Hallux valgus: immediate operation versus 1 year of waiting with or without orthoses

A randomized controlled trial of 209 patients

Markus Torkki[1,2], Antti Malmivaara[3,5], Seppo Seitsalo[1,5], Veijo Hoikka[4], Pekka Laippala[6] and Pekka Paavolainen[1]

Departments of [1]Orthopaedics, Jorvi Hospital of Espoo, [2]Orthopaedic Surgery, Helsinki University Central Hospital, Helsinki, [3]Occupational Medicine, Finnish Institute of Occupational Health, Helsinki, [4]Foot Surgery of Mehiläinen Hospital, Helsinki, [5]ORTON Orthopaedic Hospital, Invalid Foundation, Helsinki, [6]School of Public Health and Research Unit, Tampere University Hospital, Tampere, Finland.
Correspondence: markus.torkki@hus.fi
Submitted 01-12-20. Accepted 02-08-09

ABSTRACT Hallux valgus operations can not always be done immediately because of long waiting lists. In this study, 209 consecutive patients (mean age 48 years, 93% female) with a painful hallux valgus were randomized into 3 groups: immediate operation or 1 year waiting with or without foot orthoses. The follow-up period was 2 years. The main outcome measurement was the intensity of pain during walking.

During the first year, 64/71, 0/69 and 4/69 patients were operated on in the surgery, orthosis and no orthosis groups, respectively, and during the 2-year follow-up, 66, 43 and 48, respectively. At the 1-year follow-up, the pain was least intense in the surgery group. At the 2-year follow-up, the intensity of pain was similar in all groups. The satisfaction with treatment was best in the surgery and orthosis groups. The total costs of care were similar in all groups.

We conclude that immediate operation is superior to delayed operation or foot orthoses. However, if this is not possible because of limited possibilities for surgery, waiting for 1 year, with or without an orthosis, does not jeopardize the final outcome.

Access to osteotomy for painful hallux valgus is often delayed because of very long waiting lists. The waiting time may be of benefit for some patients because the symptoms may be relieved without surgery. However, a long waiting time for surgery may be regarded as poor quality health care.

In our previous article (Torkki et al. 2001), we presented the 1-year follow-up of a randomized trial comparing surgery, orthosis treatment and no treatment of hallux valgus. For ethical reasons, the patients, who gave their informed consent for participation, were told that they would be treated surgically after the 1-year follow-up, if they agreed to be randomized to one of the non-surgical treatment arms. When the follow-up period was extended to 2 years, this made it possible to compare the cost-effectiveness of immediate surgery versus 1 year of waiting time. This article is based on the results of the 2-year follow-up.

Patients and methods

Selection and evaluation of the subjects

Selection and evaluation of the subjects has been reported in another article elsewhere (Torkki et al. 2001). 211 consecutive hallux valgus patients with mild to moderate deformation were randomized into 3 groups: surgery, orthosis or watchful waiting. The patients who fulfilled the inclusion criteria were given written and oral information on the aims and content of the study in accordance with the Helsinki Declaration (1996), before asking them to participate. The ethics committee of the 4 hospitals approved the study protocol (Table 1).

The researchers dealing with the baseline and outcome data were unaware of patient assignments

Table 1. Demographic and clinical characteristics of the subjects at baseline [a]

Group	Surgery	Orthosis	Control
No. of subjects	71	69	69
Demographic features			
Age, yr	48 (10)	49 (10)	47 (9)
Gender (% women)	93	89	96
Education, college or more (%)	11	11	10
Body mass index (kg/m^2)	24 (14)	24 (13)	24 (15)
Height (cm)	166 (6)	166 (8)	165 (5)
Physical exercise 3 times or more/wk (%)	51	46	57
Work-related features			
Employed (%)	82	76	83
Heavy physical work (self-reported) (%)	13	13	16
Pain and disability			
Bilateral deformity (%)	38	39	47
Duration of foot pain > 6 months (%)	86	87	83
Intensity of foot pain [b]	47 (25)	50 (24)	45 (24)
Sick leave because of foot problems during last 12 months (%) [c]	5.6	2.9	5.7
Cosmetic disturbance [d]	3.4 (2.3)	2.7 (2.1)	3.1 (2.3)
Shoe problems (number of patients)			
None	6	4	3
Moderate	57	59	60
Severe	8	6	6
Ability to work [e]	85 (16)	83 (17)	83 (20)
Functional status			
AOFAS score [f]	60 (14)	59 (11)	62 (11)
Radiology			
Hallux valgus angle (degrees)	23 (4.5)	24 (6.0)	24 (5.6)
Intermetatarsal angle (degrees)	11 (2.0)	11 (2.4)	11 (2.3)
Congruent MTP I -joint (%)	59	44	48
Health-related quality of life index (15-D) [g]	91 (6.9)	91 (6.9)	90 (6.9)

