



Patient-reported outcome after hallux valgus surgery — a two year follow up



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ARTICLE INFO

Article history:

Received 14 September 2017

Received in revised form 15 November 2017

Accepted 27 February 2018

Keywords:

Hallux valgus

Function

Pain

Patient-reported outcome

Prospective

SEFAS

ABSTRACT

Background: Patients with hallux valgus deformity may require surgery but prospective patient-reported data is scarce.

Methods: We evaluated 53 patients with a mean age of 55.3 years (SD 14.1, 50 women), who underwent surgery due to hallux valgus. They completed the PROMs SEFAS, EQ-5D and SF-36 before and 6, 12 and 24 months after surgery.

Results: All patient-reported outcomes improved at 6, 12 and 24 months compared with the preoperative status. The greatest improvement occurred at 6 months: SEFAS Δ 10.0 (95% confidence interval 7.8–12.2), EQ-5D Δ 0.22 (0.15–0.29), EQ-VAS Δ 8.4 (4.4–12.4), PF SF-36 Δ 22.0 (14.6–29.3) and BP SF-36 Δ 30.6 (23.1–38.1).

Conclusions: Hallux valgus surgery considerably reduced pain and improved function already within 6 months after surgery. The improvement between 6 and 24 months' follow-up was minimal measured with PROMs.

Level of clinical evidence: III — prospective observational cohort study.

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1. Introduction

Hallux valgus (HV) is a deformity of the forefoot producing painful disability. Estimates of the prevalence of the HV vary widely, ranging from 21 to 70% in epidemiologic studies [1,2]. The prevalence is higher in women and increases with age [1]. The deformity is characterized by lateral deviation of the great toe, medial deviation of the first metatarsal bone including progressive subluxation of the first metatarsophalangeal joint. The patients' complaints are (i) restrictions of wearing shoes, (ii) pain over the medial eminence, (iii) pain underneath the second metatarsal head, and (iv) cosmetic concerns. HV deformity is also associated with poor balance, immobility and increased risk of falling [3]. These different aspects of the patients' problems contribute to the fact that patient-reported outcome measures (PROMs) are of great importance.

Non-surgical treatment of HV deformity includes shoe modifications, splints and physical therapy [4–7]. When non-surgical

treatment has failed several methods of surgical treatment including osteotomies, soft tissue procedures and fusions can be performed. There are several studies evaluating the outcome after HV surgery, but most of them are small, retrospective and do not include PROMs [8–18]. The most commonly used outcome measure after HV surgery is the American Orthopaedic Foot and Ankle Society (AOFAS) score [19], which is partially clinician-reported and can for that reason not be considered as a true PROM.

In a recently published review by Schrier et al. the Manchester-Oxford Foot Questionnaire (MOXFQ) and the Self-reported Foot and Ankle Score (SEFAS) were identified as the most suitable PROMs for assessment of HV treatment [20]. This recommendation supports our aim to evaluate the patient-reported outcome with the SEFAS after HV surgery in a two year follow-up study.

2. Material and methods

In this prospective study design we consecutively included patients scheduled for surgery due to hallux valgus at two orthopedic departments in the south part of Sweden, during the period January 1st 2010 to June 30st 2013. Two surgeons who used the same surgical indications performed all the operations. All patients included had a mild or moderate hallux valgus deformity

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and 9 of the patients had a concomitant hammertoe deformity at the second toe. All patients had before surgery failed non-surgical treatment including shoe modification and physical therapy. 80 patients accepted participation in the study. The surgical procedures were chosen by the surgeon based on grade of deformity and patient-specific factors. The patients underwent either a chevron or a long dorsal arm chevron osteotomy of the metatarsal bone. In 16 of the patients, a simultaneously medial wedge osteotomy of the proximal phalanx according to Akin were performed, i.e. a Chevron-Akin double osteotomy. In the 9 patients with hammertoe deformity we corrected this deformity during the same operation. The patients were, as a standardized postoperative routine, provided with a special postoperative shoe for 6 weeks. This shoe allowed full weight bearing, but reduced load under the forefoot region. After 3–5 days they were instructed to start mobilizing the great toe. They were not allowed to jump and run until 3 months postoperatively.

