Surgery vs Orthosis vs Watchful Waiting for Hallux Valgus: A Randomized Controlled Trial

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Surgery vs Orthosis vs Watchful Waiting for Hallux Valgus

A Randomized Controlled Trial

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Context Hallux valgus is a common foot deformation in adults, but evidence for effectiveness of surgical and conservative treatments for this condition is limited.

Objective To compare the effectiveness of surgical and orthotic treatment with no treatment in patients with hallux valgus.

Design and Setting Randomized controlled trial conducted in 4 general community hospitals in Finland in 1997-1998, with a follow-up period of 12 months.

Participants Two hundred nine consecutive patients (mean age, 48 years; 93% women) with a painful bunion and a hallux valgus angle 35° or less.

Interventions Patients were randomly assigned to surgery (distal chevron osteotomy; n=71), orthosis (n=69), or a 1-year waiting list (control group, n=69).

Main Outcome Measures Pain intensity during walking on a visual analog scale (0-100), patient assessment of global improvement, number of painful days, cosmetic disturbance, footwear problems, functional status, and treatment satisfaction, compared among treatment groups.

Results Follow-up rates at 6 and 12 months were 99% and 98%, respectively. At 6 months, pain intensity decreased more in the surgical group than in the control group (adjusted mean differences, –20 [95% confidence interval {CI}, –28 to –12]) and more in orthosis than in the control groups (adjusted mean difference, –14 [95% CI, –22 to –6. At 1 year, pain intensity decreased more in the surgical than in the control groups (adjusted mean difference, –19 [95% CI, –28 to –10]) and more than in the surgical and orthosis groups (adjusted mean difference, –14 [95% CI, –22 to –5]). At 1 year, 83%, 46%, and 24% in the surgery, orthosis, and control groups, respectively, thought they had improved compared with baseline (number needed to treat), 1.7 between surgical and control groups). Number of painful days, cosmetic disturbance, and footwear problems were least and functional status and satisfaction with treatment were best in the surgical group.

Conclusions Surgical osteotomy is an effective treatment for painful hallux valgus. Orthoses provide short-term symptomatic relief.

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HALLUX VALGUS IS A VERY COMmon foot deformation. Among those who wear shoes, 33% of adults have some degree of hallux valgus.[1] Although nonsurgical care is always the first option for a patient who has a hallux valgus deformity,[2] hallux valgus surgery is among the most common orthopedic operations in Western industrialized countries. It has been estimated that 209 000 people in the United States undergo hallux valgus surgery every year.[3] In Finland (population 5 million), the most common orthopedic operations in 1998 were knee arthroscopy (23 621 per year), hip arthroplasty (4424), extirpation of low back disk prolapse (4030), knee arthroplasty (3959), and correction of hallux valgus (3909).[4]

More than 100 techniques have been introduced for correction of hallux valgus.[1] Distal metatarsal (chevron) osteotomy is widely used to correct mild or moderate hallux valgus.[5] In uncontrolled case series, good clinical results have been reported in 80% to 90% of patients who have undergone the surgery.[6-8] However, recurrences or undercorrections have been reported in 10% to 14% of the cases.[5,9,10]

Conservative treatments aim to reduce the angle of the first metatarsal–great toe joint by either stretching contracted soft tissue around the joints with the use of night splints, and improving muscle strength by foot exercises or resolving abnormal function with insoles (orthoses).[11] Orthoses are considered to be most effective in the early stages of hallux valgus.[12]

Evidence for effectiveness of surgical and conservative treatments for patients with hallux valgus is very limited. A recently published systematic review found only 12 randomized trials concerning surgical or conservative treatment of hallux valgus.[11] None of the studies compared surgical treatment with any conservative treatment or with watch-

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ful waiting.[11] We thus set out to conduct a randomized controlled trial to assess the effectiveness and costs of surgical and orthotic treatments for hallux valgus patients, compared with a control group of patients who received neither surgical nor conservative treatment.

