

**Are nerve conduction studies  
necessary? The development and  
evaluation of a patient-completed  
screening version of the Carpal  
Tunnel Questionnaire for use in  
primary care**

Submitted by Carl Edwards to the University of  
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Date of Submission 03/12/2015

Signature .....

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To Mum and Dad

X

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## Foreword

My interest in hand pathology stems back 15 years. An interest which came about by default whilst working in a musculo-skeletal (MSK) physiotherapy outpatient department as it became clear that patients attending with hand pathology did so with a groan from the treating physiotherapist. The hand is a complex structure and essential for so many of our daily activities, and often taken for granted until 'something goes wrong'. It is both the complexity and functional importance that triggered my interest and in 2003 I started working closely with our hand surgeon in an Extended Scope Practitioner (ESP) role the scope of which has expanded since to incorporate all MSK upper limb pathology.

This role included managing carpal tunnel syndrome (CTS) within secondary care. What soon became apparent was the delay that was associated with nerve conduction studies (NCS) used to help quantify the function of the median nerve. At that time referrals for NCS were sent to a tertiary centre with a wait time of up to 12 months. Referral for confirmatory studies was routine practice and whilst in some instances they were undoubtedly needed there was a cohort of patients with classic signs and symptoms for whom NCS did not seem necessary.

Reducing waiting times was the primary aim, which was achieved through developing an in-house NCS service whereby patients could be seen assessed, and have NCS carried out at a single appointment. Through carrying out thousands of NCS on patients with suspected CTS results of the studies rarely surprised. It is this that prompted this work; *Are NCS necessary in patients with suspected CTS?*

After exploring current research regarding questionnaires designed to help in the diagnosis of carpal tunnel syndrome it was clear that there was a variety of measures that have been developed, however due to a lack of extensive research no single measure was being used as the gold standard. From experience of being involved in both the development and implementation of

outcome measures, what was important to me was that any scored questionnaire should be concise and easy to complete in order for compliance to be achieved. The Carpal Tunnel Questionnaire (Kamath and Stothard, 2003) seemed to offer a degree of familiarity as the constructs of the questionnaire represented questions commonly used within my assessment that provided the basis of my clinical diagnosis. It is these questions that provided a subjective ability to usually predict the outcome of the subsequent NCS, and it was for this reason that I felt compelled to explore this tool further.

The project has been structured as papers not yet submitted for publication, which whilst inevitably conferring a degree of repetition, provides a detailed logical analysis of the assessment of CTS and suggestions of how potentially to optimise orthopaedic clinic time without compromising patient care.

## **Abstract**

**Introduction:** Carpal tunnel syndrome (CTS) is the most common peripheral nerve entrapment seen within the outpatient orthopaedic clinic; therefore assessment and management of this common condition is of significant importance. Traditionally diagnosis has been made through detailed questioning; clinical examination and nerve conduction studies (NCS). There is however no true consensus as to the gold standard assessment of CTS and the use of NCS can confer additional costs and delay treatment. Previous studies have explored methods of predicting the presence of CTS including the clinician-administered Carpal Tunnel Questionnaire (CTQ) (Kamath and Stothard, 2003). The aim of the present studies is therefore to explore the versatility of the CTQ to see how a novel Patient-completed Version of the CTQ compares to the original Clinician-completed version. Psychometric properties of the questionnaire will be explored together the economic impact of integrating both versions within an orthopaedic care pathway. A further aim is to answer whether the CTQ more effective and cost-effective than NCS for patients referred to an orthopaedic clinic with suspected CTS.

**Method:** 100 patients referred for further investigation of suspected CTS were assessed using parallel patient and clinician-completed versions of the CTQ and results were subsequently compared with those obtained from NCS. Item analysis explored each of the nine constructs of the questionnaire and the original scoring algorithm was validated using binary logistic regression and compared with alternative algorithms. Sensitivity and specificity of the questionnaire when compared to results of NCS was explored using Receiver Operating Characteristic (ROC) analyses. Inter-rater reliability was explored through Pearson's correlation coefficient. Economic analysis and modelling was carried out to explore potential cost savings of use of the questionnaire rather than NCS for those with suspected CTS.

**Results** demonstrated sensitivity of 92% and specificity of 54.67% (positive predictive value 95.35%) for the patient-completed questionnaire and 96% sensitivity with 70.67% specificity (98.15 positive predictive value) for the

clinician-completed questionnaire when used to predict the outcome of NCS. Binary logistic regression confirmed the original scoring algorithm and a revised algorithm did not significantly improve sensitivity. Adoption of the clinician-completed CTQ would have screen out 54% of referrals for NCS, which in the case of the study site would have conferred cost savings of £73,305 per annum (base upon a referral rate of 750 per annum). The patient-completed CTQ in the current sample resulted in 43% of referrals with suspected CTS not requiring NCS to assist in diagnosis with a potential saving of £58,372.5 per annum. There are further considerations of the reduction in waiting times, which are explored further within the analysis.

**Conclusion:** Economic evaluation is complex due to the variety of pathways adopted by different orthopaedic departments. While the results of the Patient-complete version of the CTQ may not be as convincing as the clinician completed the study does provide validation for its use and expands the versatility of this useful adjunct to the assessment of CTS. Both versions could potentially confer significant cost savings and reduce demands on investigative services, reducing waiting times and improving the patient journey in suspected CTS.

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## Abbreviations

<b>ANN:</b>	Artificial Neural Network
<b>APB:</b>	Abductor Pollucis Brevis
<b>BCTQ:</b>	Boston Carpal Tunnel Questionnaire
<b>CTD:</b>	Carpal Tunnel Decompression
<b>CTS:</b>	Carpal Tunnel Syndrome
<b>CTQ:</b>	Carpal Tunnel Questionnaire
<b>DASH:</b>	Disabilities of the Arm Shoulder and Hand
<b>GP:</b>	General Practitioner
<b>ICC:</b>	Inter-Class Correlation
<b>IRR:</b>	Inter-Rater Reliability
<b>NCS:</b>	Nerve Conduction Studies
<b>NICE:</b>	National Institute for Health and Care Excellence
<b>PROMs:</b>	Patient Reported Outcome Measures
<b>ROC:</b>	Receiver Operator Characteristics
<b>SD:</b>	Standard Deviation
<b>UK:</b>	United Kingdom





## **Chapter 1: Background**

### **1.1 History**

Carpal Tunnel Syndrome (CTS) is common both within general practice and specialist services - a recognised syndrome that surprisingly has only been treated effectively since the 1950's. In 1854 Dr James Paget, an Orthopaedic Surgeon who was appointed Surgeon Extraordinary by Queen Victoria and subsequently the Prince of Wales, was reported to be the first to recognise that the median nerve could be compressed at the wrist (Stecco and Aldegheri, 2008). Symptoms including ulceration of the digits innervated by the median nerve were reported in two cases which was cured only by binding the wrist removing the pressure on the nerve (Paget, 1854). In 1880 James Putman, a neurologist from Boston published the first case series on CTS. This report on 37 patients described a previously unknown condition with the presence of median nerve distributed paraesthesia and pain in the hand, the symptoms of which are clearly recognised today (Pearce, 2009):

*“While differing from each other in minor respects, these cases agree in presenting as a common symptom a disturbance of the subjective sensibility of the skin, giving rise to what is known popularly as numbness, recurring periodically, coming on especially at night or very early in the morning, and affecting one or both hands...This numbness was very often excessively intense, so as to amount to real pain in itself... In some cases simply letting the arm hang out of the bed or shaking it about for some moments would drive the*

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*numbness away; in others, this could only be done by prolonged rubbing and use of the hands in ordinary employment.” (Putman, 1880)*

The majority of these 37 patients reported were women with a mean age of 35 years. What is interesting is that the majority of clinicians in the current Orthopaedic setting would recognise the above as the typical history of carpal tunnel syndrome. However even into the 1950's only a handful of cases of carpal tunnel syndrome had been reported or indeed treated through release of the transverse carpal ligament.

Putman's hypothesis however was linked to work carried out by Raynaud whose ideas that suggested that these symptoms occurred primarily due to a compromise in the blood supply to digital sensory nerves supplying the affected digits. Further observations of these symptoms noted both sensory and motor impairment in the same patients that contested the belief that this was purely a sensory condition affecting the terminal sensory fibres originally suggested by Putman (1880). It was hypothesised that symptoms were due to the compression of the brachial plexus within the thoracic outlet. This theory coincided with the introduction of X-rays (1895). It was noted that cervical ribs were often present in those with these symptoms, the removal of which became common practice for over 40 years (Stecco and Aldeheri 2008).

A paper published by Brian and Wright (1947) was the first to detail the clinical features and pathophysiology of median nerve compression through the Carpal Tunnel. They concluded that in their belief spontaneous recovery of the nerve

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was unlikely and early release of the transverse carpal ligament was recommended. This work was developed further by Phalen et al (1950) who published case reports of patients having undergone Carpal Tunnel Decompression (CTD) and also developed further clinical tests to assist in the diagnosis. In just a few years by 1960 CTS became the most frequently diagnosed and treated peripheral nerve entrapment (Pfeffer et al, 1988).

### 1.2 Anatomy

The Carpal Tunnel is a fibro-osseous canal, which is found on the volar aspect of the wrist. A tunnel by definition; the floor being formed by the carpal bones and the roof by the transverse carpal ligament/flexor retinaculum. The flexor retinaculum extends from the radial aspect of the wrist with attachments to the scaphoid tuberosity and trapezium and heads towards the hook of hamate and pisiform.

