

## Outcomes of endoscopic surgery compared with open surgery for carpal tunnel syndrome among employed patients: randomised controlled trial

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### Abstract

**Objectives** To compare endoscopic and open carpal tunnel release surgery among employed patients with carpal tunnel syndrome.

**Design and setting** Randomised controlled trial at a single orthopaedic department.

**Participants** 128 employed patients aged 25-60 years with clinically diagnosed and electrophysiologically confirmed idiopathic carpal tunnel syndrome.

**Main outcome measures** The primary outcome was severity of postoperative pain in the scar or proximal palm and the degree to which pain or tenderness limits activities, each rated on a 4 point scale, transformed into a combined score of 0 (none) to 100 (severe pain or tenderness causing severe activity limitation). The secondary outcomes were length of postoperative work absence, severity of symptoms of carpal tunnel syndrome and functional status scores, SF-12 quality of life score, and hand sensation and strength (blinded examiner); follow-up at three and six weeks and three and 12 months.

**Results** 63 patients were allocated to endoscopic surgery and 65 patients to open surgery, with no withdrawals or dropouts. Pain in the scar or proximal palm was less prevalent or severe after endoscopic surgery than after open surgery but the differences were generally small. At three months, pain in the scar or palm was reported by 33 patients (52%) in the endoscopic group and 53 patients (82%) in the open group (number needed to treat 3.4, 95% confidence interval 2.3 to 7.7) and the mean score difference for severity of pain in scar or palm and limitation of activity was 13.3 (5.3 to 21.3). No differences between the groups were found in the other outcomes. The median length of work absence after surgery was 28 days in both groups. Quality of life measures improved substantially.

**Conclusions** In carpal tunnel syndrome, endoscopic surgery was associated with less postoperative pain than open surgery, but the small size of the benefit and similarity in other outcomes make its cost effectiveness uncertain.

### Introduction

Surgery for carpal tunnel syndrome is one of the most often performed procedures.<sup>1</sup> The largest proportion

is done in working people. Open carpal tunnel release may result in prolonged pain at the scar and proximal palm.<sup>2</sup> The length of work absence after carpal tunnel surgery varies, depending on factors that still are not well understood. One such factor might be the severity of postoperative pain. Carpal tunnel syndrome is one of the most common medical causes of work absence, with almost half of all cases, including non-surgical, having an annual work loss of more than 30 days.<sup>3</sup> The longer periods probably included work absence after surgery.<sup>4</sup> The economic consequences of prolonged postoperative sick leave can therefore be substantial.

Endoscopic procedures to release the carpal tunnel have been introduced with the presumed advantage of decreased postoperative pain and subsequently faster return of patients to work.<sup>5-6</sup> No previous randomised studies comparing endoscopic and open carpal tunnel release have specifically assessed postoperative hand pain with a patient reported outcome measure. A few studies reported results of postoperative work absence favouring endoscopic surgery,<sup>6-8</sup> but others did not show such differences.<sup>9</sup> These studies had limitations, mainly inappropriate randomisation methods and inadequate numbers of employed patients. We compared open and endoscopic carpal tunnel release among employed patients with carpal tunnel syndrome with regard to postoperative pain, quality of life outcomes, and length of work absence after the operation.

### Methods

#### Eligibility criteria

The inclusion criteria were primary idiopathic carpal tunnel syndrome, age 25-60 years, currently employed, duration of symptoms of at least three months, inadequate response to six weeks' treatment with wrist splint, symptoms of classic or probable carpal tunnel syndrome,<sup>10</sup> and nerve conduction test showing median neuropathy at the wrist<sup>11</sup> but no other abnormalities.

#### Recruitment and randomisation

We did the study at a single centre, orthopaedic department with a catchment area of 170 000 popula-

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tion. Patients were recruited among those referred by primary care doctors. The recruited patients were assigned to a treatment group at the operating room immediately before surgery according to a computer generated randomisation list in blocks of eight. At the operating room the surgeon (with no knowledge of block size) opened the lowest numbered of sequentially numbered sealed opaque envelopes containing the identity of the operative method.

