Splinting vs Surgery in the Treatment of Carpal Tunnel Syndrome: A Randomized Controlled Trial

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Splinting vs Surgery in the Treatment of Carpal Tunnel Syndrome

A Randomized Controlled Trial

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Context Carpal tunnel syndrome (CTS) can be treated with nonsurgical or surgical options. However, there is no consensus on the most effective method of treatment.

Objective To compare the short-term and long-term efficacy of splinting and surgery for relieving the symptoms of CTS.

Design, Setting, and Patients A randomized controlled trial conducted from October 1998 to April 2000 at 13 neurological outpatient clinics in the Netherlands. A total of 176 patients with clinically and electrophysiologically confirmed idiopathic CTS were assigned to wrist splinting during the night for at least 6 weeks (89 patients) or open carpal tunnel release (87 patients); 147 patients (84%) completed the final follow-up assessment 18 months after randomization.

Main Outcome Measures General improvement, number of nights waking up due to symptoms, and severity of symptoms.

Results In the intention-to-treat analyses, surgery was more effective than splinting on all outcome measures. The success rates (based on general improvement) after 3 months were 80% for the surgery group (62/78 patients) vs 54% for the splinting group (46/86 patients), which is a difference of 26% (95% confidence interval [CI], 12%-40%; $P<.001$). After 18 months, the success rates increased to 90% for the surgery group (61/68 patients) vs 75% for the splinting group (59/79 patients), which is a difference of 15% (95% CI, 3%-27%; $P=.02$). However, by that time 41% of patients (32/79) in the splint group had also received the surgery treatment.

Conclusion Treatment with open carpal tunnel release surgery resulted in better outcomes than treatment with wrist splinting for patients with CTS.

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CARPAL TUNNEL SYNDROME (CTS) is the most common entrapment neuropathy and is caused by compression of the median nerve at the wrist. The prevalence of electrophysiologically confirmed CTS in the adult general population in the Netherlands is 0.6% in men and 9.2% in women.[1] While CTS may be treated with conservative options such as wrist splints, injections with corticosteroids, or both, evidence for the efficacy of most conservative treatment options is limited.[2] A recent systematic review has shown that among the various available surgical techniques, open carpal tunnel release is the preferred method.[3] However, only 1 randomized controlled trial (RCT) has compared conservative treatment (splinting) with surgery,[4] but provided no information on comparability of the groups at baseline, cointerventions, compliance with the treatment, or blinding of the outcome assessor. Furthermore, only 1 follow-up assessment was performed after 1 year, showing that the 10 patients treated surgically had complete relief of symptoms while 2 of the 10 patients treated with a wrist splint had experienced relief only temporarily.

See also p 1281 and Patient Page.

Due to limited evidence, there is no consensus on the preferred method of treatment for CTS. Advocates of surgery refer to its safety and effectiveness for electrophysiologically confirmed cases with no underlying reversible disorder,[5] and point out that conservative treatment options generally offer only temporary symptom relief. Advocates of conservative options refer to the potential benefits and safety of these treatments and to the potential complications of surgery.[6] In the Netherlands, 40% of the neurologists reported to prefer conservative treatment options, 39% reported to prefer surgery, and 21% re-

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ported to have no preference.[7] Splinting was the preferred treatment of 26% of the neurologists and is the most common. The objective of this study was to compare the short-term and long-term efficacy of splinting and surgery for relieving the symptoms of CTS.

METHODS

The medical ethics committees of the 13 participating hospitals approved the study protocol of this multicenter RCT. A detailed description of the design of this RCT has been previously published.[8]

Study Population

All patients with clinically suspected CTS had been referred to one of the participating neurologists and were examined for eligibility to participate in the study. Inclusion criteria were (1) pain, paresthesia, and/or hypoesthesia in the hand in the area innervated by the median nerve[9]; (2) electrophysiological confirmation of the diagnosis[8] (median nerve sensory conduction velocity of the index finger ≤41.9 m/s in patients <55 years or ≤37.3 m/s in patients ≥55 years, or median nerve distal sensory latency of the index finger ≥3.5 ms; or median-ulnar distal sensory latency difference of the ring finger >0.4 ms; or median nerve distal motor latency ≥4.34 ms); (3) age of 18 years or older; and (4) ability to complete written questionnaires (in Dutch). Exclusion criteria were (1) previous treatment with splinting or surgery; (2) a history of wrist trauma (eg, fracture) or surgery; (3) a history suggesting underlying causes of CTS (eg, diabetes mellitus, pregnancy); (4) clinical signs or symptoms or electrophysiological findings suggesting conditions that could mimic CTS or interfere with its validation (eg, cervical radiculopathy, polyneuropathy); and (5) severe thenar muscle atrophy.