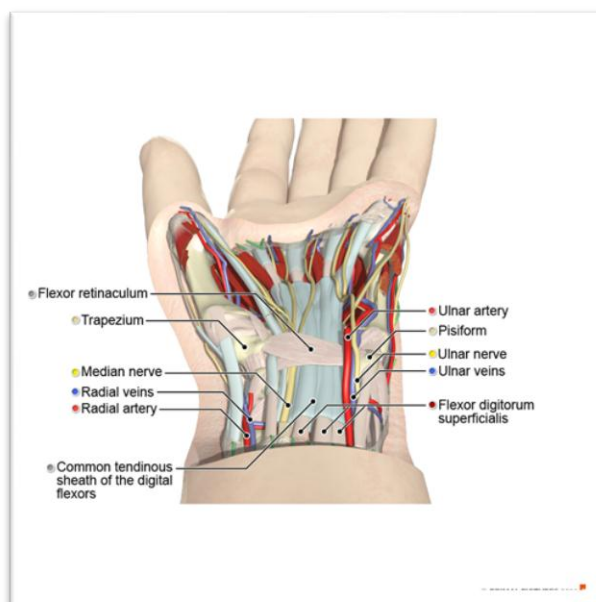


Figure 1.1 Anatomy volar aspect of the wrist (reproduced with permission from Primal Pictures, 2014) (appendix 1)

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As depicted in figure 1.1 within the Carpal Tunnel pass nine tendons responsible for flexion of all five digits including the flexor digitorum superficialis (FDS - four tendons) and flexor digitorum profundus (FDP - four tendons) and flexor pollicis longus (to the thumb) together with their own synovial sheaths. Along with these tendons passes the median nerve. The median nerve is situated superficially to the tendons of FDS with the FDP tendons lying deep to FDS. The nerve arises from the lateral and medial cords of the brachial plexus and traverses down the limb offering nerve supply to a variety of muscles en route to the hand. The median nerve has both sensory and motor supply with the typical sensory distribution including the thumb, index, middle and radial border of the ring finger together with the radial volar aspect of the palm. Before passing through the carpal tunnel the nerve divides into two branches. The palmar cutaneous branch, which travels superficial to the carpal tunnel, supplies the palmar sensation and the palmar digital cutaneous branch heads deeper through the carpal tunnel offering sensory supply to the radial three and half digits. The motor supply distal to the carpal tunnel includes abductor pollicis brevis within the thenar eminence of the hand. The carpal tunnel is deemed to be more compliant at proximal level between the pisiform and scaphoid therefore the median nerve tends to be more prone to compression distally (Gabra and Li, 2013).

The ends of the tunnel are open to communicate with the surrounding tissues; however, the tissue pressure within the tunnel (carpal tunnel pressure, CTP) is much higher in those patients with CTS (32-110 mm Hg, depending on wrist position) compared to those who are symptom free (2-31mm Hg) (Gelberman

## Chapter 1: Background

et al, 1981). Pressure within the carpal tunnel is raised by wrist extension and flexion, and finger flexion (Bland, 2007).

### **1.3 Presentation**

Carpal Tunnel Syndrome (CTS) occurs as a result of compression of the median nerve as it traverses through the fibro-osseous canal known as the Carpal Tunnel. Symptoms can vary patient to patient but typically the presentation involves paraesthesia in the distribution of the median nerve distal to the level of compression, this involves the lateral three and half digits. Patients may also commonly complain of symptoms outside the distribution of the median nerve (Claes et al, 2014). The palm of the hand despite being supplied by the median nerve is not typically affected in those suffering with CTS, as the sensory cutaneous branch of the median nerve branches off around 6 cm proximal to the transverse carpal ligament passing superficially to the ligament and is therefore not affected by pressure alteration within the carpal tunnel (Ghasemi-rad et al 2014). Symptoms involve burning or pain in the same distribution and occasional numbness (anaesthesia). Common symptoms can be recognised, as being consistent with CTS. The frequency of the symptoms is variable however there is usually a diurnal variation (Ibrahim et al, 2012). Symptoms are worse at night causing night wakening, with the patient waking with a numb/tingling hand. Typical aggravating factors are often reported such as holding a phone, reading a book, applying make up or driving. Relieving factors include shaking the hand, flicking the fingers or hanging the hand out of the side of the bed at night-time.

## Chapter 1: Background

CTS is one of the most commonly seen orthopaedic secondary care referrals being responsible for approximately 90% of all entrapment neuropathies (Aroori and Spence, 2007). CTS affects a broad spectrum of the population and its management is of considerable importance within the health service. Assessment of this condition is reliant on good clinical history appropriate physical examination and in some circumstances further investigation if diagnosis is uncertain (NICE guidelines, 2012).

Extensive research has been focused on the assessment of this condition. Studies exploring clinical examination together with various modalities such as nerve conduction studies, ultrasound scanning and Magnetic Resonance Imaging have been carried out and despite this controversy remains as to the most effective way of maintaining best practice when it comes to the diagnosis of CTS (Prime et al, 2010); consequently there is no widely agreed gold standard test for the diagnosis of CTS (Bland et al, 2011).

### **1.4 Aetiology**

The aetiology of CTS remains unclear; in most cases there is no recognisable cause (idiopathic). Numerous secondary causes have been proposed including: space occupying lesions (tumours, ganglions, fracture callus and osteophytes), possible metabolic and physiological causes (pregnancy, hypothyroidism and rheumatoid arthritis), infections, neuropathies (associated with diabetes and alcoholism), and finally familial disorders (Ashworth, 2010). Vague associations have even been related to smoking. A meta-analysis

## Chapter 1: Background

carried out by Pourmemari et al (2014) reviewed 13 studies through which it was concluded that there was an association between smoking and CTS in cross sectional studies however this was not supported through reviewing case-control studies. NICE guidelines updated 2012 provide details regarding risk factors for the development of CTS (Table 1.1)

<b>Risk Factor</b>	<b>Details</b>
Family History	one in four people with carpal tunnel syndrome have a positive family history in first degree relatives.
Inflammatory Conditions	rheumatoid arthritis, gout, pseudogout, non-specific tenosynovitis of the flexor tendons, connective tissue disease (e.g. systemic lupus erythematosus).
Metabolic Causes	hypothyroidism, diabetes mellitus, acromegaly.
Increased Canal Volume	congestive heart failure, oedema, pregnancy, obesity in younger people.
Fractures	Colles' fracture; fracture dislocation of the radiocarpal, carpal, and carpometacarpal joints.
Abnormal Anatomy	ganglion, lipoma, haemangioma, neurofibromas, median artery aneurysm or arteriovenous malformation, xanthoma, congenitally small carpal canal.
Tumours	of the median nerve.
Amyloidosis	secondary to renal failure
Infections	Lyme disease, mycobacterial infection, septic arthritis
Use of hand-held vibrating tools	Occupational risk

Table 1.1: NICE guidelines – risk factors in the development of CTS

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NICE, despite recognising these risk factors, does not support investigating all patients to screen for underlying causes or contributing factors. It is recommended by NICE to 'refer for electromyography and nerve conduction studies (NCS) if the diagnosis is uncertain'. Therefore this can be interpreted that NCS are not always necessary when a clinical diagnosis can be confidently made through careful questioning and physical examination.

### **1.5 Incidence**

The incidence of CTS is unclear. Depending upon the criteria used to diagnose CTS this varies from between 0.125%-1% and 5-16% of the population (Aroori and Spence, 2008; Priganc and Henry, 2003). CTS is more commonly seen in females in middle age however this is not exclusive as CTS is commonly found both sexes and in all ages of adulthood. Peak incidence is between 55 to 60 years (Aroori and Spence 2008). A large UK population study carried out by Bland and Rudolfer (2003) between 1991-2001 found the annual incidences (per 100 000) to be 139.4 for women and 67.2 for men in East Kent and 83.2 for women and 48.0 for men in Huddersfield. These figures were based upon new cases of neurophysiologically confirmed CTS. This would obviously be dependent upon whether the patient reported their symptoms to their General Practitioner (GP) and secondly the GP deciding that onwards referral for neurophysiological testing was appropriate. Peak ages within this study were reported as being bimodal with a peak in the 50-54 age group and the second peak between 75-84.



## **1.6 Occupational Risks**

There is a high incidence of CTS within the population; as a result occupational risks have been explored to try to account for this (Nuckols et al, 2011). In 2003 CTS was been listed as occupational disease 506.45 in the European Union's register of occupational diseases. CTS at that time was ranked sixth among the reported occupational diseases (Giersiepen and Spallek, 2011).

A common misconception is the influence that computer/mouse use (as in the secretarial field) has upon the development of CTS (Thomsen et al, 2008).

A systematic review carried out by Thomsen et al, 2008 explored the relationship between computer use and CTS. Longitudinal studies of low force, repetitive work and CTS were also evaluated. Eight epidemiological studies were evaluated, all of which had limitations. To précis in three of the studies an exposure –response association was observed but no conclusions could be drawn. Further longitudinal studies did not provide any further evidence of association. Several studies have explored the level of Carpal Tunnel Pressure (CTP) whilst the hand was positioned in the typical posture of computer users. Sustained high pressure within the carpal tunnel compromises the vascularity of the median nerve leading to local demyelination and axonal loss (Bland, 2007). CTP was deemed to be below levels considered to be harmful. Essentially there is insufficient evidence that computer/mouse work leaves individuals more prone to developing CTS.

## Chapter 1: Background

Clear associations have however been identified between occupations involving exposure to hand-transmitted vibration in isolation or combined with repeated and forceful movements of the hand or wrist (Palmer, 2011). As can be appreciated this encompasses a broad range of possible occupations. The use of pneumatic drills (Chatterjee et al, 1982) and chainsaws (Farkkila et al, 1988) has been explored to reach these conclusions.

Curti et al (2013) carried out a population-based case-control study to attempt to ascertain occupation and non-occupational risk factors for surgically treated CTS through the completion of a structured questionnaire. This multi-centre trial involved 16 sites, each of which identified 200 subjects (aged 25-59) 100 CTS cases and 100 controls (50 men and 50 women in each group) matched for age and gender. Of the 3052 patients identified by the 16 sites (1458 cases and 1594 controls) 2294 responded (1182 cases and 1112 controls). Results showed that manual workers of both sexes appeared to have a fourfold increase in their risk of developing CTS when compared to their non-manual equivalents; this appeared to be irrespective of gender.

In contrast Violante et al (2007) conducted a longitudinal cohort study on industrial and service workers starting in 2000. Outcome measures were conducted after one and two years. Each job task underwent exposure measurement following the recommendations of the American Conference of Governmental Industrial Hygienists. After exclusions 2472 workers were analysed. As with the Curti et al (2013) study a dose-response relationship between biomechanical exposures and incidence of CTS was established.

## Chapter 1: Background

However stratified analyses discovered very significant differences between genders as CTS symptoms increased dramatically by exposure among females.