[a] Mean values (SD) shown, unless otherwise stated.
[b] On day of examination, recorded on a 10-cm VAS-scale from 0 (no pain at all) to 100 (unbearable pain).
[c] Sick-leave had been shorter than 30 days in all cases
[d] Recorded on a 7-point scale from 0 (no cosmetic disturbance at all) to 6 (maximal cosmetic disturbance).
[e] Recorded on a 10-cm VAS-scale from 0 (total inability to work) to 100 (maximal working ability).
[f] Total score ranges from 0 to 100, with higher score indicating better functional ability.
[g] Scores of 15-D range from 0 to 100, with higher scores indicating better function in the most essential dimensions of general health.

to the treatment protocols. The baseline data were collected on potential confounders, effect-modifying factors and factors related to the foot disorder (Table 1). A generic health-related quality of life measure 15-D (Sintonen and Pekurinen 1992) and duration of sick-leave due to foot pain were assessed in the questionnaire.

If the patient had a bilateral deformity, the outcome characteristics of the foot problem were recorded separately for both feet. In these cases, the foot with worse symptoms was selected for the data analysis.

Randomization and treatments

The randomization process and details of surgical and orthosis treatments have been described elsewhere (Torkki et al. 2001). In the surgery group, the patients were operated on with the chevron procedure (Austin and Leventen 1981). The orthosis group was treated with individually adjusted foot orthoses. The control group had neither surgery nor orthoses during the follow-up of 1 year. After this, the patients in the orthosis and control groups were offered surgery. Initially, the patients had been evaluated by one of the authors and the chevron procedure was the operation of choice for all cases. The patient flow chart is shown in Figure 1.