METHODS

Subjects

The study was conducted in 4 hospitals of the Uusimaa Health District Area with a catchment area of about 500 000 people. The study subjects were adult patients who had been referred by general practitioners for orthopedic evaluation because of hallux valgus. All patients with mild or moderate hallux valgus deformation (see inclusion criteria) were examined by 1 of the authors (M.T.), who acted as an independent observer during the entire study period. Two hundred eleven consecutive patients (294 involved feet) were included in the study. The inclusion criteria were having a painful bunion with the hallux valgus angle 35° or less and the intermetatarsal angle of 15° degrees or less.[1] Any foot that had previously undergone bunion surgery, had hallux rigidus, or had hallux limitus was not included in the study . Other exclusion criteria were rheumatoid disease, use of functional foot orthoses, pregnancy, and age older than 60 years. Patients fulfilling the inclusion criteria received written and oral information on the aims and content of the study in accordance with the Helsinki Declaration[13] before asking for their participation decision. Participants gave a written consent, went through the physical examination, and completed the questionnaires. Patients were told that both surgical and orthotic treatments could be used to decrease symptoms of hallux valgus. The ethics committee of all 4 hospitals approved the study protocol.

Before randomization, patients completed a baseline questionnaire, which was given to the research team right after the patients had answered it. The researchers analyzing the baseline and outcome data were blinded to the treatment protocols. Baseline data were gathered 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[14] and duration of sick leave due to foot pain were assessed by means of the questionnaire.

We took radiographs of both feet (anteroposterior and lateral projections) during weight bearing in the angle and base of gait.[15] All radiographic measurements were made by the same investigator (M.T.). The intermetatarsal angle between the first and second metatarsal bones and the hallux valgus angle between the first metatarsal bone and the proximal phalanx were measured by the center-of-head method.[16] The congruency of the first metatarsophalangeal joint was determined by lines drawn at the base of the proximal phalanx and along the articular surface of the first metatarsal.[16]

All feet were scored by the hallux-metatarsophalangeal scale of the American Orthopaedic Foot and Ankle Society (AOFAS).[17] This clinical rating system combines objective and subjective data as follows: pain, 40 points; function, 45 points; and alignment, 15 points, for a total of 100 points.

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

Table 1. Demographic and Clinical Characteristics of the Study Subjects at Baseline*

Characteristics	Surgery	Orthosis	Control
No. of subjects	71	69	69
Age, mean (SD), y	48 (10)	49 (10)	47 (9)
Women	93	89	96
≥College education	11	11	10
Body mass index, mean (SD), kg/m^2	24.0 (14.0)	23.9 (13.0)	24.2 (15.0)
Height, mean (SD), cm	166 (6)	166 (8)	165 (5)
Physical exercise ≥3/wk	51	46	57
Employment characteristics			
Employed	82	76	83
Heavy physical work, self-report	13	13	16
Pain and disability			
Bilateral deformity	38	39	47
>6 mo of foot pain	86	87	83
Intensity of foot pain, mean (SD)†	47 (24)	50 (23)	45 (24)
Sick leave for foot problems during last 12 mo‡	5.6	2.9	5.7
Cosmetic disturbance, mean (SD)§	3.4 (2.3)	2.7 (2.1)	3.1 (2.3)
Footwear problems			
None	8.4	4.4	4.2
Moderate	80.2	86.8	87.1
Severe	11.3	8.8	8.6
Ability to work, mean (SD)‖	85 (16)	83 (17)	82 (20)
Functional status, mean (SD), AOFAS score¶	60 (14)	59 (11)	62 (11)
Radiolograph, mean (SD), degree			
Hallus valgus angle	23.4 (4.46)	24.3 (5.96)	23.9 (5.56)
Intermetatarsal angle	10.5 (2.02)	11.1 (2.39)	10.7 (2.28)
Congruent MTP I joint	58.5	44.4	47.5
Health-related quality of life index (15-D), mean (SD)#	90.7 (6.9)	91.1 (6.9)	90.0 (6.8)

*Data are presented as percentages unless otherwise stated. AOFAS indicates American Orthopaedic Foot and Ankle Society; MTP I, first metatarsophalangeal joint.
†Recorded on a 100-mm visual analog scale (VAS) from 0 (no pain at all) to 100 (unbearable pain).
‡Sick leave had been less than 30 days in all cases
§Recorded on a 7-point scale from 0 (no cosmetic disturbance at all) to 6 (maximal cosmetic disturbance).
‖Recorded on a 100-mm VAS from 0 (total inability to work) to 100 (maximal working ability).
¶Total score ranges from 0 to 100, with higher score indicating better functional ability.
#Scores of 15-D range from 0 to 100, with higher scores indicating better function in the most essential dimensions of general health. The number of respondents is 139 because the 15-D scale was not given to the first 70 patients.