We measured body weight and body height by standard equipment and calculated body mass index (BMI) as weight/height squared (kg/m^2). The patients completed the Self-reported Foot and Ankle Score (SEFAS), a validated region-specific score for foot and ankle disorders [21–24], the generic scores Euroqol 5-Dimensions (EQ-5D), the Euroqol Visual Analogue Scale (EQ-VAS) [25] and the Short Form 36 Questionnaire (SF-36) [26] immediately before, at 6 (range 5–9) months, at 12 (range 9–16) months and at 24 (range 21–28) months after surgery. In this study we report the results from two of the subscales in SF-36, physical function (PF) and bodily pain (BP). We have in previous studies showed that PF and BP in SF-36 have the best ability to measure changes evaluating outcome after foot and ankle surgery and therefore we used these subscales for our evaluations. After 24 months the patients also responded to the specific questions (i) would you be willing to undergo the procedure again and (ii) have you been improved by the surgery?

The study was approved by the regional ethical review board, Lund, Sweden (2009/698) and was performed according to the Declaration of Helsinki. Informed written consent was obtained from all participants prior to study start.

Statistical calculations were performed with Statistical Package of Social Science (SPSS) software version 23.0 (IBM Software Statistics[®] 2009, US). Data are presented as means \pm standard deviations (SD) or as means with 95% confidence intervals (95% CI). We present absolute score values and absolute changes between evaluations and used paired t-test to estimate temporal differences. Responsiveness, the ability of a score to detect changes after for example surgery, was

calculated as effect size (ES), i.e. the score change divided by the standard deviation of the preoperative score [27].

3. Results

In the two year follow up 53 (50 women) out of 80 patients (66%) completed all postoperative PROMs. The mean age was 55 (SD 14.1) years and the mean BMI 26.0 (SD 4.5) kg/m^2 . The 27 (25 women) excluded patients did not complete follow up data on all 3 occasions despite two reminders. The mean age for this group of patients was 55 (SD 12.3) years and the mean BMI 26.1 (SD 4.6) kg/m^2 .

The patients preoperatively reported impaired function, significant pain and reduced Health-related Quality of life (HrQoL). SEFAS total score was mean 29.5 (95% CI 27.5, 31.4) (Table 1). The SEFAS total score in the excluded group of patients was mean 30.8 (95% CI 28.3, 33.5) preoperatively.

All patient-reported outcomes improved at 6, 12 and 24 months compared with their preoperative status. The greatest improvement occurred at 6 months after surgery, thereafter no significant statistical change was found (Table 1). When evaluating the two specific questions included in the 24 months' post-surgical evaluation, 19 (36%) patients rated themselves with a clinical status without any symptoms, 24 (45%) much improved, 6 (11%) improved, 1 (2%) unchanged and 3 (6%) worse than before surgery. 94% of the patients stated that they, with the same disability as preoperatively, would once again choose to undergo the same surgical procedure.

The effect size (ES) at 6 months was 1.44 for SEFAS, 1.00 for EQ-5D, 0.59 for EQ-VAS, 1.06 for PF SF-36, and 1.65 for BP SF-36.

4. Discussion

Patients who underwent surgery due to HV reported diminished pain, improved function and HrQoL. The greatest improvement was found already at 6 months and remained unchanged up to 24 months postoperatively. This was shown by PROMs; both the generic ones and the foot-and ankle-specific SEFAS.

SEFAS has in earlier studies shown good psychometric properties [21–24] and is recommended for assessment of HV treatment [20]. Minimal important change (MIC) in patients with forefoot disorders is 5 score points [24] indicating that changes between baseline and follow-up are clinically relevant in our study.

The effect size (ES) for the HV surgery measured with PROMs was high, in accordance with earlier studies including SEFAS

Table 1

Pre- and postoperative summarized absolute and change scores for SEFAS^a, EQ-5D, EQ-VAS SF-36 PF^b, and SF-36 BP^c in 53 patients with hallux valgus surgically treated. Data are presented as means with 95% confidence intervals (95% CI).