Patients, who were eligible according to their neurologist and were interested in participation, were referred to one of the research physiotherapists in the same hospital, who verified that all selection criteria were met. After they had provided written informed consent, patients were included in the study. Subsequently, potential prognostic indicators and the baseline values of the outcome measures were assessed.

Treatment Allocation

Patients were randomly allocated to receive either splinting or surgery (FIGURE 1). If bilateral symptoms were present, the hand with the more severe symptoms (according to the patient) was treated. By preparing a list for each hospital, the randomization was stratified by center. Permuted blocks of 4 patients were formed to ensure near-equal distribution of patients over the 2 treatment groups in each hospital.[10] Despite the small block sizes, the potential for unmasking was considered to be low because the neurologists did not know the method of randomization and different neurologists selected patients in each hospital. Even if a neurologist were to know the allocation scheme, the chance was high that when he/she selected a patient, this patient would not be assigned the next treatment on the list because a patient selected by another neurologist has an earlier appointment for the trial. The random sequence of the permuted blocks was generated by using random number tables. The principal investigator (A.A.M.G.), who was not involved in the selection and allocation of patients, prepared, coded, and sealed opaque envelopes containing the treatment allocation.[11] After the baseline assessment, the next envelope was handed to the patient by the research assistant to ensure concealment of allocation.

Blinding

Attempts were made to keep the research physiotherapists unaware of the allocated treatment by encouraging the patients not to reveal any information regarding their treatment during the examination. Furthermore, before each examination, the research assistant placed a bandage over the wrist and palm of all patients to conceal the potential surgical scar. Afterward, the research physiotherapists were asked to indicate the type of treatment that they thought the patient had received and to give reasons for this assumption.[12]

Treatment

Depending on the usual procedures of the hospital, patients allocated to splinting received either a custom-made splint (made of soft cast) or a prefabricated splint (Tricodur, BSN Medical, Hamburg, Germany) that immobilized the wrist in a neutral position.[13] The patients were instructed to wear the splint during the night for at least 6 weeks, but could wear it during the day. No other types of treatment were permitted during the intervention period, except pain medication if necessary. After 6 weeks, the neurologist discussed with the patient whether any further treatment was necessary, including continued splinting, other conservative treatment options, or surgery. The decision to undergo surgery could also be made at a later stage.

Patients allocated to surgery were referred to a general surgeon, neurosurgeon, plastic surgeon, or orthopedic surgeon, depending on the usual procedures of the hospital for an outpatient standard open carpal tunnel release. Because there are waiting lists for surgery in hospitals, efforts were made to make an appointment within 4 weeks after randomization. Before surgery, no other types of treatment were permitted, except pain medication. In all surgical cases, the transverse carpal ligament was released and no concomitant procedures were performed (eg, flexor tenosynovectomy, internal neurolysis, epineurotomy). Sutures were removed after 2 weeks. Patients were instructed to perform postoperative active range-of-motion exercises and encouraged to use the hand as tolerated. None of the patients received a splint following the surgical procedure. No specific period off work was recommended.

Outcome Assessment

Patients completed questionnaires and were examined by a trained research physiotherapist in the hospital at baseline and 3, 6, and 12 months after randomization. Although different research physiotherapists assessed the outcomes, most patients were seen by the same therapist each time they vis-

ited the hospital. In the remaining months, and 18 months after randomization, questionnaires were mailed.