### 1.7 Orthopaedic Care Pathways

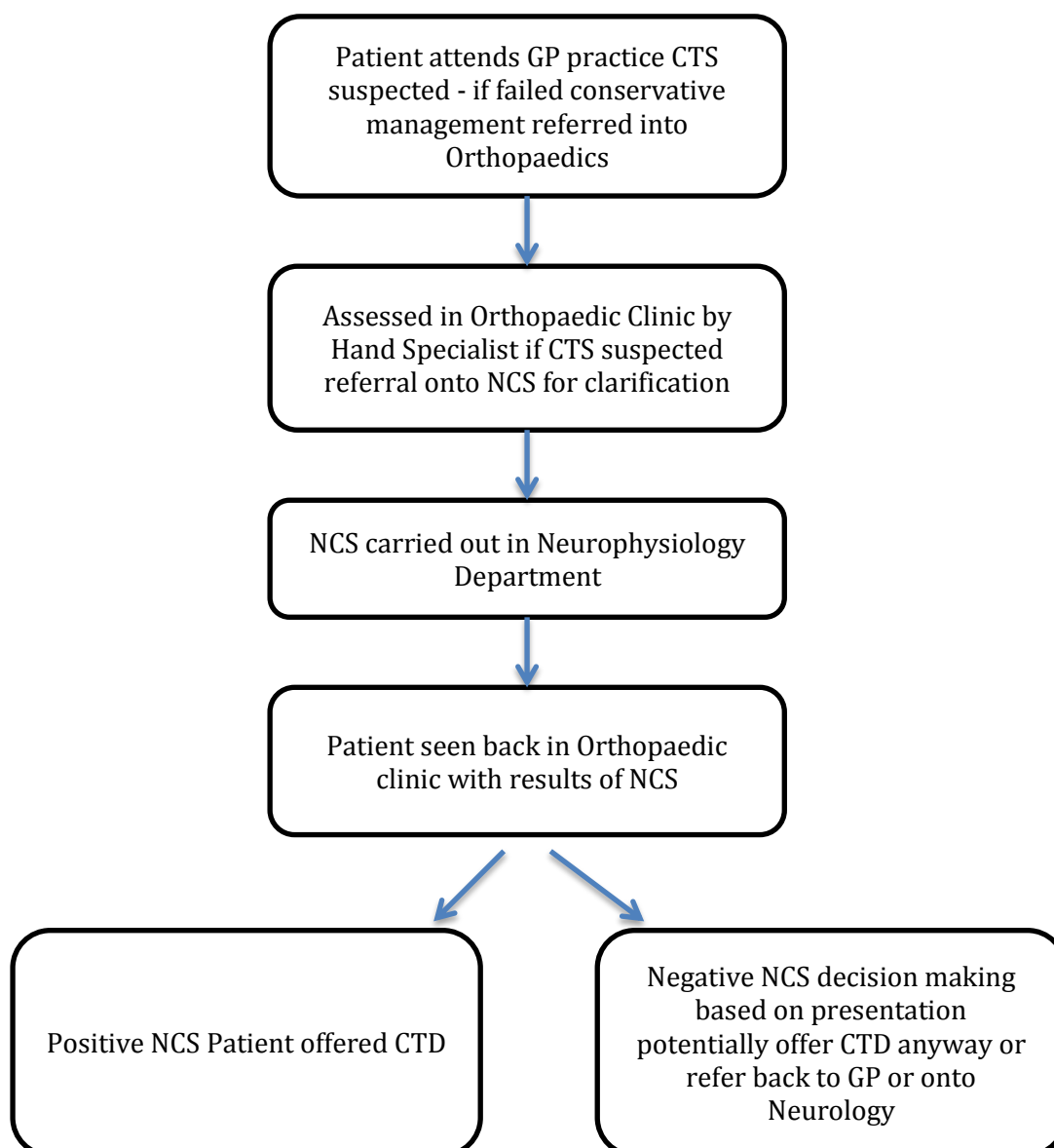


Figure 1.2 Flow Chart to demonstrate CTS care pathway where NCS is not available in clinic

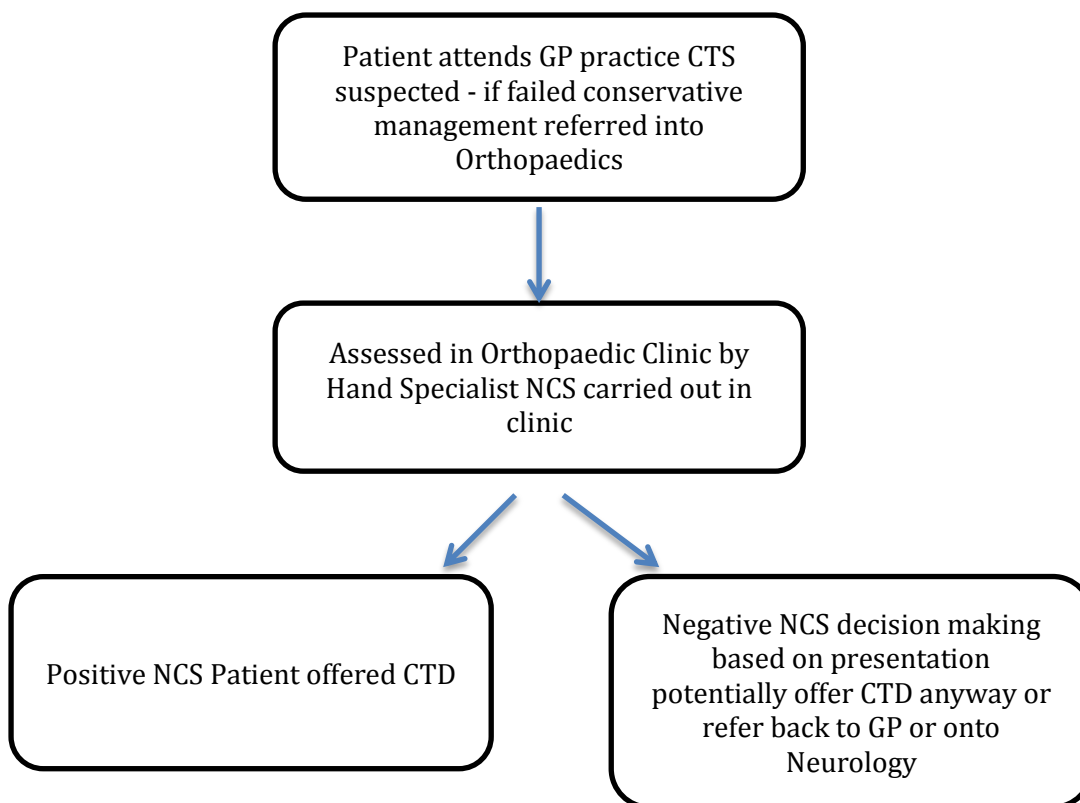


Figure 1.3 Flow Chart to demonstrate CTS care pathway where NCS is available in clinic

The usual management of patients with suspected CTS will differ between Orthopaedic departments dependant on the provision of NCS. The most common pathway involves the referral of patients with suspected CTS for NCS provided often by a tertiary provider as demonstrated in Figure 1.2. Figure 1.3 demonstrates the pathway where NCS are available in the Orthopaedic clinic. There are numerous variations to these proposed pathways dependent upon availability of services, commissioning policies and the clinical reasoning of the hand specialist. What is clear is that where NCS is available a one-stop approach can be adopted reducing the number of appointments that the

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patient needs to attend thereby reducing waiting times and leading to a more efficient/streamlined service. However even in those ideal circumstances testing still incurs costs and can subject patients to an often-unpleasant experience that is not always necessary.

### 1.8 Management of CTS

The management of CTS will often depend upon longevity of the condition and severity of the symptoms. In cases of mild signs and symptoms of relatively short duration, a watch and wait approach may well be encouraged with conservative measures including splinting, physiotherapy and sometimes injections. As symptoms become more established or if conservative measures have failed, surgery would be the next option to release the flexor retinaculum through a CTD - treatment options will be explored further in subsequent chapters.

## Chapter 1: Background

## **Chapter 2: Literature Review – Assessment of Carpal Tunnel Syndrome**

### **2.1 Background**

Carpal Tunnel Syndrome is the single most common referral into our orthopaedic upper limb clinics. Assessment is of paramount importance in establishing true diagnosis and therefore effective treatment. Numerous questionnaires have been established to assist in the diagnosis – how reliable are they?

### **2.2 Objectives**

To evaluate the effectiveness of existing questionnaires in the assessment of carpal tunnel syndrome, in comparison to other diagnostic tools.

### **2.3 Search Strategy**

A search criterion was established using the key words CARPAL TUNNEL QUESTIONNAIRE with a separate search CARPAL TUNNEL ASSESSMENT. Journal databases were searched with medline and pubmed. Studies were assessed for overall quality and those analysing the use of questionnaires in the assessment of carpal tunnel were included. Due to the apparent lack of research the search was not limited to randomised control trials.

## **2.4 Introduction**

Carpal tunnel syndrome (CTS) is a very common condition affecting between 0.125%-1% and 5-16% of the population (Aroori and Spence, 2008; Priganc and Henry, 2003). The pathology involves compression of the median nerve as it enters the hand through the carpal tunnel. Symptoms include burning pain; pins and needles and/or numbness affecting the hand in the distribution of the median nerve (lateral 3.5 digits); weakness and reduced dexterity. Common subjective complaints include night waking; dropping things; shooting sensations in the hand, symptoms are often worse when the hand is raised for example when holding a book or phone also when driving. Relief commonly gained through shaking the hand or hanging the hand out over the side of the bed.

The cause is on the whole is unknown although there are some conditions, which increase the risk of developing CTS.

When analysing the most effective management of this condition it is not surprising to know that there is a wealth of research available on the subject in view of its prevalence. When looking at the assessment of the condition numerous techniques/modalities have been evaluated. The traditional method of using nerve conduction studies and more recent innovations such as ultrasound and MRI have all been studied, it is outside the remit of this review to analyse these fully although some mention will be made within the discussion as to their comparative benefits/pitfalls.



## Chapter 2: Literature Review

Questionnaires have been established in order to predict the presence of CTS, the belief being that by definition CTS is a syndrome and therefore a collection of sign and symptoms. If these signs and symptoms are predictable then a questionnaire should effectively be able to establish those presenting with these and therefore the likelihood of the diagnosis. But is this the case?