Score	N	Absolute scores mean (95% CI)				Change scores mean (95% CI)					
		Before surgery	6 months post surgery	12 months post surgery	24 months post surgery	Change 0–6 months	Change 0–12 months	Change 0–24 months	Change 6–12 months	Change 6–24 months	Change 12–24 months
SEFAS ^a	50	29.5 (27.5, 31.4)	39.5 (37.7, 41.3)	40.3 (38.3, 42.2)	41.2 (39.5, 42.9)	10.0 (7.8, 12.2)	10.8 (8.4, 13.2)	11.7 (9.6, 13.8)	0.8 (–0.6, 2.2)	1.7 (0.2, 3.3)	0.9 (–0.2, 2.0)
EQ-5D	51	0.66 (0.60, 0.73)	0.88 (0.85, 0.92)	0.89 (0.85, 0.93)	0.87 (0.83, 0.91)	0.22 (0.15, 0.29)	0.23 (0.16, 0.30)	0.20 (0.13, 0.27)	0.01 (–0.03, 0.04)	–0.02 (–0.06, 0.02)	–0.02 (–0.06, 0.02)
EQ-VAS	49	76.1 (72.0, 80.2)	84.5 (81.1, 87.9)	84.3 (80.5, 88.2)	81.8 (77.7, 85.8)	8.4 (4.4, 12.4)	8.2 (3.9, 12.6)	5.7 (0.5, 10.8)	–0.2 (–3.7, 3.3)	–2.7 (–7.2, 1.7)	–2.6 (–6.4, 1.2)
PF ^b	52	65.8 (60.1, 71.5)	87.7 (79.9, 95.6)	83.1 (77.4, 88.7)	85.0 (79.5, 90.5)	22.0 (14.6, 29.3)	17.3 (12.0, 22.6)	19.2 (13.9, 24.6)	–4.6 (–12.1, 2.8)	–2.7 (–10.1, 4.6)	1.9 (–2.5, 6.3)
BP ^c	49	45.9 (40.5, 51.2)	76.5 (70.1, 82.9)	75.7 (68.7, 82.8)	76.2 (70.0, 82.3)	30.6 (23.1, 38.1)	29.9 (22.3, 37.5)	30.3 (23.8, 36.8)	–0.8 (–7.1, 5.6)	–0.3 (–6.6, 6.0)	0.4 (–4.2, 5.1)

^a Self-reported Foot and Ankle Score.

^b Physical function.

^c Bodily pain.

[21,22,28]. The highest ES was seen in the subscale measuring pain (SF-36, BP), which indicates that HV surgery mainly is a treatment of pain. SEFAS measures both pain and function and has an ES in between the subscales pain (BP) and physical function (PF) in SF-36 supporting the use of the shorter 12-item SEFAS.

Already at 6 months the patients had improved their total score in all PROMs and remained at the same level up to 2 years. In SEFAS this level is comparable to normative data (unpublished data), yielding that patients after HV surgery will almost completely recover.

The time to recover after different types of surgery in the foot and ankle differs. After HV surgery we found that the mean recovery time was 6 months, while after surgery for flatfoot deformity stage II the mean recovery time was 24 months [28]. This means that we can allow a shorter follow-up time evaluating HV surgery. The prerequisite for our reasoning is that there is no recurrence and we know that the recurrence rate in literature vary from 2.7 to 16% [29]. The recurrence can of course occur later than 2 years and the results of the PROMs will of course then also deteriorate why long term follow-up studies are needed.

Our included patients are representative for a normal HV population at an ordinary orthopaedic department. However, the most complex deformities needing more extensive surgery than osteotomies were excluded.

92% of the patients were improved after surgery and 94% stated that they would have undergone the procedure again. These satisfaction rates support the results of the PROMs and show that we can recommend these surgical procedures for this group of patients.

There are limitations in this study. The sample size is rather small since not all collected data could be used. However, the drop-out analyses revealed no statistically differences in age, gender distribution, BMI and preoperative total scores in SEFAS comparing the data from the subcohort of patients included in the study and the subcohort of patients excluded due to missing data. This allows us to assume that the results we received can also be applied to the excluded group.