General improvement was scored by the patient on a 6-point ordinal transition scale, ranging from "completely recovered" to "much worse."[12] Treatment success was defined a priori as "completely recovered" or "much improved." The 2 other outcome measures were number of nights that the patient awoke due to the symptoms during the past week and severity of the main complaint, pain, paresthesia, or hypoesthesia at night and during the day during the past week. Severity of the main complaint, pain, paresthesia, and hypoesthesia were scored by the patient on an 11-point numerical rating scale (with 0 equaling "no symptoms" and 10 equaling "very severe symptoms" used as anchors).[12]

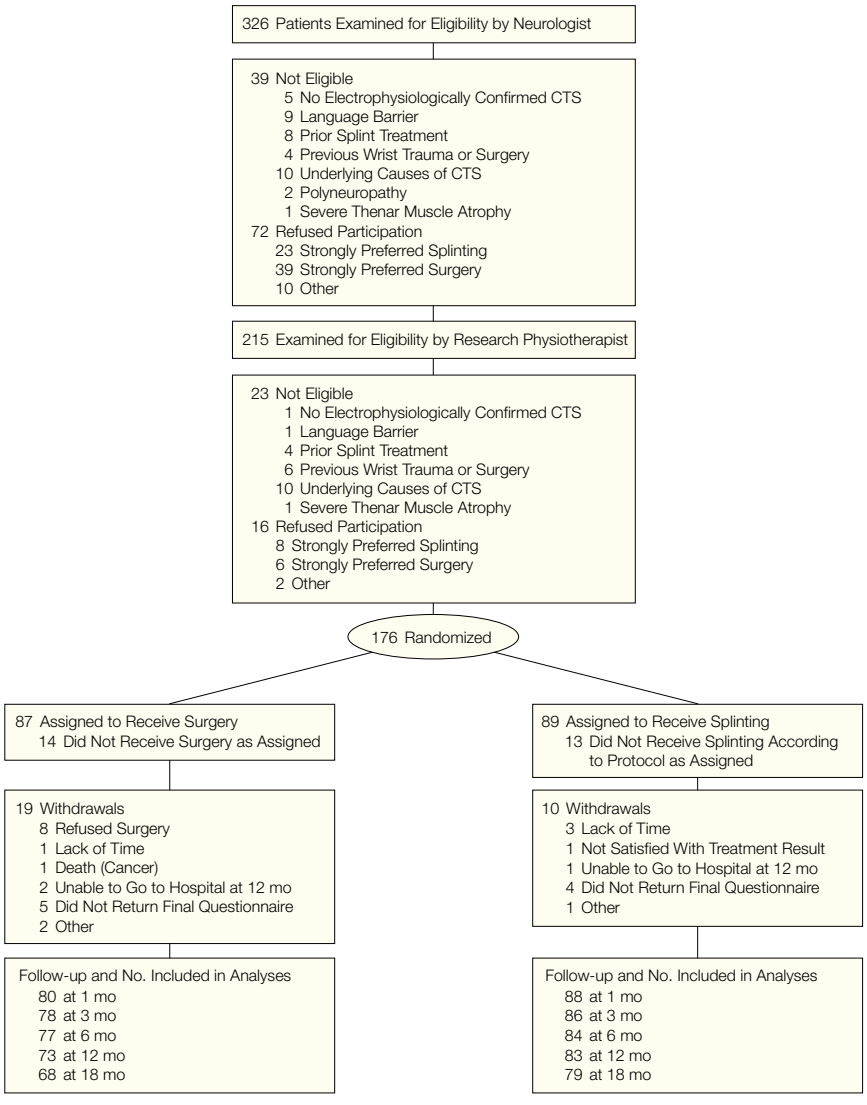
There were 3 secondary outcome measures used. Mean (SD) scores were collected using the Symptom Severity Scale (11 questions about symptoms experienced during the past 2 weeks with 1 equaling mildest and 5 equaling most severe) and the Functional Status Scale (8 items concerning difficulties in performing various activities of daily living during the past 2 weeks with 1 equaling no difficulty and 5 equaling cannot perform activity at all).[14] After a standardized history-taking and a physical examination, the overall severity of CTS complaints was scored by a research physiotherapist on an 11-point numerical rating scale with zero equaling no complaints and 10 equaling very severe complaints.[12] Results of nerve conduction studies after 12 months were also used. At each follow-up assessment, the patients were asked to record any treatment they had received and any adverse effects.

