearance of their foot, since surgery, appeared important influences on patients’ satisfaction with the outcome of their surgery.

Few studies have investigated the medium to long-term outcomes of surgery for HV and those that have mostly used a retrospective design. Findings are also commonly restricted to reporting radiographic changes and a clinical assessment (e.g. the AOFAS hallux metatarsophalangeal (MTP)-interphalangeal (IP) rating18,19; although some have included a patient satisfaction rating (e.g. a visual analogue scale; or a question with ordinal response options).20 One larger study, included 200 patient interviews to gain insights into patient satisfaction with the surgical outcome and with their pre-operative expectations.6
Findings here highlighted the importance of footwear problems, the alleviation of pain and restoration of adequate walking function as being the most important influences in the outcome of surgery for HV.

Other studies have compared the results of unilateral versus simultaneous bilateral correction for HV. One, based on AOFAS scores, patient satisfaction rating and radiographic outcomes (follow-up period ‘at least 12 months’) concluded that simultaneous bilateral HV correction produced results that were no worse than unilateral correction. Our own analysis of longer-term patient-reported data certainly supports this position.

References