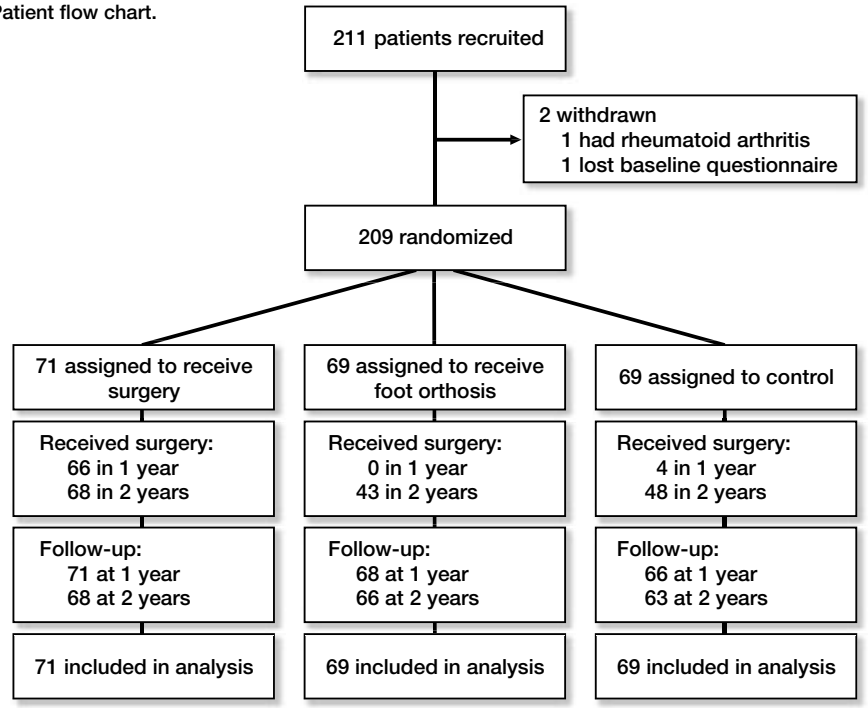
Adherence and co-interventions

In the follow-up questionnaires, all patients were asked if they had undergone surgery on the foot, if they had used functional foot orthoses, and if so, the number of days each week and the number of hours a day. Other health care services received for foot problems were also recorded. 4 years after the study was started, the records of all hospitals were checked again to determine whether the subjects had undergone surgery. Those in whom no data were available, we contacted by phone and asked if the foot in the study had been operated on during the 2-year follow-up.

Follow-up and outcome assessment

At the 1-year follow-up, the patients were exam-

Figure 1. Patient flow chart.



ined again and a questionnaire was filled in. At the 2-year follow-up, a questionnaire was sent to the patients. Those who did not reply were reminded by phone and again asked to participate.

Economic analysis

We used the Nord-DRG (Diagnosis-Related Group) price for the cost of the chevron procedure. This price includes the hospital costs of the surgery and the immediate postoperative care. In other respects, the economic analysis was based on replies to the follow-up questionnaires, which concerned the use of health care services because of hallux valgus. This included visits to a physician, physiotherapists or foot therapists, and the costs were calculated from the unit costs of these services in the Uusimaa Health District Area. The use of foot splints, braces or orthoses was also recorded according to the patients' expenses for them.

Sample size and statistics

According to the power calculations, 68 subjects in each treatment group were needed for the study to achieve a statistical power of 0.90 with an alpha of 0.05 (two-sided). The calculations were made for pain during walking (the primary outcome) on a 0–100 mm visual analogue scale, using 15 mm as a clinically significant difference between the groups and assuming a standard deviation of 15%.

Efficacy variables were analyzed on an intention-to-treat basis. The last observation carried forward was used for patients who did not complete the study or who had missing values at 6 or 12 months.

Follow-up outcomes were analyzed, using analysis of variance for repeated measures, where the model includes the following effects: group and time effects and their interaction. The outcomes were adjusted for each characteristic at baseline. As to the post-hoc testing, there is no clear choice of an appropriate error term, when testing between groups by within-subject interactions. Our post-hoc testing between the groups is therefore based on the 95% confidence intervals constructed for the change over time. Cross-tabulations were analyzed, using the chi-square test. The changes in the radiological parameters in the surgery group before and after were analyzed with the pairwise Student t-test. The calculation was done using NCSS 2000 (Jerry Hintze, UT, USA) and Statistica/Win (Version '98, StatSoft, Tulsa, USA) softwares.

Results

Study population

The final study population consisted of 209 patients, 71 of them were randomized to the immediate surgery, 69 to the orthosis and 69 to the control groups. 1 year later, follow-up information was obtained on 205 subjects (98%); at this time 3 subjects were missing from the control group, and 1 from the conservative treatment group. At the 2-year follow-up, 197 patients (94%) were seen. This time 3 subjects were missing from the surgery, 3 from the orthosis and 6 from the control groups. The dropouts did not differ markedly from the remaining subjects as a whole, or between the 3 intervention groups. The 3 groups were similar as regards all of the baseline characteristics (Table 1).

Adherence and co-interventions

During the follow-up period at 1 year, 66 patients in the surgery group had undergone an operation (Figure 1). During the follow-up at 2 years, 2 patients in the surgery group were operated on, so the total number of operated patients in the surgery group was 68/71. None of the patients in the surgery group used functional foot orthoses during the follow-up.

In the orthosis group, no patient was operated on during the follow-up at 1 year, but 43/69 patients were operated on during the follow-up at 2 years. 67/69 reported at the 1-year follow-up that they had used the orthoses, 6 days a week, and 6 hours each day, on average. At the 2-year follow-up, 54/66 reported having used the orthoses, on average, 5 days a week and 5 hours each day.