There are certain considerations when reviewing literature involving outcome measures and in particular questionnaires.

### **2.5 Questionnaires designed for the assessment of CTS**

#### **2.5.1 Boston Carpal Tunnel Questionnaire (BCTQ)**

This is the most commonly used disease specific outcome measure used in the assessment of CTS, originally developed by Levine et al (1993). This is now a well-recognised and widely used, validated outcome tool specific to Carpal Tunnel Syndrome. A consultation panel was established involving hand surgeons, rheumatologists and patients. Six critical domains were identified for the evaluation of CTS. These domains included paraesthesia; numbness; weakness; nocturnal symptoms and overall functional status, this formed the basis of a symptom severity scale. This scale involves 11 questions with five options scored from 1-5 with 5 being most severe; the score is calculated from the mean of the answered questions. A further scale assessing functional status was developed involving eight activities again being rated on a difficulty scale from 1-5 with the mean scores being used as the measure.

## Chapter 2: Literature Review

The aim of this tool was to provide an accurate patient-administered measurement of the effectiveness of carpal tunnel surgery. Prior to this, outcomes were generally evaluated by the surgeon leading to potential bias.

67 patients who had been previously diagnosed with CTS were recruited 39 (58% - Group 1) were evaluated prior to surgery and three months post-surgery, 28 (42% - Group 2) were assessed over the same period of conservative management. Group 2 were also tested on successive days to establish test-retest reliability.

Results did demonstrate a very high correlation (Pearson Correlation Coefficient 0.91) for the symptom severity scale and 0.93 for the functional severity scale. Validity correlation between scales and physical measures was significant. Sensitivity to change was assessed by comparison of preoperative and postoperative scores were presented as the effect size of 1.4 (very high) for the symptom severity scale and 0.82 (high) for the functional severity scale.

It was suggested that the two sub-scales are considered the main reasons why a patient would seek help for their symptoms; this would provide support for content validity.

The limitations are clear in that when using a functional severity scale with such a heterogeneous group certain questions are likely to be unsuitable for particular client groups this cohort ranged from aged 19-88. This was reflected

## Chapter 2: Literature Review

in the fact that there was missing data, which would have obviously impacted on the mean results.

Group 1 had their original questionnaire completed retrospectively by the patient (1 year), leading to potential bias as a patient could well base their answers on the perceived success of their surgery, plus it would be difficult to remember accurately. It is also not clear whether the application of the questionnaire was by post or delivered in a clinic setting (where the patient would be able to seek clarification from a research assistant/clinician).

Further analysis carried out by Imaeda et al (2007) compared the Japanese version of the Boston CTS questionnaire to the Disability of the Shoulder and Hand questionnaire (DASH) and SF-36. Eighty seven patients, having been diagnosed with CTS (the method of this diagnosis was not discussed) were included in the study. Seventy two patients who did not receive any conservative treatment completed the questionnaires and repeated one week later, 45 patients underwent Carpal Tunnel Decompression (CTD) and subsequent questionnaires were completed three months later.

Nine out of the 72 who completed the original questionnaires did not answer one or more items on the Boston questionnaire, two failed to answer four questions and were excluded from the study. Internal consistency (Cronbach's alpha coefficient) was 0.839. Test-retest reliability using interclass correlation was 0.82. It was deemed that the Boston questionnaire was a reliable valid tool

## Chapter 2: Literature Review

to assess the response to intervention, and it was quicker than DASH and SF-36.

Further comparison between DASH and the Boston questionnaire was carried out by Greenslade et al (2004). In a prospective study 88 patients having been diagnosed with CTS were followed. Two cohorts were established: the first were recruited on the day of surgery, DASH and BCTQ was completed and the second set of questionnaires posted to the patient three months later, and analysed regarding responsiveness to change. The second cohort completed the questionnaire and repeated two weeks later by post (this was deemed long enough to prevent the patients from remembering their initial answers).

Significant test-retest reliability was demonstrated and acceptance rated higher in the BCTQ, which was reflected by the response rate, as 10% of the returned DASH questionnaires were incomplete/invalid despite clear verbal and written instructions.

A comprehensive systematic review of the psychometric properties of the of the Boston carpal tunnel questionnaire was carried out by Leite JC et al (2006). Following clear search criteria 10 studies were reviewed. One study evaluated face-to-face content validity (in 43 patients), eight studies assessed construct validity (in 932 patients), four studies assessed reliability (in 126 patients), nine responsiveness (in 986 patients) and eight studies assessed acceptability (in 978 patients).

## Chapter 2: Literature Review

The BCTQ was compared to 12 different outcome measures related to CTS. There were generally high correlations demonstrated between all scales of measurement. However poor correlation was demonstrated between the BCTQ and clinical sensory tests. Moderate correlation was demonstrated between BCTQ and grip strength.

When looking at the test-retest reliability, all results have proved positive ranging in the four studies analysed within the review with Cronbach's alpha between 0.95 to 0.82 for the Symptom Severity Scale and 0.95 to 0.79 for the Functional Severity Scale.

Effect sizes for changes in the Symptom Severity Scale were reported to be higher than for the Functional Status Scale, however both scales demonstrated moderate ( $>0.5$ ) to large ( $>0.8$ ) responsiveness, thus suggesting that both scales were sensitive to change following an intervention. Throughout, generic measures of quality of life were less sensitive to change than the disease specific BCTQ.

Regarding the acceptability, the time taken to completed the questionnaire was reported in the Greenslade (2004) study as 5.6 minutes ( $\pm 3.5$ min) response rate was generally high; although as discussed incomplete data was an issue in all studies, though this did not prove to be restrictive.

### **2.5.2 Disabilities of the arm, shoulder and hand (DASH) outcome questionnaire.**

The DASH questionnaire is a self-administered region-specific outcome tool; it was established to provide a self-assessment measurement of upper limb disability and symptoms. It consists of a 30-item disability/symptom scale rated from 0 (no disability) to 100. These items refer to a patient's health status during the preceding week. Items relate to the degree of difficulty when carrying out a variety of physical activities due to impairment of the arm, shoulder and hand (21 items), severity of each of the symptoms of pain; activity related pain; tingling; weakness and stiffness (five items) and impact on social activity; work; sleep and self-image (four items). Each item has five response options.

Gummerson et al (2003) assessed the longitudinal construct validity of DASH and analysed change following surgery. 118 consecutive patients having been listed for upper limb orthopaedic surgery (19 CTS) were included in the study. The exclusion criteria included those not able to complete the questionnaire, however numbers of those excluded were not specified.

From completed responses the mean DASH score preoperatively was 35 (SD = 22) and postoperatively 24 (SD = 23) the mean score change was 15 (SD = 13). The effect size was 0.7. DASH demonstrated high Cronbach alpha values indicating an excellent internal consistency. This supports the use of DASH in the measurement of changes in upper limb function.

## Chapter 2: Literature Review

Itsubo et al (2009) went on to compare the correlation between a Japanese version of DASH and nerve conduction studies (NCS). 45 patients having been diagnosed with CTS questionnaires were completed pre-operatively and three months post-operatively and NCS were performed at the same time periods. Selection criteria were not made clear. It was found that both NCS and the questionnaire were highly responsive to change/treatment although they were not parallel. The NCS were deemed to be insensitive to subjective findings. The study concluded by suggesting that DASH could be used as an outcome measure to compare treatment modalities, but both NCS and the questionnaire are both needed in view of their independence.

### **2.5.3 Katz-Stirratt Hand Diagram**

A brief mention of the Katz-Stirratt hand diagram (Katz and Stirrat, 1990) should be included. Although technically not a questionnaire this measure was identified in the search and is a self-reported measure of hand symptoms. This is based on a hand diagram; patients complete by shading in the location of their symptoms and dependent upon the area of shading they are scored by a rater on a four point ordinal scale expressing the likelihood of CTS (unlikely; possible; probable or classic).

Dale et al (2008) carried out an inter-rater reliability study. Three expert raters independently scored 333 hand diagrams of patients who had reported pins and needles within their hands. Despite what seemed to be high level of agreement (0.83 - 95%CI:0.78 - 0.87), it was clear that the assessment of the diagrams was not as objective as predicted. Despite clear instructions to shade

## Chapter 2: Literature Review

the area of the hand where a patient experienced symptoms the subject may circle parts of the hand or use a careless shading method resulting in many stray lines, reducing the specificity of the rater judgment.

Previous studies have generally conceded that clinic-based assessment have shown a good correlation between the diagram and NCS, whereas population based studies have been poor, suggesting patients needed guidance to complete the questionnaire.

Prignac and Henry (2003) looked at the relationship between five common tests and the severity of carpal tunnel syndrome. Two of these five were the Katz-Stirratt hand diagram and the BCTQ. Despite some correlation it was found that predicting the severity, as determined by NCS, was poor with both the hand diagram and BCTQ.

### **2.5.4 Carpal Tunnel Questionnaire**

Kamath and Stothard (2003) investigated the BCTQ and adapted it to provide a clinical questionnaire for the diagnosis of CTS. A scored Carpal Tunnel Questionnaire (CTQ) was devised based on the domains established by the panel in the Levine et al (1993) study. Correlations have been established between the questionnaire and both NCS and results of surgery (Kamath and Stothard, 2003; Bridges et al, 2011). A predictive score indicated the likelihood of someone presenting with CTS and therefore the necessity for NCS. The questionnaire in the Kamath and Stothard study was completed by a hand specialist and not self-administered. This questionnaire consists of nine items



## Chapter 2: Literature Review

which are scored with different weightings, however the methodological decision-making in establishing the scoring algorithm is not made clear. Kamath and Stothard (2003) compared the results of this scored questionnaire to results of NCS in diagnosing CTS using outcome of surgery as the gold standard. Results showed a sensitivity of 85% for the CTQ and 92% for NCS; it was suggested that this questionnaire could replace NCS in the assessment of CTS. Bridges et al (2011) took this study further: 211 consecutive patients completed the questionnaire, although the method by which this was administered was not clear. A single clinician was responsible for carrying out the NCS and administering the questionnaire; he/she was subsequently not blinded to the results of the questionnaire prior to the tests. A threshold was established with a score of 6 or more indicating likely CTS and below 3 unlikely. Sensitivity and specificity was reported to be equal at 87%.

