Current Status of Outcomes Research in Carpal Tunnel Surgery

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Abstract More than 3,000 publications on carpal tunnel syndrome (CTS) have been presented in the literature. Although surgery for treating CTS is commonly performed, the outcomes of these surgical procedures are still relatively unclear. This paper will summarize relevant publications on the surgical treatment of CTS to critically examine outcomes data based on the best available evidence.

Keywords Outcomes · Carpal tunnel syndrome · Surgery · MHQ

Since Phalen's initial description of the surgical treatment for carpal tunnel syndrome (CTS) in 1950 [22], the surgical treatment of CTS has been a subject of great interest in medicine. A MedLine search from 1966 to 2004 with the key words of "carpal tunnel" yielded 3,053 articles. With the large number of publications on this subject, it is difficult to distill the abundant amount of data into a condensed form that is easy to understand.

The purpose of this paper is to present the current status of outcomes data of carpal tunnel surgery. This paper synthesizes the most relevant publications on this topic and provides a synthesis of available data to give the readers a clear understanding of the outcomes of carpal tunnel

surgery. This paper has three specific aims: (1) to discuss how to measure outcomes in CTS, (2) to present controversial issues relating to open versus endoscopic carpal tunnel surgery, and (3) to discuss outcomes of carpal tunnel surgery in different study samples.

What Is the Prevalence of CTS and Is Surgery the Only Way to Go?

The prevalence of CTS in the United States was estimated at 3.7% (0.9–4.7%) [21]. It is quite similar to the prevalence of this condition in Sweden, which was estimated at 2.7% (2.1–3.4%) [3] and in the Netherlands at 5.8% (3.5–8.1%) [9]. Therefore, CTS is one of the most common diseases in the world.

Many nonsurgical treatments have been proposed for treating CTS. For example, the preliminary communication article published in *JAMA* in 1998, entitled "Yoga-Based Intervention for CTS: a Randomized Trial," [10] advocated yoga as a treatment modality for CTS. In this study, patients were randomized into a splinting group or a yoga group who underwent 8 weeks of yoga treatment with 11 yoga postures for strengthening, stretching, and balancing. This was a single-blinded randomized controlled trial and only the evaluator was blinded to the treatment assignments. The authors found that the splinting group had some improvement but this improvement was not significant. However, the yoga group had improvement in grip strength, pain reduction, and Phalen's sign. Although this study was rather novel and interesting, this paper was published in the preliminary communications section of *JAMA*, which aimed to present preliminary data. In addition, this paper contained the classic Hawthorne effect, when the study group (yoga group) received considerable attention. The

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attention given to the yoga group and the unconscious wish of the participants of the yoga group to validate the aim of this study may have inflated the effects of the intervention. The paper also had several additional biases, which included small sample sizes, unmatched groups, and questionable outcome measures. Therefore, the take home message from this example was that the etiology of CTS is still elusive and we still do not know what the best treatment is for this condition.

How Effective Is Carpal Tunnel Surgery?

To answer this question, one must discuss what outcome parameters are needed to evaluate the effectiveness of surgical treatment for CTS. Although we do not know the etiology of CTS, empiric evidence has shown that carpal tunnel surgery is effective. In the United States, carpal tunnel surgery is the most commonly performed surgical procedure on the hand [20]. In the current era of evidence-based medicine, it is important that data are presented to justify treatment. Support of a surgical procedure must be based on evidence and not rely on expert opinions alone. One of the most important advancements in carpal tunnel research is the development of outcomes questionnaires that are specific for CTS. In the seminary article from the *Journal of Bone Joint and Surgery (A)* in 1993, Levine et al. [17] presented a carpal tunnel questionnaire (CTQ) that measures symptom and functional outcomes for this condition. In this paper, 67 patients with CTS were prospectively enrolled. Thirty-nine patients had carpal tunnel release, whereas 28 were managed nonoperatively. The responsiveness to change of this questionnaire was based on 26 out of the 39 operated patients. The patients completed the CTQ preoperatively and 3 months postoperatively. This study did not evaluate each hand separately. The results of this paper are presented in Table 1. Using a 0–5 scale, 0 indicating “no symptoms” and 5 indicating “maximum symptoms,” the mean preoperative score of this cohort was 3.1 ± 0.9 , which improved at 3 months to 2.0 ± 1.0 ($p < 0.01$) with a standardized response mean (SRM) of 0.8. The interpreta-

tion of this data is that symptoms improved a great deal after carpal tunnel surgery, as was shown by the SRM (0.3 indicates small effects, 0.5 indicates medium effect, and 0.8 or greater indicates large effect). Therefore, the effect of carpal tunnel surgery was substantial in symptom relief. However, it should be noted that many patients in this cohort still have residual symptoms. A mean postoperative score at 3 months of 2.0 indicated that despite a great deal of improvement, this cohort of patients still complained of quite a bit of symptoms relating to CTS.