In the control group, 4 patients were operated on during the first year and 44 more during the second year (total 48 of 69). None of the patients used foot orthoses during the study.

The patients' and physicians' expectations

Because of the study protocol, we could not blind the patients or the independent observer. To assess preferences for a treatment we asked the patients and the independent observer just after the randomization, whether or not they expected that the foot involved would be better after the follow-up at 1 year. The independent observer expected that the foot would be better in 100%, 89% and 11% in the surgical, orthosis and control groups, respectively. The patients' expectations in the 3 groups were 100%, 83% and 18%, respectively.

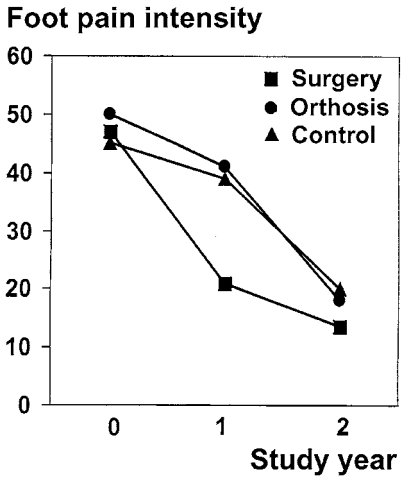


Figure 2. Mean intensity of foot pain (visual analogue scale from 0 to 100) at baseline, 1 year and 2 years in the surgery, orthosis and control groups.

1-year outcome

In the surgery group, the severity of pain (Figure 2), cosmetic disturbance and footwear problems were less than in the orthosis and control groups (Table 2). The satisfaction with the treatment was best in the surgery group.

2-year outcome

We found no differences in the severity of foot pain (Figure 2) or footwear problems (Table 3) between the groups. Cosmetic disturbance was worse in the orthosis than in the surgery group, but satisfaction with the treatment was better in both groups than in the control group.

Costs and use of services

Total costs during the study were 1111, 971 and 1126 Euros in surgery, orthosis and control groups, respectively. The visits to doctors were significantly more frequent in the surgery and control groups (Table 4).

Table 2. Outcomes in the three groups at the 1-year follow-up [a]

Group	Surgery	Orthosis	Control
Number of subjects	71	69	69
Pain and disability			
Intensity of foot pain [b]	21 (23)	41 (23)	39 (26)
Ability to work [c]	89 (20)	82 (25)	84 (24)
Cosmetic disturbance [d]	1.9 (2.2)	2.6 (2.0)	2.7 (2.3)
Shoe problems (number of patients)			
None / Moderate / Severe	23 / 44 / 4	3 / 59 / 7	5 / 60 / 4
Satisfaction with treatment [e]	80 (28)	70 (26)	61 (37)
Health-related quality of life index (15-D) [f]	93 (6.2)	93 (6.1)	93 (6.6)
Differences in adjusted group means (95% CI) [a]	Surgery minus control	Orthosis minus control	Surgery minus orthosis
Pain and disability			
Intensity of foot pain [b]	–20 (–29 to –11)	–5.0 (–14 to 4.2)	–15 (–24 to –5.6)
Ability to work [c]	3.3 (–3.8 to 10)	–2.2 (–9.4 to 4.9)	5.5 (–1.6 to 13)
Cosmetic disturbance [d]	–1.1 (–1.7 to –0.46)	0.28 (–0.36 to 0.92)	–1.4 (–2.0 to –0.75)
Shoe problems (%)	p < 0.001	p = 0.5	p < 0.001
Satisfaction with treatment [e]	20 (10 to 30)	9 (–1 to 20)	11 (1 to 21)
Health-related quality of life index (15-D) [f]	0.19 (–2.2 to 2.6)	–0.24 (–2.7 to 2.3)	0.43 (–1.9 to 2.9)

[a] Mean values (SD) shown, unless otherwise stated.
[b] On day of examination, recorded on a 10-cm VAS-scale from 0 (no pain at all) to 100 (unbearable pain).
[c] Recorded on a 10-cm VAS-scale from 0 (total inability to work) to 100 (maximal working ability).
[d] Recorded on a 7-point scale from 0 (no cosmetic disturbance at all) to 6 (maximal cosmetic disturbance).
[e] Recorded on a 10-cm VAS-scale from 0 (entirely dissatisfied) to 100 (entirely satisfied).
[f] Scores of 15-D range from 0 to 100, with higher scores indicating better function in the most essential dimensions of general health.