Statistical Analysis

The groups were primarily compared at 3, 6, and 12 months because all outcomes were assessed during the visits at the hospital. Furthermore, to obtain a clear picture of the short-term effects, the follow-up assessment time of 1 month was chosen. To determine the long-term effects, the assessment time of 18 months after randomization was chosen. Differences in success rates between the treatment groups along with 95% confidence intervals were calculated using χ^2 tests. Continuous outcomes were analyzed as change scores (difference between baseline assessment and each follow-up assessment). Subsequently, differences in improvement between the groups (mean change score in surgery group minus mean change score in splint group) along with 95% confidence intervals were calculated using *t* tests. Multivariate analyses (logistic or linear regression) were performed to adjust for the influence of eventual differences between the groups at baseline in prognostic indicators (age, sex, duration of current episode of CTS complaints, bilateral CTS complaints, dominant side more severely affected, previous episodes of CTS complaints, and patients' preference for splinting or surgery).

All analyses were performed according to the following intention-to-treat principle: the patients remained in the group to which they were allocated at baseline.[15] Two additional analyses were

Figure 1. Progress of Patients Through Carpal Tunnel Syndrome (CTS) Trial



performed. In the first analysis, patients who received surgery after splinting were considered to be not improved. In the second analysis, patients in the splint group who had received surgery were compared with patients in the same group who had not. All patients who withdrew from the study were included in the analysis until the time of withdrawal. For patients who occasionally missed a follow-up assessment, the available data from completed assessments were included.

Sample-size calculation was based on the ability to detect a clinically important difference in success rates of 20% or more 3 months after randomization. A total sample size of 190 patients was required (2-sided $\alpha = .05$, $\beta = .20$). Values of $P < .05$ were considered statistically significant. Data were analyzed using SPSS statistical software (Version 10.1; SPSS Inc, Chicago Ill).

RESULTS

Study Population

During a period of 18 months (October 1998 to April 2000), 326 patients were examined for eligibility by the neurologists. There were 111 patients who were either ineligible or not interested in participation (Figure 1). The remaining 215 patients were referred to one of the research physiotherapists who verified that all selection criteria were met. Of these patients, 39 were not randomized for various reasons (Figure 1), and the remaining 176 were allocated to either splinting (89 patients) or surgery (87 patients). By October 2001, 147 patients had completed the follow-up assessment 18 months after randomization, resulting in a final follow-up rate of 84%. Reasons for withdrawal are presented in Figure 1. In both of the groups, some patients occasionally missed a follow-up assessment, but some of them completed the questionnaire at home.

TABLE 1 shows the frequency of potential prognostic indicators and the baseline values of the outcome assessments for each group. There were small differences between the groups with regard to sex, duration of current episode of CTS complaints, and patients' preference for treatment.

Table 1. Prognostic Indicators and Baseline Values of Outcomes*

Prognostic Indicator	Surgery (n = 87)	Splinting (n = 89)
Age, mean (SD), y	49 (11)	49 (12)
Women, No. (%)	66 (76)	77 (87)
Duration of current episode of CTS complaints, median (IQR), wk	40 (16-104)	52 (24-104)
Bilateral CTS complaints, No. (%)	48 (55)	56 (63)
Dominant side more severely affected, No. (%)	59 (68)	57 (64)
Previous episodes of CTS complaints, No. (%)	29 (33)	24 (27)
Patients' preference for treatment, No. (%)		
Surgery	22 (25)	29 (33)
Splinting	20 (23)	23 (26)
No preference	46 (53)	37 (42)
Primary Outcomes at Baseline, Median (IQR)†		
No. of nights waking up due to symptoms (0-7)	4 (1-7)	4 (1-7)
Severity of the main complaint	7 (6-8)	7 (5-8)
Pain		
During day	4 (1-6)	4 (0-6)
During night	5 (0-8)	4 (0-7)
Paresthesia		
During day	6 (4-8)	6 (3-8)
During night	6 (2-8)	6 (3-8)
Hypoesthesia		
During day	4 (0-7)	3 (0.5-7)
During night	5 (0-8)	5 (0-8)
Secondary Outcomes at Baseline, Median (IQR)†		
Symptom severity score (1-5)	2.5 (1.9-3.1)	2.4 (1.8-2.9)
Functional status score (1-5)	2.3 (1.5-3.0)	2.0 (1.5-2.9)
Severity of complaints rated by a research physiotherapist	6 (4-7)	7 (5-7)
Nerve conduction studies, mean (SD), ms		
DSL (index finger)	**(n = 78)** 4.2 (1.0)	**(n = 77)** 4.1 (1.0)
Median-ulnar DSL difference (ring finger)	**(n = 66)** 1.7 (1.1)	**(n = 64)** 1.8 (1.4)
DML median nerve	**(n = 84)** 5.6 (1.5)	**(n = 87)** 5.7 (1.9)