(lower scores on the AOFAS scale) was selected for the data analysis.

Randomization and Treatments

The randomization process, performed by a research assistant, was based on a list of numbers in a random number table using numbered sealed envelopes. Block size for randomization, not previously known for the investigators, was 15. After patients who met inclusion criteria had given their informed consent, the independent observer opened an envelope and gave the protocol instructions to each patient. The chevron procedure was used for in the surgical group. Three experienced orthopedic surgeons, one of whom is an author (S.S.), performed most of the operations. The operations were performed with spinal nerve block, and a tourniquet was used. A medial, slightly curved, longitudinal incision was made. After the medial capsulotomy, the medial exostosis was removed. The adductor tendon was released interarticularly with a sharp dissection. According to the original method described by Austin,[4] the fixation of the osteotomy was not used routinely (a K-wire fixation for 6 weeks was used only for 1 patient). After surgery, the patients used an abduction splint (toe hold) for 6 weeks. Patients were allowed to bear weight on the heel and on the lateral part of the foot immediately after surgery. After 2 weeks, plantigrade walking was allowed and active exercises of the great toe were started. Employed patients were prescribed a 6-week leave of absence from work.

For the orthosis group, the functional foot orthoses were made by negative cast technique.[18] Negative casts were taken by 1 of the authors (V.H.) who had 5 years' clinical experience with functional foot orthoses therapy. The negative casts with individual prescription written according to the foot deformity[19,20] were sent to ProLab (South San Francisco, Calif). ProLab fabricated the polypropylene orthoses for both feet and sent the orthoses and usage instructions to the patients within 8 weeks. Patients in the control group were asked to avoid surgical and foot orthotic therapy during the follow-up period. In both orthosis and control groups, the patients were advised to contact the independent observer if their foot pain had so worsened that they required surgery before the end of the follow-up.

Adherence and Cointerventions

In the follow-up questionnaires, all patients were asked whether they had had surgery for the foot included in the study and whether they had used functional foot orthoses. If they answered yes, they were asked the number of days per week and the number of hours per day that they had used the orthoses. Any other health care services received for foot problems were recorded.

Assessment

The follow-up questionnaires were sent to the patients 6 months after the randomization. The measured outcomes were duration of foot pain, foot pain intensity, ability to work, cosmetic disturbance, footwear problems, health-related quality of life index (15-D), satisfaction with treatment, and costs related to foot care. Those who did not answer were contacted by telephone and asked to participate.

At the 1-year follow-up, the patients were examined and completed another questionnaire. The outcome measures were duration of foot pain, foot pain intensity, ability to work, cosmetic disturbance, footwear problems, AOFAS score, health-related quality of life index (15-D), satisfaction with treatment, global assessment by patient, and costs related to foot care. In the surgical group, radiographs of the foot bearing weight (anteroposterior and lateral projections) were taken. In all groups, the follow-up period (6 and 12 months) was determined from the time of randomization.

Economic Analysis

We used the Nord-DRG (Nordic Diagnosis Related Group) price for the cost of the chevron procedure. The price includes the hospital costs of the surgery and the immediate postsurgical care. Otherwise economic analysis was based on responses to the 6-month and 1-year follow-up questionnaires asking about the use of health care services related to hallux valgus. This included visits to a physician and to a physical or foot therapist. 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 on the basis of the patients' own expenditure on them. Dollar costs were calculated at the 1998 exchange rate ($1 = 5.096 Finnish marks). Because of the controversy over human capital and friction cost analysis, the monetary value of sick leaves was not estimated.[21] According to Finnish law, the compensation is 100% during the first 60 days of absence due to sickness.

Statistical Analysis

According to the power calculations, 68 subjects per treatment group were needed for the study to achieve a statistical power of .90 with an α of .05 (2-tailed). The calculations were made for pain during walking (the primary outcome) on a 0- to 100-mm visual analogue scale, considering 15 mm as a clinically significant difference between the groups and assuming an SD of 15%.