### **2.5.5 The development of a web-based questionnaire**

Extensive work into the development of questionnaire tools in the assessment of carpal tunnel syndrome has been carried out by Dr Jeremy Bland, a Consultant in Clinical Neurophysiology based at Kent and Canterbury Hospital and also at Kings College Hospital in London. In year 2000 Bland published a paper exploring the value of the clinical history in the diagnosis of CTS (Bland, 2000). This was a retrospective study exploring the results obtained from a short symptom questionnaire over an 8-year period. The study population included patients with suspected CTS who had been referred for NCS.

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Eight thousand, two hundred and twenty-three questionnaires were completed with 7,768 patients (some patients attended on more than one occasion).

4,690 (57%) of the sample demonstrated neurophysiological evidence of CTS while 3,533 (43%) did not. The questionnaires were analysed by backward stepwise multiple regression using the presence or absence of abnormal NCS as the dependent variable.

The constructs of the questionnaire were divided into binary, categorical and continuous variables, which did lead to the necessity of a complex statistical analysis. The regression model achieved a sensitivity of 79% and specificity of 54% this was gained through using a ROC analysis to ascertain the cut-off score. Despite reasonable results further work was recommended to expand the questionnaire to see if more extensive history taking would improve the accuracy of the model.

Bland and Rudolfer (2011) explored further the effectiveness of questionnaire tools in predicting the results of NCS in patients with suspected CTS. Two previously published questionnaires together with two newly developed were explored. Retrospective analysis of anonymised patient data from 5280 patients over a 7-year period (2000-2007) was explored. The Kamath and Stothard (2003) CTQ questionnaire was completed (although not all of the information was available due to the reliance on retrospective completion). The seven-item Carpel Tunnel Syndrome (CTS-7) questionnaire was used which explored clinical findings (Tinel's/Phalen's). A revised version of the questionnaire published by Bland (2000) was explored using a logistic

## Chapter 2: Literature Review

regression model and artificial neural network (ANN). Both of these models were devised using 125 variables (as opposed to nine within the CTQ).

Results indicated that the newly-devised tool performed better than existing questionnaires, achieving sensitivity of 88% and specificity of 50% in predicting abnormal NCS suggestive of CTS. When both models were combined 96% sensitivity and 50% specificity were achieved. However, it should be noted that this is an extensive questionnaire with a very complex computer-based scoring mechanism.

Bland et al (2014) published work exploring the conversion of their carpal tunnel questionnaire to a web-based version. A prospective comparison of the probability of CTS obtained through the web-based with results of NCS was carried out. The population included 2821 patients out of a sample of 4899 were able to complete the online questionnaire.

Results demonstrated a sensitivity of 78% and 68% specificity in predicting results of NCS in those with suspected CTS. Results were deemed to be as accurate as the original paper version although there does seem to be some clear disparity from the published figures. The area under the curve through ROC analysis was 0.79, suggesting that the optimum sensitivity/specificity threshold was significantly better than chance at predicting the outcome of NCS.

## **2.6 Discussion**

Outcome measures are an essential component in evidencing treatment effectiveness, particularly for patient-reported improvements. What can be seen from the evidence regarding questionnaires and their role in the assessment of CTS is that the aim has been to use them for analysis of outcome rather than as a stand-alone assessment. The adapted BCTQ developed by Kamath and Stothard (2003) was designed for the purpose of primary assessment; this has been shown to correlate significantly with NCS (Kamath and Stothard, 2003; Bridges et al, 2011).

A consideration has to be made when using NCS as the gold standard, since research has demonstrated a variable rate of false negative NCS when used in the assessment of CTS (Gunnarson et al, 1997; Kuntzer, 1994). Kamath and Stothard (2003) compared the BCTQ to the outcome of surgery, which was considered as the gold standard for the diagnosis of CTS – and a significant correlation was observed. The questionnaire however was not self-administered.

A recurring theme in the literature is that questionnaires generally have not been shown to be reflective of severity of nerve compression. Subjective findings targeted through questionnaires are not parallel with results of nerve conduction studies, but does this matter? Patient satisfaction is generally based on symptoms being resolved through an intervention, not in improving the speed of conduction of a nerve. It is clear that nerve conduction is a good

## Chapter 2: Literature Review

indicator of nerve dysfunction, however does it reflect symptoms accurately? Of course, patients are not solely treated on the basis of numbers obtained through tests. With that in mind would it be safe to suggest that subjective history - and therefore findings from symptom specific questionnaires - would be a better indicator of the need for surgery than NCS? Unfortunately there is not enough evidence available to answer this question at present.

It is still therefore necessary to establish whether the Carpal Tunnel Questionnaire (Kamath and Stothard, 2003) could be used as a self-administered tool, whether in this form it is as reliable as NCS in predicting need for surgery, and also whether it would be a good indicator for patient satisfaction and symptom resolution following a CTD. The method by which the scoring algorithm was devised was also not made clear by the Kamath and Stothard (2003) study.

### **2.7 Conclusion**

It is clear that there is a wealth of research regarding Carpal Tunnel Syndrome and specifically its diagnosis and management. Diagnostic tests are of clear importance for accurate assessment and therefore effective management. From an overview of the evidence there have been some well-designed trials investigating the value of technologies including NCS, Magnetic Resonance Imaging (MRI) and Ultrasonography; all expensive methods each of which has limitations.

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The use of questionnaires has been explored within this brief review. The dominant focus of previous research has been on the use of questionnaires as outcome measures analysing their responsiveness to change (following surgery). Disease specific questionnaires have been investigated demonstrating independent value in the assessment of this condition. Further additions to this evidence in large population studies could well lead to a change in direction in the management of CTS, shifting the focus to patient-reported outcomes of improvement in functional activities of daily life.

## **Chapter 3: Piloting**

### **3.1 Title**

Predicting the Outcome of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Using an Existing Carpal Tunnel Assessment Tool (Edwards, C., & Frampton, I. 2014; see Appendix 2)

### **3.2 Summary**

This service evaluation and pilot study was designed to establish whether a clinical questionnaire could be incorporated within a secondary care Carpal Tunnel Service, the purpose of the questionnaire being to predict positive and negative results of Nerve Conduction Studies (NCS) in those patients with suspected Carpal Tunnel Syndrome. The hand specialist, preceding NCS administered the questionnaire; it was then scored at a later date.

Results showed a sensitivity of 86% and specificity of 84% referring to the ability to predict a positive NCS when using a predetermined cut-off score. When analysed with Receiver Operating Characteristics threshold scores could be determined in order to obtain 100% sensitivity/specificity.

This questionnaire can be used as a useful adjunct to assessment of those presenting with suspected Carpal Tunnel Syndrome. Using the questionnaire to identify those patients scoring outside a predetermined threshold range would reduce the need for NCS by nearly 50%, with significant cost and clinical practice implications. (see Appendix 2 for a copy of the published paper).





## **Chapter 4: Research Methods**

### **4.1 Aims**

1. To evaluate the value of questionnaire approach as an alternative to NCS as a reliable valid and cost effective approach in the assessment of CTS
2. To explore the psychometric properties of the Carpal Tunnel Questionnaire.
3. To establish whether this tool can be self-administered rather than being used as an assessment tool being completed by a hand specialist.
4. To ascertain the inter-rater reliability of the Carpal Tunnel Questionnaire, specifically whether it can be used in a reliable manner between specialists with advanced training and non-specialists with no training.

### **4.2 Research Questions**

1. Can a validated assessment tool used in the diagnosis of Carpal Tunnel Syndrome be used in primary care?
2. Can this assessment tool be used as a self-administered questionnaire?
3. Does this tool demonstrate a high inter-rater and non-specialist reliability?

### **4.3 Title**

Are nerve conduction studies necessary? The development and evaluation of a Patient-completed screening version of the Carpal Tunnel Questionnaire for use in primary care.

#### **4.4 Research Site**

Research was carried out within the Orthopaedic department of Torbay Hospital – South Devon Healthcare NHS Foundation Trust. The Trust's catchment area covers over 300 square miles with an approximate population of 300,000.

#### **4.5 Ethical approval**

A favourable ethical opinion was granted by the proportionate review sub-committee of the South-West Wales Research Ethics Committee February 2013 (Appendix 3). The University of Exeter acted as sponsor (Appendix 4), providing the necessary cover for indemnity and insurance (Appendix 5).

#### **4.6 Piloting Questionnaire**

##### **4.6.1 Piloting with Physiotherapists**

Piloting of the questionnaire was carried out through two methods. Members of staff within the local Physiotherapy Department were asked to review the questionnaire to assess its perceived acceptability for the proposed cohort of patients. Five asymptomatic physiotherapists were asked to complete the questionnaire. Feedback was collated and responses included:

##### **Physiotherapist 1**

*“Questionnaire simple to use quick and easy to understand”*

**Physiotherapist 2**

*“easy to use, and importantly short and concise and should therefore be acceptable to both patients and therapists”*

**Physiotherapist 3**

*“short questionnaire, should be easy to adopt into usual practice but, are the questions too leading?”*

**Physiotherapist 4**

*“easy to use but I have concerns that it may not address myelopathy as a differential diagnosis should further questions be added to rule this out such as reduced dexterity and gait disturbance?”*

**Physiotherapist 5**

*“clear and easy to fill in”*

Within healthcare practice it is important to measure patients' perceptions of their health in relation to specific medical conditions. To this end patient reported outcome measures (PROMs) have been developed and have been adopted by health service providers to assess both treatment outcomes and the patients' perspective on their care (Dawson et al, 2010). These PROMs have formed an important part of a patient's assessment however this adds another level of paperwork to the clinician and can come with significant levels of resistance and result in poor compliance. The feedback from the physiotherapists has reflected how easy and quick this questionnaire is to

## Chapter 4: Research Methods

complete, will not impact too much upon the available clinic appointment time and should therefore be an acceptable addition to current practice.

Physiotherapist 4 made a comment that myelopathy may well be missed as it was not specifically addressed within the constructs of the questionnaire.