**Interventions**

Surgeons used the two portal endoscopic method (Smith & Nephew Endoscopy, Andover, Massachusetts, USA). They did all procedures under local anaesthesia, injected subcutaneously at the proximal and distal portals (endoscopic) or along the length of the incision (open), and they used a tourniquet. Each of the two skin incisions in the endoscopic procedure was 1 cm long. Dressing and sutures were removed 10 days postoperatively. No physical or occupational therapy was prescribed (in accordance with clinical practice).

**Outcome measures**

The patients were evaluated with disease specific and quality of life questionnaires and physical examination at baseline (during the week before surgery) and at three weeks, six weeks, and three months, and with the questionnaires at 12 months after surgery.

**Primary outcome**

The primary outcome was the severity of postoperative pain experienced in the scar and proximal palm, and the degree to which activity related pain in scar and palm or tenderness caused limitation of activity. This was measured with a two item pain scale (adapted from the short form 36 questionnaire (SF-36) bodily pain scale) previously shown to have high internal consistency.<sup>12</sup>

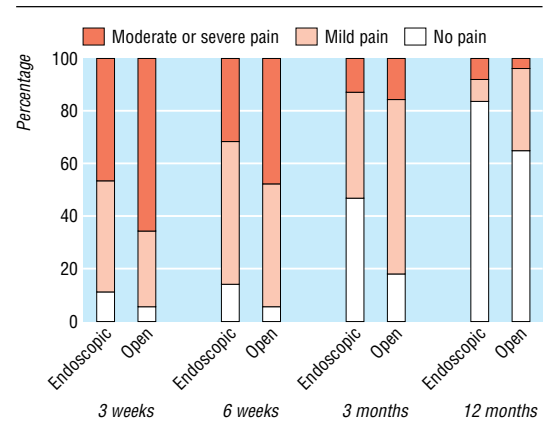
**Secondary outcomes**

The secondary outcomes were the length of work absence after surgery, the carpal tunnel syndrome questionnaire's symptom severity score and functional status score,<sup>13 14</sup> the SF-12 physical health score, and changes in hand sensation and strength measured by a single blinded examiner (scars concealed with dressing covering palm and distal forearm).

**Results**

**Study population**

Recruitment started in January 1998 and was completed in December 2002. Of 324 patients screened for eligibility, 128 patients were eligible and were randomised; 65 patients to open release and 63 patients to endoscopic



**Fig 1** Proportion of patients for each self rated category of postoperative pain in the scar and proximal palm after endoscopic and open surgery

release. The two groups were generally similar in patient characteristics (see [bmj.com](http://bmj.com)).

**Postoperative pain**

The patients in the endoscopic group had less postoperative pain in the scar and proximal palm and activity limitation than those in the open group at three weeks, six weeks, and three months, but the differences were generally small (table). The changes from three weeks to the following follow-up times did not differ significantly between the groups. The number of patients reporting scar and palm pain at three months was 33 (52%) in the endoscopic group and 53 (82%) in the open group (fig 1), yielding a number needed to treat of 3.4 (95% confidence interval 2.3 to 7.7).

**Patient reported outcomes**

We found no significant differences in the carpal tunnel syndrome symptom severity scores or in score changes over time between the groups at any follow-up time. The endoscopic group had a better improvement in functional status score at three weeks postoperatively (a small difference that reached significance); we found no significant differences at the other follow-up times. For both groups the carpal tunnel syndrome symptom severity scores and the functional status scores improved significantly after surgery ( $P < 0.0001$ ). We found no significant differences in the SF-12 physical health score between the groups at any follow-up time.