Efficacy variables were analyzed on an intention-to-treat basis. 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, for which the model included group and time effects and their interaction. The outcomes were adjusted for each characteristic at baseline. The post hoc testing showed no clear choice of an appropriate error term when testing involved between group by within-subject interactions. Accordingly, our post hoc testing between the groups is based on 95 % confidence intervals (CIs) constructed for the change over the time. Cross-tabulations were analyzed using a χ^2 test. The changes of radiological parameters in the surgical group before and after surgery were analyzed with the pairwise *t* test. Computation was carried out using NCSS 2000

(Jerry Hintze; Kaysville, Utah) and Statistica/Win (Version '98; StatSoft; Tulsa, Okla) software programs.

RESULTS

Study Population

The 211 eligible participants were randomly assigned to the 3 treatment groups (FIGURE 1). Two were withdrawn: one because the baseline questionnaire was not obtained and the other because rheumatoid arthritis was diagnosed 3 months after recruitment. Withdrawal was made without knowing the patient's group assignment. Of these withdrawals the former would have been in the orthosis group and the latter in the control group.

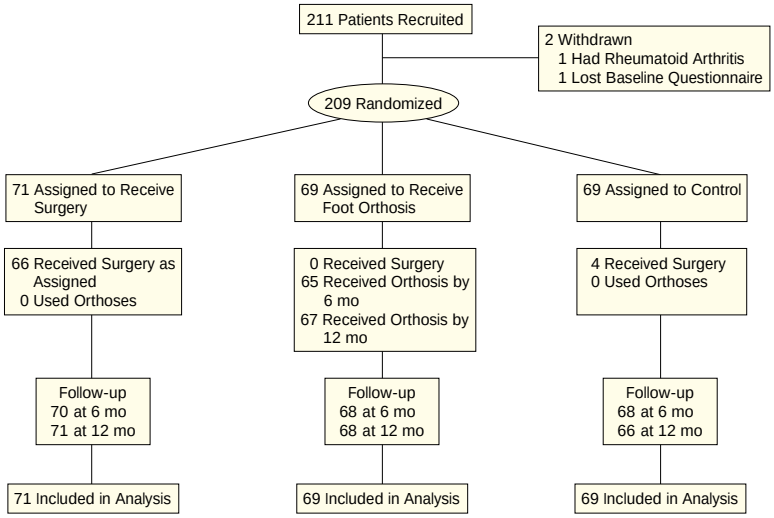
The final study population consisted of 209 patients. Seventy-one patients were randomized to the surgical group, 69 to the orthosis group, and 69 to the control group. The follow-up information was obtained 6 months later for 206 subjects (99%); one subject was absent from each group. After a year, information was obtained for 205 subjects (98%); at this phase 3 subjects had dropped out. The dropouts did not differ markedly from those remaining in the study. The 3 groups were similar in all of the baseline characteristics (Table 1).

Adherence and Cointerventions

At the 6- and 12-month follow-up visit, 66 patients in the surgical group had undergone surgery. The chevron procedure was performed on 65 patients and Keller arthroplasty was required in one patient because of osteoarthritic changes. Of the 5 patients who did not undergo surgery, 2 had canceled the operation due to a work conflict, 1 had become pregnant, 1 had severe depression, and 1 refused because of personal reasons. None of the patients in the surgical group used functional foot orthoses during the follow-up period. At the 6-month follow-up visit, 65 patients (95%) in the orthosis group reported that they had used, on average, the orthoses for 5.8 hours, 6 days a week.[8] At the 12-month follow-up period, 67 patients (97%) reported having used, on average, the orthoses for 5.5 hours, 6 days a week.[5] No patients in the orthoses group underwent surgery during the 12-month follow-up period.

None of the patients in the control group used foot orthoses during the study; however, 4 patients underwent surgery during the 12-month follow-up period, all because of severe foot pain.

Figure 1. Patient Flow Chart



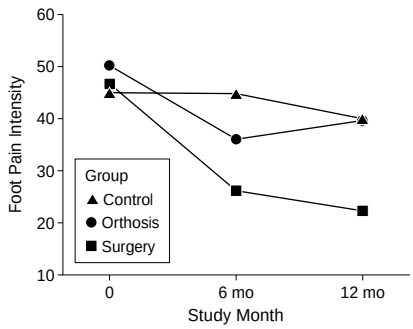
Patient and Physician Expectations

Because of the study protocol, it was not possible to blind the patients or the independent observer. To assess any possible preferences toward the treatments, both the patients and the independent observer were asked just after the randomization if they expected that the foot involved would be better or not after the follow-up of 1 year. The independent observer expected that after a year, 100% of those in the surgical group, 89% of those in the orthosis group, and 11 % of those in the control group would be better. The patients' 1-year expectations were 100%, 83 %, and 18 %, respectively.