*CTS indicates carpal tunnel syndrome; IQR, interquartile range; DSL, distal sensory latency; and DML, distal motor latency.
†Range of scores is 0-10 (10 indicating severe complaints), unless otherwise indicated. The scores represent the status in the previous week, except for symptom severity and functional status scores, which represent the status in the previous 2 weeks.

Allocated Treatment

All 89 patients allocated to splinting received a splint, either custom-made (28 patients [31%]) or prefabricated (61 patients [68%]), within a median period of 2 days after randomization (interquartile range, 0-5 days). However, 13 patients (15%) did not receive the treatment according to protocol: 2 received additional treatment, 1 received physiotherapy, 1 received Mensendieck (exercise) therapy, and 11 did not wear the splint every night for at least 6 weeks. Twenty-four patients (27%) indicated that they had also worn the splint during the day. Eleven patients (12%) used pain medication during the intervention period.

Of the 87 patients allocated to surgery, 73 (84%) actually underwent this treatment within a median period of 35 days (interquartile range, 20-55 days) after randomization. Of the patients who completed follow-up assessments, 36% had undergone surgery after 1 month (29/80), 80% after 3 months (62/78), and 92% after 6 (71/77), 12 (67/73), and 18 (63/68) months. Of the 14 patients who did not undergo carpal tunnel surgery, 9 did not receive any treatment and

5 were treated differently. Two patients received physiotherapy, 2 received pain medication, and 1 received a splint. Seven patients (8%) used pain medication before surgery.

Additional Treatment

In the splint group, 74 (83%) of 89 patients continued to wear the splint after the intervention period for a varying period of time. Furthermore, 52 (58%) of 89 patients received 1 or more additional treatment options after 6 weeks. Twenty-nine patients received pain medication, 4 received physiotherapy, 1 received manual therapy, 2 received Mensendieck (exercise) therapy, 1 received occupational therapy, 5 received 1 or 2 local corticosteroid injections, and 35 received surgery. Of the patients who had completed follow-up assessment, 7% (6/86) received surgery after 3 months, 31% (26/84) after 6 months, 39% (32/83) after 12 months, and 41% (32/79) after 18 months.

In the surgery group, 26 (30%) of 87 patients received 1 or more additional treatment options after surgery. Twenty-five patients received pain medication primarily to relieve pain caused by the operation, 2 received physiotherapy, 1 received occupational therapy, and 1 received a local corticosteroid injection and surgery to relieve pain caused by reflex sympathetic dystrophy.

Treatment Efficacy

Comparisons between the univariate and multivariate analyses showed that adjustment for potential prognostic indicators and the baseline values of the outcome measures minimally influenced the results. Therefore, only the unadjusted analyses are presented.

Intention-to-Treat Analyses

After 1 month, more patients in the splint group had improved than in the surgery group, but more patients in the surgery group improved after 3, 6, 12, and 18 months (TABLE 2 and FIGURE 2).