Furthermore, we did not record additional surgery or other foot-related events during the follow-up time, which might have affected the results.

The prospective design is a strength of the study in which the patients truly concluded the PROMs before and after surgery. Schneider et al. showed that retrospective patient-reported scoring of the preoperative status gave worse result and lead to overestimation of the effect of surgery. Their conclusion was that a prospective study design is preferred evaluating results after HV surgery [30]. Another strength is that the SEFAS is a true patient-reported score in which patients and their perceptions are involved. AOFAS, the far most used foot and ankle-specific score evaluating HV surgery, is not patient-reported and often used retrospectively and consequently the results are insecure. In the future it will be an advantage if foot and ankle surgeons worldwide start to use thoroughly validated and recommended PROMs, for example SEFAS and MOXFQ, evaluating HV surgery.

There is a need for larger sample sizes to evaluate HV surgery. By including well validated PROMs like SEFAS in registries, such data can be collected.

5. Conclusion

Foot and ankle-specific PROMs such as SEFAS contribute with valuable information after HV surgery. Patients perceived normalized pain, function and Health related Quality of Life already within 6 months after surgery. The improvement between 6 and 24 months' follow-up was minimal measured with PROMs.

Conflict of interest statement

The authors disclose that there were no conflicts to declare.

Financial support

Financial support was received from the Kalmar Regional Funds, Herman Järhardtts stiftelse, Stiftelsen för Skobranschens utvecklingsfond, Kockska stiftelsen and Svenska Reumakirurgiska föreningen (SRK).