While symptoms improved a great deal, functional outcome improvement was modest. The outcomes score decreased from a preoperative mean of 2.7 ± 1.0 to 2.1 ± 1.1 , with a p value of 0.04 and an SRM of 0.4. This paper is one of the first to present evidence-based data using patients’ self-assessment of their perceived outcomes. It also clearly illustrated the responsiveness of a patient-rated questionnaire for CTS to demonstrate symptom relief being the most important effect of carpal tunnel surgery. Traditional outcomes measures such as grip strength and pinch strength were not responsive.

Currently, many other outcomes questionnaires have been developed, which include the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire from the American Academy of Orthopaedic Surgery as part of the MODEMS project [13] and the Michigan Hand Outcomes Questionnaire (MHQ), which was supported by the Robert Wood Johnson Foundation [6, 8]. These two questionnaires have the advantage of being able to measure outcomes for many hand-related conditions.

With Many Outcomes Questionnaires Available Today, What Is the Best Questionnaire for CTS?

Of the different outcomes questionnaires available today, how does a researcher choose among these questionnaires to apply to carpal tunnel surgery research? In 1996, Amadio et al. [2] compared the disease-specific CTQ with more generic questionnaires (SF-36 and AIMS2). The purpose of this study was to measure the responsiveness of different types of questionnaires for measurement of carpal tunnel surgery outcomes. Responsiveness, or sensitivity to clinical change, is an outcomes questionnaire property that indicates the ability of a questionnaire to pick up changes in patients’ conditions when indeed these changes have occurred. This study showed that a disease-specific questionnaire, such as the CTQ, is more sensitive to clinical change than general questionnaires such as the SF-36 or the AIMS2 questionnaire that was specifically designed for rheumatic diseases. More recently (2005), Kotsis and Chung [16] compared the responsiveness of the MHQ with the DASH. In this study, 50 patients completed the MHQ

Table 1 Results from the Levine et al. [17] study.

Scales	Mean preoperative score $\pm$ SD	Mean postoperative score $\pm$ SD	p	Standardized response mean
Symptom severity	3.1 ± 0.9	2.0 ± 1.0	<0.01	0.8
Functional status	2.7 ± 1.0	2.1 ± 1.1	0.04	0.4

Standardized response mean = (preoperative mean – postoperative mean) $\div$ (SD of difference between means).

and the DASH before and 6 months after carpal tunnel release. The data for this study were compared to results from published CTQ data. Table 2 shows that the SRMs for MHQ functional domains such as function, activity of daily living, and work were in the range of 0.5–0.6, which are quite similar to the SRMs of the functional domain of the CTQ. The pain domain of the MHQ had an SRM of 0.9, which was similar to the symptom severity SRM of 0.8 in the CTQ. This paper concluded that both the MHQ and the DASH are responsive to measuring outcomes for CTS. The DASH is more focused on functional outcomes, whereas the MHQ has both functional and symptom scales that are rather similar to the content of the CTQ. Another advantage of the MHQ is that it can measure the right and left hand separately.

What Are the Outcomes Data Comparing OCTR versus ECTR?

The availability of hand-specific outcomes questionnaires has spurred intense effort to evaluate new surgical treatments for CTS. The controversy surrounding endoscopic carpal tunnel release (ECTR) versus open carpal tunnel release (OCTR) has raged on for over 10 years. The initial randomized controlled studies compared ECTR to OCTR and the findings indicated that ECTR patients return to work earlier than patients undergoing OCTR [1, 4]. In a 2003 clinical trial comparing ECTR versus OCTR, MacDermid et al. [18] showed no return to work difference between these two procedures. In this study, 91 patients were randomized to ECTR, whereas 32 patients were randomized to OCTR in an unbalanced randomized scheme of 3 to 1. The outcomes were measured with the CTQ, the McGill Pain Questionnaire, and hand function tests. Patients were evaluated before surgery and after surgery at 1 week, 6 weeks, 12 weeks, and 3 years. Evaluations were performed by a blinded evaluator. This study showed that 5% of ECTR patients had repeat carpal tunnel surgery within 4 years of the initial procedure versus 0% for OCTR patients. Eighty-five percent of ECTR patients were satisfied with the surgical procedure versus 93% of OCTR patients (not a significant

difference). The authors concluded that there was no substantive difference in outcomes between these two methods. They also noted there was no difference in the return to work outcomes; however, return to work outcomes is a difficult outcome parameter to measure because it is dependent on many factors, including availability of work, patient motivation, and patients' working environment.