The results of the other outcome measure assessments are also shown in Table 2 and TABLE 3. Scores for pain and hypoesthesia are not presented because the

Table 2. Success Rates and Improvement in Primary Outcomes After 1, 3, 6, 12, and 18 Months (Intention-to-Treat Analyses)*

Primary Outcome by Month	Surgery	Splinting	Difference†	*P* Value
Success rate, No./total (%)				
1	23/80 (29)	37/88 (42)	−13 (−28 to 1)	.07
3	62/78 (80)	46/86 (54)	26 (12 to 40)	<.001
6	72/77 (94)	57/84 (68)	26 (14 to 37)	<.001
12	67/73 (92)	60/83 (72)	20 (8 to 31)	.002
18	61/68 (90)	59/79 (75)	15 (3 to 27)	.02
No. of nights waking up due to symptoms, mean (SD)				
1	0.8 (3.2)	2.0 (3.0)	−1.2 (−2.2 to −0.3)	.008
3	2.6 (3.5)	2.2 (3.1)	0.4 (−0.7 to 1.4)	.49
6	3.6 (2.8)	2.6 (3.1)	1.0 (0.1 to 2.0)	.03
12	3.6 (2.9)	2.9 (3.0)	0.7 (−0.2 to 1.7)	.13
18	3.6 (2.9)	3.2 (3.1)	0.4 (−0.6 to 1.4)	.44
Severity of the main complaint, mean (SD)				
1	1.6 (2.9)	2.1 (2.2)	−0.5 (−1.3 to 0.3)	.22
3	5.1 (3.3)	3.2 (2.7)	1.9 (1.0 to 2.8)	<.001
6	6.6 (2.4)	4.4 (3.2)	2.2 (1.4 to 3.1)	<.001
12	6.4 (2.7)	5.1 (3.1)	1.3 (0.4 to 2.2)	.005
18	6.2 (2.8)	5.0 (3.3)	1.2 (0.2 to 2.3)	.02
Paresthesia during the day, mean (SD)				
1	1.5 (3.0)	1.4 (2.1)	0.1 (−0.6 to 1.0)	.66
3	4.8 (3.2)	2.2 (3.2)	2.6 (1.6 to 3.6)	<.001
6	5.5 (2.9)	3.7 (3.2)	1.8 (0.8 to 2.8)	<.001
12	5.5 (2.9)	4.0 (3.4)	1.5 (0.5 to 2.5)	.004
18	5.3 (3.0)	4.0 (3.6)	1.3 (0.3 to 2.5)	.01
Paresthesia at night, mean (SD)				
1	1.3 (3.1)	2.5 (3.0)	−1.2 (−2.1 to −0.2)	.02
3	4.6 (3.8)	3.5 (3.3)	1.1 (0 to 2.2)	.046
6	5.4 (3.5)	4.1 (3.7)	1.3 (0.2 to 2.4)	.02
12	5.2 (3.6)	4.5 (3.4)	0.7 (−0.4 to 1.8)	.20
18	5.0 (3.6)	4.4 (3.6)	0.6 (−0.6 to 1.7)	.35

*Patient cohorts are presented in Figure 1. The values are expressed as the mean (SD) improvements from baseline unless otherwise indicated.
†Indicates the differences (surgery minus splint) in success rates and in the mean improvements from baseline (95% confidence interval).

Figure 2. Success Rates at Each Follow-up Measurement

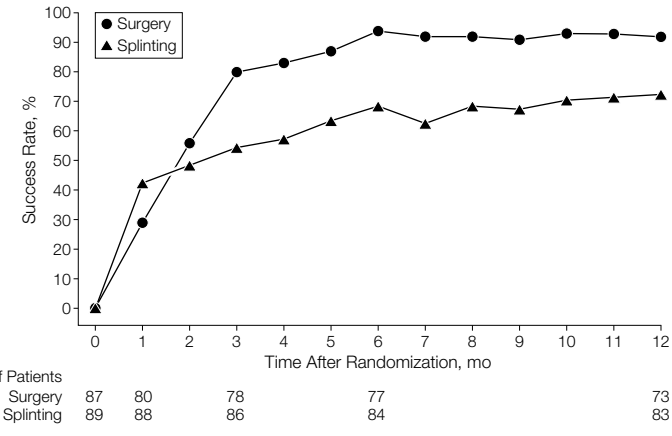


Table 3. Improvement in Secondary Outcomes After 3, 6, 12, and 18 Months (Intention-to-Treat Analyses)*