References

- [1] Roddy E, Zhang W, Doherty M. Prevalence and associations of hallux valgus in a primary care population. *Arthritis Rheum* 2008;59:857–62.
- [2] Nix S, Smith M, Vicenzino B. Prevalence of hallux valgus in the general population: a systematic review and meta-analysis. *J Foot Ankle Res* 2010;3:21.
- [3] Benvenuti F, Ferrucci L, Guralnik JM, Gangemi S, Baroni A. Foot pain and disability in older persons: an epidemiologic survey. *J Am Geriatr Soc* 1995;43:479–84.
- [4] Fuhrmann RA, Rippel W, Traub A. Conservative treatment of hallux valgus: what can be achieved with splints and insoles? *Orthopade* 2017;46:395–401.
- [5] du Plessis M, Zipfel B, Brantingham JW, Parkin-Smith GF, Birdsey P, Globe G, et al. Manual and manipulative therapy compared to night splint for symptomatic hallux abducto valgus: an exploratory randomised clinical trial. *Foot (Edinb)* 2011;21:71–8.
- [6] Uritani D, Fukumoto T, Matsumoto D, Shima M. Associations between toe grip strength and hallux valgus, toe curl ability, and foot arch height in Japanese adults aged 20 to 79 years: a cross-sectional study. *J Foot Ankle Res* 2015;8:18.
- [7] Kim MH, Kwon OY, Kim SH, Jung DY. Comparison of muscle activities of abductor hallucis and adductor hallucis between the short foot and toe-spread-out exercises in subjects with mild hallux valgus. *J Back Musculoskelet Rehabil* 2013;26:163–8.
- [8] Buciuo R. Prospective randomized study of chevron osteotomy versus Mitchell's osteotomy in hallux valgus. *Foot Ankle Int* 2014;35:1268–76.
- [9] Lechler P, Feldmann C, Kock FX, Schaumburger J, Grifka J, Handel M. Clinical outcome after Chevron-Akin double osteotomy versus isolated Chevron procedure: a prospective matched group analysis. *Arch Orthop Trauma Surg* 2012;132:9–13.
- [10] Chiodo CP, Schon LC, Myerson MS. Clinical results with the Ludloff osteotomy for correction of adult hallux valgus. *Foot Ankle Int* 2004;25:532–6.
- [11] Schneider W, Aigner N, Pinggera O, Knahr K. Chevron osteotomy in hallux valgus. Ten-year results of 112 cases. *J Bone Joint Surg Br* 2004;86:1016–20.
- [12] van Groningen B, van der Steen MC, Reijman M, Bos J, Hendriks JG. Outcomes in chevron osteotomy for hallux valgus in a large cohort. *Foot (Edinb)* 2016;29:18–24.
- [13] Saro C, Jensen I, Lindgren U, Fellander-Tsai L. Quality-of-life outcome after hallux valgus surgery. *Qual Life Res* 2007;16:731–8.
- [14] Lambers Heerspink FO, Verburg H, Reininga IH, van Raaij TM. Chevron versus Mitchell osteotomy in hallux valgus surgery: a comparative study. *J Foot Ankle Surg* 2015;54:361–4.
- [15] Deenik AR, Pilot P, Brandt SE, van Mameren H, Geesink RG, Draijer WF. Scarf versus chevron osteotomy in hallux valgus: a randomized controlled trial in 96 patients. *Foot Ankle Int* 2007;28:537–41.
- [16] Bai LB, Lee KB, Seo CY, Song EK, Yoon TR. Distal chevron osteotomy with distal soft tissue procedure for moderate to severe hallux valgus deformity. *Foot Ankle Int* 2010;31:683–8.
- [17] Knoth C, Carow L, Zettl R, Welter J, Hess F. Short- and long-term outcomes following hallux-valgus correction: a modified Kramer osteotomy. *Arch Orthop Trauma Surg* 2016;136:1349–55.
- [18] Trnka HJ, Zemsch A, Easley ME, Salzer M, Ritschl P, Myerson MS. The chevron osteotomy for correction of hallux valgus. Comparison of findings after two and five years of follow-up. *J Bone Joint Surg Am* 2000;82-A:1373–8.
- [19] Kitaoka HB, Alexander JJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int* 1994;15:349–53.
- [20] Schrier JC, Palmen LN, Verheyen CC, Jansen J, Koeter S. Patient-reported outcome measures in hallux valgus surgery: a review of literature. *J Foot Ankle Surg* 2015;21:11–5.
- [21] Coster M, Karlsson MK, Nilsson JA, Carlsson A. Validity, reliability, and responsiveness of a self-reported foot and ankle score (SEFAS). *Acta Orthop* 2012;83:197–203.
- [22] Coster MC, Bremander A, Rosengren BE, Magnusson H, Carlsson A, Karlsson MK. Validity, reliability, and responsiveness of the self-reported foot and ankle score (SEFAS) in forefoot, hindfoot, and ankle disorders. *Acta Orthop* 2014;85:187–94.
- [23] Coster MC, Rosengren BE, Bremander A, Brudin L, Karlsson MK. Comparison of the Self-reported Foot and Ankle Score (SEFAS) and the American Orthopedic Foot and Ankle Society Score (AOFAS). *Foot Ankle Int* 2014;35:1031–6.
- [24] Coster MC, Nilsson JA, Brudin L, Bremander A. Minimally important change, measurement error, and responsiveness for the self-reported foot and ankle score. *Acta Orthop* 2017;88:300–4.

- [25] EuroQol G. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.
- [26] Sullivan M, Karlsson J. The Swedish SF-36 Health Survey III. Evaluation of criterion-based validity: results from normative population. *J Clin Epidemiol* 1998;51:1105–13.
- [27] Cohen J. *Statistical power analysis for the behavioral sciences*. New York: Academic Press; 1978.
- [28] Coster MC, Rosengren BE, Bremander A, Karlsson MK. Surgery for adult acquired flatfoot due to posterior tibial tendon dysfunction reduces pain, improves function and health related quality of life. *J Foot Ankle Surg* 2015;21:286–9.
- [29] Raikin SM, Miller AG, Daniel J. Recurrence of hallux valgus: a review. *Foot Ankle Clin* 2014;19(2):259–74.
- [30] Schneider W, Knahr K. Poor agreement between prospective and retrospective assessment of hallux surgery using the AOFAS Hallux Scale. *Foot Ankle Int* 2005;26:1062–6.