Table 3. Outcomes in the three groups at the 2-year follow-up [a]

Group	Surgery	Orthosis	Control
Number of subjects	71	69	69
Pain and disability			
Intensity of foot pain [b]	15 (21)	16 (17)	19 (22)
Ability to work [c]	92 (15)	84 (26)	88 (22)
Cosmetic disturbance [d]	1.7 (2.1)	1.8 (2.0)	1.9 (2.1)
Shoe problems (number of subjects)			
None / Moderate / Severe	32 / 36 / 3	23 / 44 / 2	20 / 47 / 2
Satisfaction with treatment [e]	84 (25)	82 (22)	71 (33)
Health-related quality of life index (15-D) [f]	93 (6.6)	93 (6.3)	91 (13)
Differences in adjusted group means (95% CI) [a]	Surgery minus control	Orthosis minus control	Surgery minus orthosis
Pain and disability			
Intensity of foot pain [b]	–6 (–15 to 4)	–9 (–18 to 1)	3 (–7 to 12)
Ability to work [c]	2 (–4 to 9)	–4 (–11 to 3)	6 (–0.6 to 13)
Cosmetic disturbance [d]	–0.5 (–1.2 to 0.2)	0.3 (–0.4 to 1.0)	–0.8 (–1.5 to –-0.1)
Shoe problems (%)	p = 0.1	p = 0.9	p = 0.3
Satisfaction with treatment [e]	13 (3.7 to 21)	11 (1.6 to 19)	2 (–6.9 to 11)
Health-related quality of life index (15-D) [f]	1.1 (–1.3 to 3.5)	1.1 (–1.4 to 3.7)	0.0 (–2.5 to 2.4)

[a-f] See Table 2.

Table 4. Mean costs of foot care over a 2-year period [a]

Type of cost	Surgery (n = 70)	Orthosis (n = 64)	Control (n = 61)
Study treatments after randomization	923 [b]	208	0
HMO services for foot care			
Visits to doctor [c]	86	91	169
Visits to physiotherapists or foot therapists [d]	102	52	231
Surgical treatment [e]	0	620	726
Total costs	1111	971	1126

[a] Costs are in Euros. The groups were smaller than in the outcome analyses because those with missing data were excluded.
[b] The price of the chevron osteotomy (including postoperative care of one day) is 965 Euros, according to the Nord-DRG price list of Jorvi hospital. Because the procedure was performed in 67 (of 70) patients in the surgery group, the price of the intervention per patient was calculated as follows: 965 Euros × 67/70 = 923 Euros.
[c] These costs include visits to doctors during the follow-up period. The sums are expressed as mean price per patient.
[d] These costs include visits to physiotherapists or foot therapists because of foot problems during the follow-up period. The sums are expressed as mean price per patient.
[e] 43 patients (of 64) in the orthosis group and 48 (of 61) in the control group were operated on during the follow-up.
The cost of these co-interventions were calculated as follows: 923 Euros × 43 / 64 = 620 Euros; 923 Euros × 48/61 = 726 Euro, respectively.

Discussion

In our previous article, based on the analysis of data at 1 year, we found surgery to be an effective treatment for hallux valgus patients (Torkki et al. 2001). We now present the results of the 2-year follow-up of the same material. Surgery was offered to the patients in the nonsurgical treatment arms at the 1-year follow-up.

At the 2-year follow-up, the main outcome measure—intensity of foot pain—was similar in the 3 groups. The same level of pain was achieved in the orthosis and control groups with one third fewer operations. This confirms that in several patients with hallux valgus, the symptoms may decrease with time—e.g., due to transient bursitis. However, fewer operations in the orthosis and control groups did not reduce the costs: in the 3 groups, the total costs of foot care were the same.