Cervical myelopathy occurs due to narrowing of the spinal canal which compromises cord function. Patients may well present with balance disturbance, poor coordination, weakness and numbness. Cervical myelopathy is usually progressive and there are various classifications that determine the severity of the cord compression. When considering pins and needles, particularly when present bilaterally in the hands, myelopathy needs to be considered. There are various objective tests available to the clinician when considering a myelopathy and what is important is that this is addressed during the clinical examination of a patient presenting with suspected bilateral CTS. The concerns raised by Physiotherapist 4 are valid; however the questionnaire is only an adjunct to assessment; the clinical examination and subjective questioning carry most credence and allow for consideration of myelopathy to be addressed and explored fully. Patients would be assessed within primary care prior to referral into the orthopaedic setting, a suspected diagnosis of CTS on a referral form and a high score on the CTQ will not deter the hand specialist from considering all potential differential diagnoses.

### **4.6.2 Piloting with Service Users**

Subsequent analysis was carried on twenty consecutive patients who met the inclusion criteria for the study. These patients were asked to complete the

## Chapter 4: Research Methods

questionnaire prior to their clinic appointment. Routine clinical assessment and NCS were carried out and treatment decisions made irrespective of the Questionnaire results.

The lead researcher completed a parallel questionnaire as a component of clinical assessment. Results of the two questionnaires were compared and discussed with the patient. There was one particular question, which presented with considerable discrepancy, needed further analysis. The question “Do you have any trick movements to make the tingling, numbness go from your hands?”

It became clear that this question was possibly not specific enough (As has previously been discussed the basis for the inclusion of this question is the ‘Flick Test’; a positive test Flick Test referring to the patient gaining relief from their symptoms through shaking/flicking their fingers). Through questioning the patients it was apparent that all but one of those presenting with positive NCS had a positive flick test; therefore on the clinician-completed questionnaire had a positive response to the above referenced question. However when looking at the patient-completed questionnaire the responses to this question was frequently negative.

Such negative responses to the ‘trick movement’ question were given even though patients had specifically responded that during the night when awoken with the symptoms relief was acquired through shaking the hand. An amendment was therefore made to the question, adding “... such as shaking your hand, or hanging it out of the bed at night.”

## Chapter 4: Research Methods

The questionnaire was retested with 10 patients and responses obtained. In this revised version there was no specific discrepancy with any one particular item. The questionnaire was then deemed ready to progress to the formal evaluation.

### **4.7 Methodology for the Study**

#### **4.7.1 Materials**

The Carpal Tunnel Questionnaire (CTQ, see Appendix 6) consists of nine questions related to the common symptoms reported by patients suffering with CTS. The questions are differentially weighted (based on the original method described by Kamath & Stothard, 2003) giving a scoring range of between -2 and +11 (Appendix 7).

#### **4.7.2 Population**

The cohort of patients for this study was acquired through direct referral from either primary care (usually their own General Practitioner) or through secondary care via other specialist clinics. These patients were referred with the direct question as to whether they did, or did not have CTS.

#### **4.7.1 Inclusion Criteria**

- Those able to offer informed consent
- Patients having been referred with suspected Carpal Tunnel Syndrome
- Patient aged over 18 year (no upper age limit)
- Those patients who are suitable for NCS

#### **4.7.2 Exclusion Criteria**

- Peripheral Neuropathy including those diagnosed with Diabetes Mellitus
- Pregnancy
- Patients who have undergone renal transplant
- Previous Carpal Tunnel Decompression on the same side
- Those unable to give informed consent
- Those under the age of 18 years

Diagnosis of CTS in patients with diabetic neuropathy is difficult as the two conditions may affect the median nerve in a similar way. Renal transplant patients (often requiring more involved surgery including the removal of amyloid tissue) and pregnant patients will be also excluded. CTS can reoccur but it is rare and this may well complicate matters, all patients returning to an orthopaedic clinic with recurrence of symptoms would require NCS.

#### **4.7.3 Sample size**

100 patients meeting the inclusion criteria were included within the study. Power was determined through reviewing previous research including the original study carried out by Levine et al (1993) exploring the use of a questionnaire in the assessment of CTS (n=67). The questionnaire developed and evaluated by Kamath and Stothard (2003) included 107 consecutive patients referred into a hand clinic with suspected CTS, of whom 74 met the inclusion criteria and 16 were lost to follow up, giving a total sample size in that study of 58.

#### **4.7.4 Patient Information**

Patient Information Leaflets were formulated (Appendix 8) with the initial aim of sending these out along with the appointment details to the patients. Upon exploring this further it became evident that due to both practical issues and cost implications this was not feasible.

Regarding the feasibility, the cohorts of patients attending the clinic have mixed pathology – not all have suspected CTS. Clearly it would not have been appropriate to send all patients the information leaflet regarding this study. The difficulty, which presented itself, was the ability to triage all referrals into the clinic and selecting those appropriate for the study. Referrals arrive from different sources (within both primary and secondary care), which again complicate the triaging process.

When considering the cost implications, appointment details are not sent directly from our own organisation but through a private company; any additional paperwork sent along with the appointment details entails an individual additional cost. This cost was not budgeted for through the development of this study, and therefore a contingency was made. The importance of providing patient information is clear, it was decided that it would be appropriate to provide the information within the Orthopaedic Department prior to the appointment.



#### **4.7.5 Triaging**

Clinic notes were reviewed and those meeting the inclusion criteria were selected. Those patients deemed appropriate for the study were provided with the patient information leaflet and questionnaire upon their attendance. Sufficient time was offered in order for the patients to decide whether or not they wished to participate in the study. It was made specifically clear at this point that being included within the study would have no effect on the outcome of their clinic appointment. Sufficient time was determined by the patient with them being offered flexible appointment times with assurances that they would not miss their appointment. If more time was needed to consider the implications further appointments were offered on another day at the patient's convenience.

#### **4.7.6 Completion of the patient-completed version of the questionnaire**

Once the patient had agreed to participate and had been consented (by the lead researcher, see Appendix 9) they were coded and asked to complete the questionnaire. This questionnaire, once completed was put into a box file with the lead researcher blinded to the results.

#### **4.7.7 Clinical Appointment**

Detailed subjective clinical history was taken. This involved questioning regarding duration and nature of the symptoms; aggravating and relieving factors; past medical history; medication and social history. Physical examination was carried out. Sensory and motor assessment together with examination of the cervical spine was completed.

#### **4.7.8 Nerve Conduction Studies**

A carpal tunnel screen was carried out on all patients. Motor testing of right and left sides of abductor pollicis brevis (median nerve, APB) and abductor digiti minimi (ulna nerve) were carried out. Sensory tests were then completed involving testing of right and left index finger, middle finger and little finger as well as transpalmar testing. Analysis of any potential demyelination and axonal degeneration was completed.

The method of interpretation of results was based on the Kamath and Stothard (2003) study. Criteria for normal values were matched, with terminal latency to APB less than 4.0ms and a sensory conduction from digit 2 to wrist greater than 47m/s. Further routine tests included transpalmar recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

Following the examination but prior to the neurophysiological testing the specialist-completed questionnaire was completed. The hand specialist asking the questions and documenting the responses completed the questionnaire. The questionnaire was coded as per the patient-completed questionnaire and entered into a separate box file to be scored at a later date. Clinical decision-making was made entirely with the benefit of the history, examination and NCS. Questionnaires were not scored until the completion of the study and therefore had no bearing upon clinic outcome.

#### **4.8 Statistical Analysis**

Data were explored with regard to validity, internal consistency, inter-rater reliability, and to measure the relationship between the outcome of the questionnaire and its individual constructs. As the questionnaire was only administered once at the point of assessment, test-retest reliability and responsiveness to change were not explored in this study. Statistical models fitted for each study are as follows:

##### **4.8.1 Study 1**

#### **Predicting the Outcome of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Using an Existing Carpal Tunnel Assessment Tool**

Study 1 describes the work carried out by Edwards and Frampton (2014) to test the feasibility of implementing the CTQ in current practice. Participants meeting the inclusion criteria (n=68) were to be included within the study, questionnaires were completed by the hand specialist and results subsequently compared with NCS.

Validity refers to whether or not the questionnaire does actually measure what it is designed to do. In this case can the questionnaire predict the outcome of the NCS? Assessment of the correlation between questionnaire scores and NCS was achieved through exploring sensitivity and specificity. Receiver operating characteristics (ROC) analyses explored false positive rate against true positive. The curve is generated through plotting a curve between true positive rates (sensitivity) and false positive rate (1-specificity); this curve will

depict the performance of the questionnaire in predicting positive NCS at various cut-off thresholds.

#### **4.8.2 Study 2**

##### **Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample**

Study 2 will verify the scoring algorithm for the CTQ originally developed by Kamath and Stothard (2003). The aim being to use binary logistic regression to predict the binary response from a binary predictor, in essence using logistic regression to predict the probability of positive NCS in a patient with suspected CTS based on the values of several covariates (Bland et al, 2011). In a clinical context logistic regression may be used to predict whether a patient actually has CTS/positive NCS based on the observed characteristics of the patient or their responses within the questionnaire.

Raw scores on the CTQ for each participant will be entered into a binary logistic model predicting NCS outcome (positive or negative). Beta coefficients will be extracted for each item in the questionnaire and applied as a weighting. Beta values obtained through regression modelling will be used to formulate a new algorithm and comparisons made with the original. Comparisons between the newly devised algorithm and original will be based on assessing specificity and sensitivity using the original cut-off score.

### **4.8.3 Study 3**

#### **Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a clinician completed and patient-completed version.**

Study 3 will build on existing studies of the CTQ and also explore the versatility of the questionnaire with the aim of exploring whether the CTQ could be used as a patient-completed tool. 100 participants who meet the inclusion criteria will complete the CTQ and then be assessed by the hand specialist who will complete a further CTQ prior to carrying out NCS. Results of CTQ and NCS will subsequently be assessed.

Statistical analysis will explore sensitivity and specificity reflecting the CTQ's ability to predict results of NCS in those with suspected CTS. ROC analysis will be carried out to explore effects on sensitivity and specificity at various threshold scores. Comparisons between the patient-completed version and clinician-completed will be explored and expanded upon in further studies.

### **4.8.4 Study 4**

#### **Exploring the potential for using a Carpal Tunnel Questionnaire as a patient-reported measure – An Inter-rater Reliability Study**

This study explores the inter-rater reliability (IRR) between patient self-rating and specialist rater completing the questionnaires. The aim of establishing the IRR will be to demonstrate the degree of consistency among scores provided by patient self-report and specialists (Hallgren, 2012).