Secondary Outcome by Month	Surgery	Splinting	Difference†	*P* Value
Symptom severity score				
3	1.0 (0.9)	0.6 (0.7)	0.4 (0.2 to 0.7)	<.001
6	1.3 (0.8)	0.9 (0.8)	0.4 (0.2 to 0.7)	.001
12	1.3 (0.8)	0.9 (0.9)	0.4 (0.1 to 0.7)	.003
18	1.3 (0.8)	0.9 (0.9)	0.4 (0.1 to 0.6)	.02
Functional status score				
3	0.6 (0.9)	0.4 (0.7)	0.2 (0 to 0.5)	.07
6	1.0 (0.9)	0.5 (0.8)	0.5 (0.2 to 0.7)	.001
12	1.0 (0.9)	0.7 (0.8)	0.3 (0 to 0.6)	.03
18	0.9 (0.9)	0.7 (0.8)	0.2 (–0.1 to 0.5)	.12
Severity of complaints rated by a research physiotherapist, mo				
3	**(n = 69)** 3.5 (3.4)	**(n = 80)** 2.2 (2.6)	1.3 (0.4 to 2.4)	.007
6	**(n = 70)** 5.4 (2.5)	**(n = 76)** 3.3 (2.7)	2.1 (1.2 to 2.9)	<.001
12	**(n = 67)** 5.3 (3.0)	**(n = 77)** 3.7 (3.0)	1.6 (0.6 to 2.6)	.002
Nerve conduction studies at 12 mo, ms				
Distal sensory latency (index finger)	**(n = 56)** 1.0 (1.0)	**(n = 59)** 0.7 (0.8)	0.3 (0 to 0.7)	.04
Median-ulner distal sensory latency difference (ring finger)	**(n = 48)** 1.1 (1.2)	**(n = 50)** 0.7 (1.2)	0.4 (0 to 0.9)	.07
Distal motor latency median nerve	**(n = 63)** 1.3 (1.5)	**(n = 70)** 1.0 (1.5)	0.3 (–0.2 to 0.8)	.25

*Patient cohorts are presented in Figure 1. The values are expressed as the mean (SD) improvements from baseline unless otherwise indicated.
†Indicates the differences (surgery minus splint) in success rates and in the mean improvements from baseline (95% confidence interval).

Table 4. Adverse Effects Reported by the Patients During the Follow-up Period of 18 Months

No. of Patients Who Reported	Surgery (n = 87)	Splinting (n = 89)
Adverse effects, No. (%)	58 (67)	46 (52)
Painful or hypertrophic scar	53	20
Stiffness of the wrist, hand, or fingers	24	31
Skin irritation	19	8
Wound hematoma	10	1
Wound infection	5	2
Discomfort caused by pressure of the splint	0	6
Swelling of the wrist, hand, or fingers	0	4
Severe pillar pain	2	0
Reflex sympathetic dystrophy	1	0

findings were similar to those for paresthesia. After 1 month, the differences in the primary outcome measures were mainly in favor of splinting. However, after 3, 6, 12, and 18 months, surgery was found to be more effective than splinting and with regard to the secondary outcomes. There was no difference in outcomes between patients in the splint group using a custom-made splint and those using a prefabricated splint.

An additional analysis was performed for the outcome measure success rate, using last observation carried forward for the patients who withdrew from the study. When this was done for the 10 patients who withdrew from the splint group, the success rates for this group were 52% (46/89) after 3 months, 66% (59/89) after 6 months, 71% (63/89) after 12 months, and 72% (64/89) after 18 months. Four patients in the surgery group did not have any of the follow-up assessments taken and were regarded as not improved. In addition, in the analysis using the last observation carried forward for the other 15 patients who withdrew from the surgery group, the success rates were 26% (23/87) after 1 month, 74% (64/87) after 3 months, 87% (76/87) after 6 months, 86% (75/87) after 12 months, and 85% (74/87) after 18 months.

Withdrawal was not related to general improvement. Of the 10 patients who withdrew from the splint group, 5 indicated to be much improved at the time of withdrawal, 2 indicated to be slightly improved, 1 indicated that no change had occurred, 1 indicated to be slightly worse, and 1 indicated to be much worse. Of the 19 patients who withdrew from the surgery group, 4 did not have any follow-up assessments, 10 indicated to be completely recovered at the time of withdrawal, 3 indicated to be much improved, 1 indicated to be slightly improved, and 1 indicated no change.