**Work absence**

The two groups did not differ regarding the proportion of blue collar workers and white collar

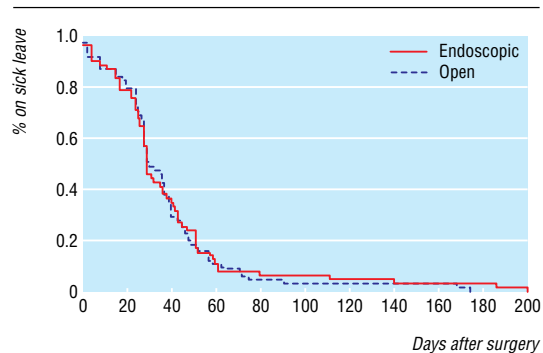
Postoperative pain scores and pain related limitation of activity\*

Time	Mean (SD), open surgery	Mean (SD), endoscopic surgery	Difference between the two groups			
			Difference in means (95% CI)†	P value	Change over time‡ mean (95% CI)	P value
3 weeks	60.5 (23)	52.1 (23)	8.6 (1.0 to 16.3)	0.028	Reference	
6 weeks	51.3 (23)	43.3 (23)	8.7 (1.0 to 16.4)	0.030	-0.8 (-9.3 to 7.8)	0.86
3 months	36.2 (20)	23.5 (26)	13.3 (5.3 to 21.3)	0.001	4.2 (-4.3 to 12.7)	0.33
12 months	13.9 (22)	8.7 (21)	5.8 (1.7 to 13.3)	0.13	-3.3 (-11.8 to 5.2)	0.45

\*Score range from 0 (no pain or tenderness in scar or proximal palm and no activity limitation) to 100 (severe pain in scar or proximal palm and severe activity limitation because of pain or tenderness).

†Analysis of covariance adjusting for baseline characteristics.

‡Mixed model analysis for difference between open and endoscopic groups in change over time (follow-up score–baseline score) adjusting for baseline characteristics.



**Fig 2** Kaplan-Meier survival curve for the duration of work absence after surgery

workers or the frequency of performing any of the work related activities inquired about at baseline. The Kaplan-Meier survival curve analysis showed no significant difference ( $P=0.9$ ) between the groups in length of work absence after surgery (fig 2). The 16 patients who were on sick leave before surgery had a significantly longer work absence after surgery than the 112 patients who were not on sick leave before surgery ( $P<0.001$ ). The length of work absence after surgery for blue collar workers (mean 44, SD 36, median 36 days) was significantly longer than that for white collar employees (mean 19, SD 14, median 21 days;  $P<0.001$ ).

#### Sensation and strength

We found no significant differences between the two groups in the results of sensory measurements; in both groups sensation improved. We found no significant differences between the groups in changes in strength over time although there was a tendency for less strength loss in the endoscopic group. Grip strength, which decreased after surgery, was in both groups at almost preoperative level at three months and pinch strength showed a faster recovery and was better than before the operation at three months after it.

#### Discussion

Endoscopic surgery in carpal tunnel syndrome resulted in less postoperative pain in the scar and proximal palm and related limitation of activity than open surgery, but the differences were generally small. From the patient's perspective, reduced postoperative pain may be an important benefit. However, the largest difference, at three months, was 13% on a score that considered severity of pain and limitation of activity and corresponded to a number needed to treat of 3.4, which means four patients have to be treated for one to benefit (avoid scar or proximal palm pain of any severity). Moreover, the difference did not make any impact on the length of work absence after surgery. Either the magnitude of difference in pain was not large enough to influence the capacity to work or there might be other factors with a larger impact on return to work. Work status before surgery and type of work seem to be such factors.