Outcomes

At six months, the intensity of foot pain (FIGURE 2) was less in the surgical and orthosis treatment groups than in the control group (TABLE 2). The surgical group had the least cosmetic disturbance compared with the other 2 groups. Also, the proportion of the patients with

Figure 2. Mean Intensity of Foot Pain



Visual analogue scale scores from 0 to 100, where 100 depicts the most pain, at baseline, 6 months, and 12 months in the surgery, orthosis, and control groups.

footwear problems was the least in the surgical group. The satisfaction with the treatment was the poorest in the control group (Table 2). At 12 months, the intensity of pain (Figure 2), number of painful days, cosmetic disturbance, and footwear problems were less in the surgical group than in the orthosis and control groups (TABLE 3). The functional status, determined according to the AOFAS score, was better in the surgical group than in the other 2 groups. The satisfaction with the treatment and global assessment by patient were better in the surgical group than in the other 2 groups (number needed to treat, 1.7 between surgical and control groups). In addi-

tion, global assessment of the patients in the orthosis group was better than that in the control group.

Radiological Findings

At the 12-month follow-up visit, the mean (SD) hallux valgus angle in the surgical group was 13.4° (5.4°). The intermetatarsal angle was 6.7° (2.5°). The change from baseline was 10.4° ($P<.001$) and 3.8° ($P<.001$), respectively. At baseline, 59% involved feet treated in the surgical group had congruent first metatarsophalangeal joint; at the 12-month follow-up visit, the percentage had increased to 88% ($P<.001$).

Complications and Recurrences

Seventy patients underwent surgery (66 in the surgical, 4 in the control group). Twenty-seven of those had a bilateral procedure, increasing the number of involved feet treated surgically to 97. During the follow-up, 1 patient had a superficial wound infection, 1 had stress fracture of the second metatarsal bone 7 months after the operation, 1 had a transient peroneal nerve paralysis postsurgically, and 1 had clear recurrence of hallux valgus at the 12-month follow-up visit.

Costs

Total foot care costs were the least in the control group. Excluding the cost of intervention, health care costs were the least in the orthosis group. Physician visits were significantly more frequent in the surgical and the control groups (TABLE 4). The mean sick leave taken from work during the 12-month follow-up period was 53 days in the surgical, 0 in the orthosis, and 12 in the control groups.

COMMENT

Although patients recruited to the study had only mild to moderate hallux valgus deformity, the bunion pain while walking caused considerable disability. According to current clinical knowledge, surgery was warranted. Because the most severe cases were excluded, conservative treatment with foot orthoses or watchful waiting could be considered an option.

Randomization resulted in good comparability in the baseline characteristics between the 3 groups, and therefore no adjustments (except for each outcome measure) were made in the statistical analyses. A common source of bias in randomized controlled trials is poor adherence to the study protocol.[22] In our study, the adherence remained good. Analysis of the treatment effect was executed according to intention-to-treat principle due to its superior validity. Only 2% of patients were lost to follow-up, and the baseline characteristics of those with missing follow-up data did not differ from those who completed the study.

Table 2. Outcomes at the 6-Month Follow-up*

Characteristics	Surgery (n-71)	Orthosis (n = 69)	Control (n = 69)
Pain and disability			
Pain in last 6 months, d	67 (51)	66 (59)	73 (65)
Intensity of foot pain†	26 (23)	36 (24)	45 (23)
Ability to work‡	85 (24)	84 (25)	80 (28)
Cosmetic disturbance§	2.5 (2.4)	2.6 (2.1)	3.1 (2.3)
Footwear problems, %			
None	25.0	3.0	5.8
Moderate	69.1	83.6	86.8
Severe	5.9	13.4	7.4
Health-related quality of life index (15-D)‖	92.0 (7.3)	92.0 (6.5)	90.5 (8.2)
Satisfaction with treatment¶	74 (32)	66 (26)	41 (36)
	Differences in Adjusted Group Means (95% Confidence Interval)#		
	Surgery Minus Control	Orthosis Minus Control	Surgery Minus Orthosis
Pain and disability			
Pain in last 6 months, d	−6 (−25 to 14)	−7 (−26 to 13)	1 (−18 to 20)
Intensity of foot pain†	−20 (−28 to −12)	−14 (−22 to −6)	−6 (−14 to 2)
Ability to work‡	3 (−5 to 10.0)	4 (−4 to 11)	−1 (−9 to −7)
Cosmetic disturbance§	−1.0 (−1.6 to −0.4)	−0.2 (−0.8 to 0.4)	−0.8 (−1.4 to −0.3)
Health-related quality of life index (15-D)‖	0.8 (−1.4 to 2.9)	0.3 (−2.0 to 2.5)	0.5 (−1.7 to 2.7)
Satisfaction with treatment¶	32 (22 to 43)	24 (13 to 34)	9 (−2 to 19)
		P Value	
Footwear problems	<.01	.41	<.01