What Is the Economic Data Comparing OCTR and ECTR?

In 1998, Chung et al. [7] performed a cost–utility analysis comparing ECTR and OCTR. In this study, the costs were assessed using Medicare data and data from a private nonprofit community hospital. Quality-adjusted life year (QALY) data were collected from medical professionals. The outcomes data were collected from two multicenter clinical trials [1, 4]. This study showed that the cost of ECTR is greater than OCTR in both the Medicare and the community hospital settings. However, QALYs were greater with ECTR than OCTR for all age groups when no complication occurred. When a new technology is more costly and more effective, a cost–utility ratio can be calculated to measure whether the incremental cost is justified by the incremental increase in the QALYs. In other words, is the increased cost supported by an improvement in the quality of life for the patient? In a series of complex economic analyses, the authors showed ECTR to be highly effective using Medicare data with cost–utility ratios ranging from \$195 to \$1,074 per QALY. When compared to accepted interventions in medicine such as breast cancer screening (\$4,836 per QALY) or laparoscopic cholecystectomy (\$43,400 per QALY), ECTR appears to be a highly cost-effective intervention. However, in economic analysis, one must perform sensitivity analyses to evaluate whether the results are stable when assumptions are varied by using the upper and lower limits of cost, utility, and outcome probabilities. The sensitivity analyses of this study showed that if patients sustained a higher incidence of a major complication, such as median nerve injury, ECTR is less cost-effective than OCTR. ECTR is very sensitive to small changes in the complication rates. The take-home message of this paper is that ECTR and OCTR are relatively equivalent strategies in the economic analysis modeling. Neither surgical procedure is a dominant strategy.

A subsequent study published in 1999 [23] supported the result of Chung's study by applying a decision analysis model to compare OCTR and ECTR. In this study, it was noted that these two techniques have similar total cost, but ECTR is more costly if the complication rate exceeds 6.2% and the difference between the two techniques in mean return-to-work time is less than 21 days. The authors also noted that the available data on cost and outcomes were too

Table 2 Results from the Kotsis and Chung [16] study.

	Scales	Standardized response mean
Michigan Hand Outcomes Questionnaire	Function	0.6
	Activities of daily living	0.5
	Work	0.5
	Pain	0.9
	Satisfaction	1.1
Carpal Tunnel Questionnaire	Symptom severity	0.8
	Functional status	0.4

imprecise and the result is highly sensitive to small changes in the complication rate, which is similar to the conclusion of the Chung study. In summary, the dust has now settled in this controversial issue. Both ECTR and OCTR are excellent operations if performed by experienced surgeons and for the appropriate patients. Neither procedure is dominant.

How Effective Is Carpal Tunnel Surgery?

In this era of evidence-based medicine, randomized controlled clinical trials (RCTs) are highly valued because known and unknown confounding variables will be randomly distributed between the two interventions. However, type I evidence from RCTs is very difficult to obtain in surgical trials because of issues relating to equipoise—the inherent belief of a surgeon that his/her preferred surgical technique gives the best outcome. The issues of the conduct of hand surgical clinical trials were discussed in an editorial [5] published in the *Journal of Hand Surgery*.

Rigorously performed RCTs in hand surgery are possible. A recent paper published in *JAMA* from the Netherlands compared splinting versus surgery for treating CTS [11]. All patients in this RCT had positive electrodiagnostic studies for CTS. The evaluators were blinded to the treatment assignments, and study subjects were followed up at 3 and 18 months. This paper showed that at the 3-month follow-up period, 80% of the surgery subjects had general improvement versus 54% of the splinting subjects. At 18 months, general improvement was seen in 90% of the surgery versus 75% of the splinting subjects. At first glance, this difference does not seem to be significant, but one of the tenets of RCTs is to use an intention-to-treat analysis whereby the study groups are analyzed based on the initial treatment assignment. Therefore, subjects in the splinting group were analyzed based on this assignment; however, 41% of the splinting group crossed over to surgery because of lack of improvement. Therefore, this study is the first RCT to confirm the effectiveness of carpal tunnel surgery with type I evidence.

We Know that Carpal Tunnel Surgery Is Effective, but How Effective Is Carpal Tunnel Surgery for Different Populations?