Total scores will be analysed comparing the results obtained between the self-completed (study 3) and clinician completed (study 2) CTQ . Mean scores will be analysed together with Pearson's Correlation Coefficient using version 22 of the Statistical Package for the Social Sciences (SPSS).

### **4.8.5 Study 5**

#### **Cost Analysis and Modelling**

Potential impact upon an orthopaedic service adopting the CTQ as a screening tool will be explored. Analysing cost saving and potential impact upon waiting lists will be carried out together with exploring the overall impact upon the patient.

### **4.9 Dissemination plan**

The structure of the studies will allow for publication of the various studies. Dissemination via journal publication with the target Journal – Journal of Hand Surgery is planned. Abstracts will be sent to both Physiotherapy UK conference and British Society for Surgery of the Hand (BSSH)/ British Association of Hand Therapists (BAHT) Autumn Scientific Meeting 2016.

## **5.1 Title**

### **Item analysis of the Carpel Tunnel Questionnaire**

## **5.2 Abstract**

Carpal Tunnel Syndrome (CTS) accounts for 90% of entrapment neuropathy (Aroori and Spence, 2008) being the most common entrapment neuropathy presenting to the Orthopaedic outpatient department affecting between 5-16% of the population (Priganc and Henry, 2003). Debate remains as to how best assess and diagnose this condition. Nerve conduction studies are an effective way of objectively measuring the presence of CTS yet they are often costly and lead to an increase in waiting times and they are also not always necessary. Kamath and Stothard (2003) developed a questionnaire in order to assess the likelihood of a patient presenting with CTS this has been subsequently explored and shown to have high levels of specificity when used to predict outcomes of NCS in those with suspected CTS (Bridge, 2011; Edwards and Frampton 2014). This study has the aim of building upon current theory exploring the individual constructs of the questionnaire and how each of them contribute to the to the overall function of the CTQ in predicting the outcome of nerve conduction studies in patients with suspected CTS. Results demonstrate that there is no one question that provides all the information that we need to confidently predict the outcome of NCS. It is the combination of questions that

provide the predictive validity of the CTQ. Background theory into the selection of these constructs is explored.

### **5.3 Introduction**

Carpal Tunnel Syndrome (CTS) is the most common entrapment neuropathy presenting to the Orthopaedic outpatient department affecting between 5-16% of the population (Priganc and Henry 2003). Assessment of CTS depends on detailed history taking, clinical examination and nerve conduction studies (NCS). NCS carry a cost and often delay treatment due to additional waiting times. Nerve conduction studies (NCS) have traditionally been viewed as the effective method of assessment for CTS. NCS however have their limitations and there is no true gold standard in the diagnosis of CTS.

A questionnaire developed by Kamath and Stothard (2003) based on original work by Levine et al (1993) has been shown to demonstrate a high sensitivity when compared to positive results from NCS (Bridge et al 2011; Edwards Frampton 2014) and outcome from surgery (carpal tunnel decompression; Kamath and Stothard, 2003). The 9-item questionnaire is scored using an algorithm with items being weighted differently.

This item analysis aims to explore each construct of the questionnaire to explore how each question contributes to the overall reliability of the CTQ.



## **5.4 Methodology**

### **5.4.1 Participants**

100 consecutive patients attending the orthopaedic hand clinic with suspected Carpal Tunnel Syndrome (CTS) who met the inclusion criteria were selected for the study. Power was assumed through reviewing previous studies most notably the original study carried out by Levine et al (1993) that explored the use of a questionnaire in the assessment of CTS (n=67). The questionnaire developed and assessed by Kamath and Stothard (2003) (upon which this study is based) involved 107 consecutive patients referred into a hand clinic with suspected CTS. 74 met the inclusion criteria and 16 were lost to follow up.

The cohort of patients for this study was acquired through direct referral from either primary care (usually their own General Practitioner) or through secondary care via other specialist clinics. These patients were referred with the direct question as to whether they did, or did not have CTS.

### **5.4.2 Inclusion Criteria**

- Those able to offer informed consent
- Patients having been referred with suspected Carpal Tunnel Syndrome
- Patient aged over 18 year (no upper age limit)
- Those patients who are suitable for NCS

### 5.4.3 Exclusion Criteria

- Peripheral Neuropathy including those diagnosed with Diabetes Mellitus
- Pregnancy
- Patients who have undergone renal transplant
- Previous Carpal Tunnel Decompression on the same side
- Those unable to give informed consent
- Those under the age of 18 years

Diagnosis of CTS in patients with diabetic neuropathy is difficult as the two conditions may affect the median nerve in a similar way. Renal transplant patients (often requiring more involved surgery including the removal of amyloid tissue) and pregnant patients will be also excluded. Carpal tunnel syndrome can recur but it is rare and this may well complicate matters, all patients returning to an orthopaedic clinic with recurrence of symptoms would require NCS.

Prior to the commencement of the clinic notes were triaged and those meeting the inclusion criteria were selected. Those patients deemed appropriate for the study were provided with the patient information leaflet and questionnaire upon their attendance. It was made specifically clear at this point that being included within the study would have absolutely no effect on the outcome of their clinic appointment.

#### **5.4.4 Procedure**

Consecutive participants who consented and who met the inclusion criteria completed the CTQ prior to entering the clinic room. Completed questionnaires were posted into a sealed box and were not seen by the hand specialist. Participants then underwent subjective/objective examination by the hand specialist who completed the questionnaire and NCS was carried out. CTQ was not analysed until a later date and had no influence over the clinical management of the patient's symptoms. Criteria for the interpretation of NCS were based on the Kamath and Stothard (2003) study. Criteria for normal values were matched, with terminal latency to abductor pollicis brevis less than 4.0ms and a sensory conduction from digit 2 to wrist greater than 47m/s. Further routine tests included transpalmar recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

#### **5.4.5 Materials**

The CTQ consists of nine questions related to the common symptoms reported by patients suffering with CTS.

#### **5.4.6 Data Analysis**

Total CTQ scores for each participant were computed using the original weighting algorithm. Using the original threshold of CTQ weighted score  $\geq 5$ , specificity and sensitivity together with positive and negative predictive values in relation to obtained positive NCS results were compared with each question.

## Chapter 5: Item Analysis

A descriptive analysis of each item was completed to ascertain the reason for its inclusion within the questionnaire. Percentage agreements between individual questions and results of NCS were calculated.

### 5.5 Results

#### 5.5.1 Analysis of individual item responses of the clinician completed

#### CTQ

Question/Item	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
1	72	44	79.41	34.38
2	94.67	40	82.56	71.43
3	69.33	80	91.23	46.51
4	74.67	56	83.58	42.42
5	64	76	88.89	41.3
6	85.33	56	85.33	56
7	45.45	100	100	14.29
8	54.29	80	90.48	33.33
9	64	40	76.19	27.03

Table 5.1 Sensitivity, specificity, positive and negative predictive values for individual items of the clinician completed CTQ compared to results of NCS

**5.5.2 Analysis of individual item responses of the patient-completed version of the CTQ**

Question/Item	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
1	78.57	27.27	77.46	28.57
2	85.14	21.74	77.78	31.25
3	64.79	72.73	88.46	39.02
4	63.38	40.91	77.59	25.71
5	58.82	86.36	93.02	40.43
6	84.93	45.45	83.78	47.62
7	26.67	100	100	8.33
8	47.37	77.78	90	25.93
9	63.89	47.62	80.70	27.78

Table 5.2 Sensitivity, specificity, positive and negative predictive values for individual items of the patient-completed CTQ compared to results of NCS

**5.5.3 Percentage Agreements between Question responses and NCS**

Question	Clinician Completed Questionnaire							Patient-Completed Questionnaire						
	Positive NCS			Negative NCS			% agreement with NCS	Positive NCS			Negative NCS			% agreement with NCS
	yes	no	N/A	yes	no	N/A		yes	no	N/A	yes	no	N/A	
1	54	21	0	14	11	0	65	55	15	5	16	6	3	61
2	71	4	0	15	10	0	81	63	11	1	18	5	2	68
3	52	23	0	5	20	0	72	46	25	4	6	16	3	62
4	56	19	0	11	14	0	70	45	26	4	13	9	3	54
5	27	48	0	19	6	0	67	28	40	7	19	3	3	59
6	64	11	0	11	14	0	78	62	11	2	12	10	3	72
7	5	6	64	0	1	24	6	4	11	60	0	1	24	5
8	19	16	40	2	8	15	27	18	20	37	2	7	16	25
9	27	48	0	10	15	0	58	26	46	3	10	11	4	56

Table 5.3 Responses of all questions from both clinician completed and patient-completed questionnaires together with % agreement with NCS

Table 5.3 depicts the percentage agreement between the responses from the clinician and patient-completed questionnaires. Percentage agreement between individual clinician completed questions and NCS ranges from

## Chapter 5: Item Analysis

between 6-81%. Percentage agreement between individual patient-completed questions and NCS ranges from between 5-72%.

### **5.5.4 Score Ranges**

	Sensitivity Range (%)	Specificity Range (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
Patient-Completed	26.67-85.14	21.74-100	77.46-100	8.33-47.62
Clinician-Completed	45.45-94.67	40-100	76.19-100	14.29-71.43

Table 5.4 Ranges of Sensitivities, Specificities, Positive Predictive Value and Negative Predictive Value for all items within the questionnaire.

Table 5.4 represents the ranges of Sensitivities, Specificities, Positive Predictive Value and Negative Predictive Value for all items within the questionnaire.

### **5.6 Discussion**

The questions developed for the CTQ questionnaire were based on the Boston Carpal Tunnel Questionnaire (BCTQ: Levine et al 1993), a patient perception of disease scale which assesses both the severity of hand symptoms and functional limitations they cause relating to both clinical and epidemiological considerations. When exploring the construct analysis of the BCTQ there are two clear distinct domains being severity of hand symptoms and functional limitations. A study by Ortiz-Corredor et al (2011) looked into the factor analysis of the BCTQ in relation to NCS. In a sample of 403 patients who had clinical signs of CTS and/or positive NCS three factors were identified that

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accounted for nearly 60% of the variance of the instrument. The questions were devolved into three factors reflecting functional status (factor one), sensory symptoms (factor two) and pain (factor three).