*Data are presented as mean (SD) unless otherwise indicated.
†Recorded on a 100-mm visual analog scale (VAS) from 0 (no pain at all) to 100 (unbearable pain).
‡Recorded on a 100-mm VAS from 0 (total inability to work) to 100 (maximal working ability).
§Recorded on a 7-point scale from 0 (no cosmetic disturbance at all) to 6 (maximal cosmetic disturbance).
‖Scores of 15-D range from 0 to 100, with higher scores indicating better function in the most essential dimensions of general health. The number of respondents is 139 because the 15-D scale was not given to the first 70 patients.
¶Recorded on a 100-mm VAS from 0 (totally unsatisfied) to 100 (totally satisfied).
#Adjusted for each baseline characteristic.

Because double blinding was not feasible, we assessed the expectations for recovery after randomization, as well as the satisfaction for the treatment. The patients' and physicians' expectations at baseline for the interventions were most favorable in the surgical group. Patients' expectations could somewhat influence the subjective assessments of outcome. However, because the follow-up assessments on several outcome measures were made after 6 and 12 months, we consider it probable that the subjective disabilities represent unbiasedly the condition at the time of assessment. The satisfaction with the treatment at the 6-month follow-up visit was in accordance with decreased foot pain intensity in the surgical and orthosis groups. At the 12-month follow-up visit, several outcome characteristics favored the surgical treatment; whereas, in the orthosis group, only the global assessment of improvement was superior to that in the control group. The latter finding contrasts with no advantage of the orthoses over the control group in terms of other outcome measures. A possible reason for poor result of orthotic therapy is that the orthoses can only compensate the foot deformity that causes malfunction of the foot. The orthoses do not correct the abductovalgus deformity of the great toe. All the patients included in the study had their foot problems concentrated on the bunion itself and did not have a widespread foot pain. In fact, widespread foot pain may be considered as a contraindication of chevron osteotomy.[1]

To our knowledge, no previous randomized trial that has been published compares the effectiveness of surgical and orthotic treatment or either 1 of these treatments with an option of watchful waiting for painful hallux val-

Table 3. Outcomes at the 12-Month Follow-up*

Characteristics	Surgery (n-71)	Orthosis (n = 69)	Control (n = 69)
Pain and disability			
Pain in last 6 months, d	45 (54)	79 (65)	66 (67)
Intensity of foot pain†	23 (23)	40 (23)	40 (26)
Ability to work‡	89 (19)	81 (26)	83 (25)
Cosmetic disturbance§	1.9 (2.2)	2.6 (2.0)	2.8 (2.3)
Footwear problems, %			
None	35.4	4.5	7.5
Moderate	61.5	86.4	86.4
Severe	3.1	9.1	6.1
Functional status			
AOFAS score‖	75 (13)	64 (10)	66 (10)
Health-related quality of life index (15-D)¶	92.9 (6.2)	92.7 (7.0)	92.2 (7.4)
Satisfaction with treatment#	80 (28)	70 (26)	61 (37)
Global foot assessment, self-report, %			
Better than 1 year ago	83	46	24
As good as 1 year ago	11	43	42
Worse than 1 year ago	6	11	34