All 211 patients wished to be operated on at the baseline. One of the authors systematically assessed the inclusion criteria for chevron osteotomy. Despite that, as much as one third of the patients in the orthosis and control groups did not want to have surgery after the 1-year follow-up. Obviously, this figure may be larger in real-life waiting lists, because the surgical indications of different surgeons vary.

The main outcome—pain intensity—declined most during the first year of the follow-up in the surgery group where 93% of the operations were done immediately after the randomization. In the other two groups, effective pain relief was not gained until they were operated on—i.e., during the later follow-up. Cosmetic disturbance remained less in the surgery group than in the orthosis group. The best cosmetic result can apparently be achieved only with surgical correction of the foot, and the same pertains to footwear problems. Similarly, we also found significant differences in several other outcomes between the groups at the 1-year follow-up, which were related to various differences in the surgical interventions.

The effect of treatment was analyzed using the intention-to-treat principle. With this method of analysis, we compared the results of surgery undergone immediately and after a 1-year wait. Such a comparison may not be valid for longer follow-up outcomes, because the outcome measures were evaluated 2 years after the operation in the surgery group and 1 year after the operation in the other 2 groups. The knowledge about the long-term outcome of hallux valgus surgery is limited. Trnka et al. (2000) found only minimal changes between 2- and 6-year follow-ups after chevron osteotomy with lateral capsular release. These findings contrast with those of Klosok et al. (1993), who reviewed the results at an average of 22 and 38 months after chevron osteotomy without a lateral capsular release. The hallux valgus angle was corrected from an average of 30 degrees preoperatively to an average of 21 degrees at the short-term follow-up evaluation, but correction was lost: at the 38-month follow-up evaluation, the average hallux valgus angle was 26 degrees. Foot pain was not reported in Klosok's study. In our study, we routinely performed a lateral capsular release, which may have helped to maintain the

correction and some outcomes in the surgery group with immediate operation were better at the 2-year than those at the 1-year follow-up.

We conclude that immediate surgery is an effective treatment for mild to moderate hallux valgus. If the ability to perform surgery limited, waiting for 1 year, with or without orthoses, does not jeopardize the results. Foot problems may become less severe while waiting and some operations can be cancelled, but this does not seem to reduce the use of health care facilities. However, during waiting, most patients have considerable pain, which can be resolved only with surgery.

We are indebted to the physicians and nurses at the Jorvi, Peijas, Lohja and Kiljava Hospitals for their contributions to this study. We thank secretary Monika Fredriksson for data management.

This study was supported by a grant from the Finnish Office for Health Technology Assessment, the Finnish Medical Foundation, the Scientific Foundation of Jorvi Hospital and the Scientific Foundation of Mehiläinen Hospital. No competing interests declared.

Austin D W, Leventen E O. A new osteotomy for hallux valgus: a horizontally directed "V" displacement osteotomy of the metatarsal head for hallux valgus and primus varus. Clin Orthop 1981; 157: 25-30.

Declaration of Helsinki. World Medical Assembly; South Africa; 1996. Available at: http://www.etikkom.no/NEM/REK/declaration96.htm.

Klosok J K, Pring D J, Jessop J H, Maffulli N. Chevron or Wilson metatarsal osteotomy for hallux valgus. A prospective randomized trial. J Bone Joint Surg (Am) 1993; 5: 825-9.

Sintonen H, Pekurinen M. A fifteen-dimensional measure of health-related quality of life and its applications. In: Quality of Life Assessment: Key Issues in the 1990 (Eds Walker S R, Rosser R M). Dordrecht, The Netherlands: Kluwer Academic Publishers 1992.

Torkki M, Malmivaara A, Seitsalo S, Hoikka V, Laippala P, Paavolainen P. Operative vs orthotic treatment vs watchful waiting for hallux valgus: A randomized controlled trial. JAMA 2001; 285: 2474-80.

Trnka H J, Zembsch A, Easley M E, Salzer M, Ritschl P, Myerson M S. 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; 10: 1373-8.