In an article published by Katz et al. [15] in *Arthritis and Rheumatism* in 2001, the authors evaluated predictors of outcomes for carpal tunnel surgery. The authors analyzed data from the Maine carpal tunnel study, which is an effectiveness study involving 25 surgeons from Maine. An effectiveness study is different from an efficacy study. An efficacy study is based on the best-scenario practice, which typically has data derived from academic medical centers where a high level of technology and special expertise are available. However, an

efficacy study does not simulate the real-life situation of an effectiveness study whereby the data are derived from community practices. The Maine carpal tunnel study obtained data from a collection of community surgeons from Maine, giving a “real-life” situation regarding carpal tunnel surgery outcomes. A total of 241 patients completed the CTQ preoperatively and postoperatively at 6, 18, and 30 months. The authors noted that symptom and functional improvements were noted at 6 months and maintained over the 30-month period. Sixty-seven percent of the patients were completely or very satisfied with the surgical results. Predictors of poor outcomes were worse preoperative functional and mental status, alcohol use, and involvement of attorneys. They concluded that outcomes of carpal tunnel surgery in the community setting are excellent. Using the same data, the authors showed that carpal tunnel patients have a 45% symptom and a 25% functional improvement after surgery [14]. Although surgery patients are satisfied with their outcomes, many still have residual symptoms. This finding is similar to the Levine et al. data in the development of the CTQ. On the other hand, nonsurgical patients showed little improvement at follow-ups. This effectiveness study proved that carpal tunnel surgery is much better than conservative management alone, based on a real-life community practice situation. In this paper, the authors also evaluated the effect of Workers’ Compensation (WC) status on outcomes. They noted that symptom severity and functional scores showed the least improvement in WC patients. WC patients are more likely to report moderate or severe scar tenderness at the 6-month follow-up. WC patients were significantly less likely than non-WC recipients to report complete resolution of nocturnal pain, daytime pain, and numbness (all $p > 0.1$).

What Is the Effect of Workers’ Compensation Status on Outcomes after Carpal Tunnel Surgery?

A recent cross-sectional study of Ontario workers by Manktelow [19] evaluated outcomes of Canadian worker compensation subjects. In Ontario, Canada, CTS is the most frequent work-related musculoskeletal disorder of the upper extremity. It was estimated that one out of 70 workers would develop CTS over their working lifetime severe enough to require time off work. Therefore, CTS is a costly condition for the Canadian healthcare system. In this study, the authors recruited 984 Ontario workers registered with the Ontario Workers Safety and Insurance Board who were off work with newly diagnosed CTS. The outcomes were assessed by a questionnaire 4 years postoperatively. The authors found that 75% of the workers with the diagnosis of CTS had surgery. The average return to work time after surgery was 3 months. Four years postoperatively, 46% had moderate to severe pain, 52% had moderate to severe numbness, and 40% had

difficulty grasping and using small objects. Sixty-four percent of the study subjects returned to the same job and only 14% were symptom free.

Do Workers' Compensation Patients Truly Have Worse Outcomes After Surgery?

A recent article in *JAMA* entitled, "Association Between Compensation Status and Outcome after Surgery, a Meta-Analysis" [12] addressed precisely this question. This is a literature review of surgical trials in which the effect of WC status was investigated. A total of 211 studies were reviewed and 175 reported worse outcomes in the WC group. One hundred twenty-nine studies had adequate outcomes scores that the authors categorized as satisfactory and unsatisfactory outcomes. The study contained 7,244 WC and 13,254 non-WC patients. The results of this study showed that 124 studies had unsatisfactory outcomes associated with WC status with an odds ratio of 3.12 (2.89–3.36). In their subgroup analysis of CTS, they noted the same odds ratio after controlling for study design, follow-up time, and completeness of follow-up. The strongest association of poor CTS outcomes with WC status was found in Europe, followed by Canada and the United States. Australia has the weakest association, most likely related to the rules and regulations regarding the Australia WC system. This study showed quite clearly that unknown effect of WC status has a definite adversarial influence on outcomes after carpal tunnel surgery and after most surgical conditions.

In summary, the outcomes movement has advanced our understanding of treating CTS. This is a complex disease of unknown etiology. The data from the literature showed that CTS surgery is effective, but many patients will still have residual symptoms after the surgical treatment. However, outcomes of surgery are better than no surgery. In addition, the outcomes of CTS are influenced by the study sample, particularly when related to WC status. The commonly stated concept in treating CTS still holds true: carpal tunnel surgery for the suitable patient, with the correct diagnosis, by an experienced surgeon, is an effective treatment.

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