	Differences in Adjusted Group Means (95% Confidence Interval)**		
	Surgery Minus Control	Orthosis Minus Control	Surgery Minus Orthosis
Pain and disability			
Pain in last 6 months, d	−22 (−42 to −1)	13 (−8 to 33)	−34 (−55 to −14)
Intensity of foot pain†	−19 (−28 to −10)	−6 (−15 to 3)	−14 (−22 to −5)
Ability to work‡	4 (−3 to 11)	−2 (−9 to 5)	6 (0 to 13)
Cosmetic disturbance§	−1.2 (−1.8 to −0.6)	0.2 (−0.4 to 0.8)	−1.4 (−2.1 to −0.8)
Functional status			
AOFAS score‖	11 (7 to 16)	0 (−4 to 5)	11 (7 to 15)
Health-related quality of life index (15-D)¶	0 (−2.5 to 2.3)	−0.7 (−3.1 to 1.9)	0.6 (−1.9 to 3.0)
Satisfaction with treatment#	20 (10 to 30)	9 (−1 to 20)	11 (1 to 21)
		P Value	
Footwear problems, %	<.01	.50	<.001
Global assessment by patient, %	<.001	<.01	<.001

*Data are presented as mean (SD) unless otherwise indicated.
†Recorded on a 100-mm visual analog scale (VAS) from 0 (no pain at all) to 100 (unbearable pain).
‡Recorded on a 100-mm VAS from 0 (total inability to work) to 100 (maximal working ability).
§Recorded on a 7-point scale from 0 (no cosmetic disturbance at all) to 6 (maximal cosmetic disturbance).
‖Total score ranges from 0 to 100. Higher scores indicate better functional ability.
¶Scores of 15-D range from 0 to 100, with higher scores indicating better function in the most essential dimensions of general health. The number of respondents is 139 because the 15-D scale was not given to the first 70 patients.
#Recorded on a 100-mm VAS from 0 totally unsatisfied to 100 (totally satisfied).
**Adjusted for each baseline characteristic.

Table 4. Mean Cost of Foot Care Over a 12-Month Period*

Type of Cost	Surgery (n = 70)	Orthosis (n = 67)	Control (n = 66)
Study treatments	845†	196	0
Health maintenance organization foot care service			
Physician visit‡	66	18	30
Physical therapy visit§	29	7	40
Operative treatment‖	0	0	55
Total	**930**	**221**	**125**

*Costs are in 1998 US dollars. The groups were smaller than in the outcome analyses because those with missing data were excluded.
†The price of the chevron osteotomy (including postoperative care of 1 day) is US $910, according to Nordic Diagnosis Group–price list of Jorvi Hospital. Because the procedure was performed for 65 patients in the surgery group, the price of the intervention per patient was calculated as follows: US $910 × 65/70 = US $845.
‡These costs include visits to physicians during the follow-up period. The sums are expressed as mean price per patient.
§These costs include visits to physical therapists or foot therapists because of foot problems during the follow-up period. The sums are expressed as mean price per patient.
‖Four patients in the control group underwent surgery during the follow-up period. The cost of this cointervention was calculated as US $910 × 4/66 = US $55.

gus.[11] In this trial, we were able to evaluate the effectiveness of the 2 treatment options. The surgical treatment showed considerable effectiveness in the primary outcome, ie, pain while walking and also in several other clinically relevant measures of effectiveness. In addition, the surgery resulted in a rather good cosmetic outcome. Although unable to correct the deformity, the orthotic treatment showed effectiveness at the 6-month follow-up visit and can be considered as an option when the waiting time for surgery is extended.

Because all the patients had moderately severe symptoms and were waiting for surgery, we did not consider it ethical to extend nonsurgical treatment beyond a year. Thus, from our data, we cannot make any inferences of what might have been the long-term effectiveness of the surgical treatment.

Our economic assessment showed that the cost of the surgery exceeded that of orthotic treatment and resulted in indirect costs due to sick leave after operation. Health care practices differ between countries, which makes international comparisons of the costs complicated. For example, the average hospital stay for a hallux valgus operation is longer in Finland than in the United States. Therefore, the economical results cannot be generalized to other countries without a careful examination of the similarities and contrasts in health care practices.

In conclusion, the chevron operation is an effective treatment for patients who have a mild to moderate hallux valgus deformity and bunion pain while walking as their main symptom. Effectiveness is shown on several relevant outcome measures, and the effect increases during the postsurgical year. Orthotic treatment resulted in favorable outcome at the 6-month follow-up visit, after which the effect fades. Orthotic treatment may be considered an option when patients with disabling hallux valgus pain must wait for the surgery.

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