#### Meaning of the study

This study provides strong evidence that endoscopic carpal tunnel release yields a similar large degree of

#### What is already known about this topic

Carpal tunnel syndrome is common among working persons and often requires surgery

Open surgery is effective but may be followed by prolonged pain at the scar or proximal palm delaying patient return to work; endoscopic surgery has been suggested to reduce these problems

Previous randomised studies were limited by unreported or inappropriate randomisation methods and inadequate number of employed patients

#### What this study adds

Endoscopic surgery is associated with modestly less pain than open surgery up to three months after operation but has no advantage regarding length of work absence

Both methods have equal efficacy in relieving symptoms of carpal tunnel syndrome

The small size of the benefit makes cost effectiveness of endoscopic surgery uncertain

symptom relief and improvement in health related quality of life as open release. The 95% confidence intervals for the difference between the two groups in carpal tunnel syndrome symptom severity scores were smaller than clinically relevant values, which implies the equivalence of the methods regarding these outcomes. The two methods did not differ in complication rates, but repeat surgery was needed in two patients after endoscopic surgery and one patient after open surgery. Although concern has been raised about the risk of complications in endoscopic surgery, the reported incidence of serious complications, such as irreversible major injury to the nerve, has been low (none in the reportedly randomised studies and less than 2% in observational studies).<sup>15</sup> A very large sample would therefore be needed for a trial to detect a possible difference in rate of serious complications.

Postoperative pain was self rated, and blinding the patients to the surgical procedure throughout follow-up would not have been possible. However, the finding that on repeated measurement occasions the severity scores for symptoms of carpal tunnel syndrome were highly similar, while postoperative pain showed a small difference consistently over time, implies it is less likely that non-blinding of patients caused the observed differences.

#### Conclusion

Considering the fact that endoscopic surgery is associated with higher direct costs, mainly of instrumentation, and although diminished postoperative pain may result in decreased need for therapy and rehabilitation costs, the small size of the benefit, the similar duration of work absence, and the possibility of a higher rate of repeat surgery make the cost effectiveness of endoscopic surgery uncertain.

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## Effects of Sure Start local programmes on children and families: early findings from a quasi-experimental, cross sectional study

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### Abstract

**Objective** To evaluate the effects of Sure Start local programmes (SSLPs) on children and their families. To assess whether variations in the effectiveness of SSLPs are due to differences in implementation.

**Design** Quasi-experimental cross sectional study using interviews with mothers and cognitive assessment of children aged 36 months who speak English.

**Setting** Socially deprived communities in England: 150 communities with ongoing SSLPs and 50 comparison communities.

**Participants** Mothers of 12 575 children aged 9 months and 3927 children aged 36 months in SSLP areas; mothers of 1509 children aged 9 months and 1101 children aged 36 months in comparison communities.

**Outcome measures** Mothers' reports of community services and local area, family functioning and parenting skills, child health and development, and verbal ability at 36 months.

**Results** Differences between SSLP areas and comparison areas were limited, small, and varied by degree of social deprivation. SSLPs had beneficial effects on non-teenage mothers (better parenting, better social functioning in children) and adverse effects on children of teenage mothers (poorer social functioning) and children of single parents or parents who did not work (lower verbal ability). SSLPs led by health services were slightly more effective than other SSLPs.

**Conclusion** SSLPs seem to benefit relatively less socially deprived parents (who have greater personal resources) and their children but seem to have an adverse effect on the most disadvantaged children. Programmes led by health services seem to be more effective than programmes led by other agencies.

### Introduction

Sure Start local programmes (SSLPs) represent a large scale, area based effort by the government of the United Kingdom to enhance the health and development of children under 4 years and their families who live in socially deprived communities in England. SSLPs are a unique approach to enhancing the life prospects of disadvantaged children, in that all children aged 0-3 years and their families living in a prescribed area are "targets" of intervention. All SSLPs are expected to provide core services of outreach or home visiting; family support; support for good quality play, learning, and childcare experiences; primary and community health care; advice about child and family health and development; and support for people with special needs. Community participation is central to the mission of these programmes. Our report aims to evaluate the impact of SSLPs on children and their families by investigating differences between children

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