In the first additional analysis, patients who received surgery after splinting were considered to be "not improved." After 18 months, only 29 of 79 patients indicated to be improved by splinting alone, resulting in a final success rate of 37% for the splint group.

In the second additional analysis, patients in the splint group who had received surgery were compared with patients in the same group who had not. After 18 months, the success rate in the group of patients who received surgery after splinting was 94% (30/32 patients) compared with 62% (29/47 patients) in the group who did not undergo surgical treatment. Also with regard to the other primary outcomes, the patients in the splint group who received surgery showed statistically significant more improvement after 18 months than the patients who did not have surgery.

Adverse Effects

TABLE 4 shows the frequency of adverse effects reported by the patients in each group during the 18 months of follow-up. Although many patients reported adverse effects, most of these were relatively mild and of short duration. However, 1 patient in the surgery group developed reflex sympathetic dystrophy.

Success of Blinding

The physiotherapists correctly indicated the treatment received 85% (139/164) of the time after 3 months, 71% (114/161) after 6 months, and 65% (101/156) after 12 months. Many patients inadvertently mentioned their treatment,

and guesses were often based on the course of symptoms during the follow-up period and on the way patients reacted to the physical examinations.

COMMENT

This RCT compared the short-term and long-term efficacy of surgery and splinting for relieving the symptoms of CTS. Although only 176 patients were included, instead of the 190 originally planned, this did not reduce the power of the trial because the differences between the groups were large enough to be detected. Furthermore, although many outcomes were analyzed at different follow-up times, the results are not likely to be due to chance, as they all are in the same direction.

The results of the intention-to-treat analyses showed that surgery was more effective than splinting after 3, 6, 12, and 18 months. These differences became smaller after 12 months, probably because a large proportion of patients in the splint group received additional surgery. The differences after 1 month were mainly in favor of splinting, which might have resulted from patients allocated to splinting having started their treatment almost immediately after randomization, in contrast to patients in the surgery group. Randomization was chosen as the reference point for the timing of the follow-up assessments, and not the actual start of the treatment because including the time waiting to undergo surgery reflects current clinical practice. However, as the median time to undergo surgery was 35 days, taking the actual start of the treatment as a reference point would result in a shift to the left (of 1 month) of the line of the surgery group in Figure 2.

We believe the results of this trial are applicable to most patients with clinically and electrophysiologically confirmed idiopathic CTS. However, the least severe and the most severe cases were probably not included in this trial. These patients (or physicians) typically have a strong preference for splinting or surgery.

This trial was mainly based on subjective, patient-reported outcomes because the perspective of the patient was considered to be the most important. As blinding of the patients for the allocated treatment was not possible, the results could be biased because patients tend to report greater effects from their preferred method of treatment.[16] However, subgroup analyses showed that treatment effects did not depend on the patients' preference prior to randomization (data not shown). An attempt was made to include a more objective evaluation of outcome by involving blinded research physiotherapists who scored the overall severity of CTS complaints. However, blinding of the research physiotherapists was not successful in most cases.

Treatment success was defined a priori as "completely recovered" or "much improved." When analyzing the data, it was found that most of the successes in the surgery group were "completely recovered," while patients in the splint group were only "much improved." Thus, if success was solely defined as "completely recovered," the differences between the groups would have been even more pronounced.

The American Academy of Neurology recommends treatment of CTS with noninvasive options (eg, wrist splints) first, and open carpal tunnel release only if noninvasive treatment proves to be ineffective.[17] This RCT showed that treatment of CTS with surgery results in better outcomes. A splint might be used while a patient waits for surgery because the waiting period for open carpal tunnel release in practice is often longer than in this study, as efforts were made to make an appointment for the patients within 4 weeks after randomization. Patients not willing to undergo surgery could also be offered a splint. Another recently conducted RCT found that patients wearing a wrist splint showed more relief from symptoms than patients not receiving any treatment.[18]

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