Analysis went on to compare responses from the questions in each of these factors to NCS. Ortiz-Corredor et al (2011) found that questions related to sensory symptoms (factor two) had a significant statistical correlation with both sensory and motor analysis of the median nerve. Questions related to functional status (factor one) only correlated to sensory conduction velocity of the 4<sup>th</sup> digit and factor three (pain) and demonstrated no statistical correlation with NCS, indeed those scoring high on the pain related questions often recorded faster sensory conduction velocities and shorter distal motor latencies which is clearly a paradoxical finding (Ortiz-Corredor et al, 2011). Clinically it is often found and widely accepted that paraesthesia and nocturnal waking with pins and needles/numbness are usually a sign of peripheral nerve entrapment and pain more likely related to underlying joint or soft tissue pathology.

When exploring the questions with the CTQ there is a bias towards the questions addressing factor two (sensory symptoms: questions 2,3,4,5,8) two questions related to factor three (pain: questions 1 and 9). Only one question related to factor one (function: question 6). Despite there being a common theme of symptoms with those presenting with CTS variability does occur.

When the symptoms of CTS present themselves in the early stages patients will usually complain of sensory disturbance with commonly a burning sensation being reported. As the severity of the condition increases weakness

is often reported as the motor elements of the nerve become impaired (Aroori and Spence, 2008).

### **5.6.1 Question 1**

#### **Has pain in the wrist woken you up at night?**

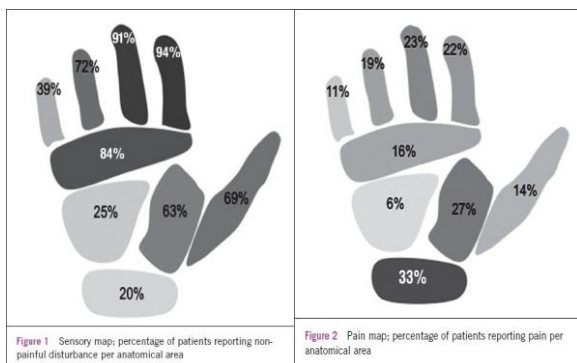
Patients in the early stage of the condition will commonly complain of burning pain associated with pins and needles. This burning sensation is often nocturnal. From the results of question 1 the percentage agreement between a positive response and positive NCS was 65% for the clinician-completed questionnaire and 61% for the patient-completed questionnaire. The sensitivity and specificity (depicted in Tables 5.2 and 5.3) suggests that there is a fair positive predictive value however the negative predictive value was low therefore a significant number of patients who despite not complaining of pain still present with positive NCS. In the present cohort of patients 21% of those with the clinician completed questionnaire answered 'no' to question 1 yet still went on to have positive NCS (15% of the patient-completed questionnaire). It is widely recognised that common features of peripheral nerve entrapment include pain associated with pins and needles/numbness. What is observed in practice is those with CTS often present with pins and needles/numbness in the absence of pain which is reflected in the responses from the questionnaires.

Clark et al (2011) completed sensory mapping and pain mapping on 64 patients with confirmed CTS (Figure 5.1). This mapping was carried out through the completion of hand diagrams where patients shaded in areas



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where they felt pain and then completed another diagram representing their sensory disturbance.



**Figure 5.1** Sensory and Pain mapping of symptoms in patients with CTS from Clark et al (2011)

It is clear from the results of this study that sensory disturbance dominated pain. The most common distribution of pain was over the wrist (overlying the Carpal Tunnel) with 33% of subjects reporting this yet 94% reported non-painful altered sensation within the index finger being supplied by the median nerve. This reflects the contrasting results between question 1 (discussed here) and question 2 (discussed below).

### 5.6.2 Question 2

#### **Has numbness and tingling in your hand woken you during the night?**

Widely regarded, as the most common feature of CTS, numbness and pins and needles are dominant features of those presenting with a peripheral nerve entrapment. Symptoms of CTS are commonly present with diurnal variation. Night wakening is a common complaint; theories regarding the cause of this are controversial but include fluid retention or a redistribution of body fluids

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whilst in a lying posture (McCabe et al 2007) increasing pressure within the carpal tunnel when lying/sleeping together with flexed or extending wrist postures adopted whilst in sleep which are known to increase carpal tunnel pressure (Luchetti et al 1989). McCabe et al (2007) explored the literature regarding the epidemiology of CTS specifically looking into sleep disturbance. Further causes of sleep disturbances were explored including obesity, sleep apnoea and age to see if a common link existed. It was hypothesised that these common causative factors lead to an increased risk of developing CTS symptoms through sleep posture in particular lying on your side. In side lying the wrist is more likely to develop a flexed or extended position increasing carpal tunnel pressure and in turn pressure on the median nerve.

Percentage agreement between the responses of the questionnaire and results of NCS were 81% for the clinician completed and 68% for the patient-completed questionnaire (Table 5.3). Sensitivity rates for clinician-completed and patient-completed questionnaires were 94.67% and 85.14 respectively (Tables 5.1 and 5.2). This represents the importance of this question within the subjective examination of CTS. This is reflected through the Katz-Stirrat hand diagram (Katz et al, 1990) that uses the distribution of pins and needles and numbness as a basis for predicting the probability of CTS.

### **5.6.3 Question 3**

**Has tingling and numbness in your hand been more pronounced first thing in the morning?**

Responses to this question offered 72% agreement for the clinician-completed questionnaires and NCS results and 62% for the patient-completed

questionnaire (Table 5.3). Positive predictive of 91.23 and 88.46% and negative predictive values of 46.51% and 39.02% (Tables 5.1 and 5.2) were recorded for the clinician-completed and patient-completed questionnaires respectively. Theory behind this question is developed through the latent effect of the increasing symptoms overnight; the reasoning behind increasing nocturnal symptoms has already been discussed. Results of this question were not as convincing as those occurring overnight through question 2.

#### **5.6.4 Question 4**

**Do you have any trick movements to make the tingling, numbness go from your hands (such as shaking or hanging your hand out of the side of the bed)?**

Another commonly reported feature of CTS relates to symptoms abating when the hand is hung out of the side of the bed and shook or dropped to one side when driving or carrying out activities when the hand is raised. Flick sign was described as a flicking movement of the wrist and hand similar to when flicking/shaking a thermometer which was demonstrated by a patient in response to the question 'what do you do when the symptoms are bad?'

Pyrse-Phillips (1984) explored this commonly-reported method of how patients tend to alleviate the symptoms of carpal tunnel syndrome. The original study looked at 505 patients (some retrospectively) over an 11-year period (1972-1983). The validity of the Flick sign was determined by the false negative rate whereby the number of patients who met the diagnostic criteria for CTS (including positive NCS) did not report a positive Flick sign. It has been claimed

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that positive Flick sign predicted electrophysiological signs of CTS in 93% of cases with false positive rates below 5%. With such high sensitivity and specificity it was suggested that Flick test could well be a reliable test to use in the diagnosis of CTS when NCS are not available. However a report published soon after by Krendel et al (1986) disputed the significance of the test. Through analysing 56 patients who met the same diagnostic criteria for CTS as Pryse-Phillips (1984) only 14 (25%) had a positive Flick test. Pryse-Phillips (1986) in response suggested that such variation in results could well be due to patient population, patient selection, or interpretation of the sign. There has been limited reliable evidence exploring Flick test further and certainly nothing to reproduce the level of sensitivity or specificity produced by Pryse-Phillips (1984).

Despite this item not solely relating to flick test, relatively high positive predictive value in both the patient-completed (77.59%) and clinician-completed (83.58%) (Tables 5.1 and 5.2) versions of the questionnaire would suggest flick test to be effective in discriminating patients who would likely go on to have positive NCS. Negative predictive value for both the patient-completed version (25.71%) and clinician-completed version (42.42%) (Tables 5.1 and 5.2) was low which suggests a poor ability to correctly predict those patients who did not have carpal tunnel syndrome.

### **5.6.5 Question 5**

#### **Do you have any tingling or numbness in your little finger at any time?**

Question 5 relates to the anatomy involved in the process of CTS. CTS involves the compression of the median nerve as it passes through the carpal tunnel. The median nerve has a specific sensory distribution within the hand typically involving the lateral three and half digits (sparing the little finger). In descriptions of the classic presentation of CTS this depiction of the sensory loss is often referred to. In clinical practice however this is not always the case. Symptoms of CTS are often worse at night and patients often describe pins and needles affecting the whole hand. CTS commonly presents bilaterally; in that instance it would be very difficult to self-assess the distribution of the symptoms.

Nevertheless, results in the current study demonstrated significant levels of sensitivity. The patient-completed questionnaire resulted in a positive predictive value of 93.02% and the clinician-completed questionnaire 88.89% (Table 5.1 and 5.2). These results reflect the weighting of this item in the scoring algorithm.

Work carried out by Claes et al (2014) explored the importance of sensory distribution in the diagnosis of CTS. This prospective cohort study initially involved 228 subjects having been referred to a hand clinic via their GP with suspected CTS. These patients met the predetermined diagnostic criteria for CTS. Subjects were allocated into two groups with group 1 (n=131) including those patients with paraesthesia isolated to the distribution of the median nerve

territory and group 2 (n=97) still meeting the diagnostic criteria but describing symptoms outside the distribution of the median nerve (in the little finger). Both groups underwent neurophysiological testing and subsequent treatment – only 19 were treated conservatively. Symptom severity scores (SSS) (Levine et al 1993) were used as outcome measures and there was no significant difference between changes in SSS between the two groups following treatment.

Symptoms outside the distribution of the median nerve in those presenting with CTS is not uncommon. This has been explored in numerous studies. Clark et al (2011) examined the distribution of symptoms in patients with CTS. This included 64 patients having had CTS confirmed with NCS, objective measures of sensation were taken together with subjective measures using a hand diagram completed by the patient (Figure 5.1). The results of these were correlated with NCS. Symptoms were predominantly felt in the distribution of the median nerve (index finger 94%) however a significant percentage (39%) complained of symptoms within the little finger. This study demonstrated that atypical distribution of symptoms is common and it was suggested that the assessment (whether objective or subjective) of sensation might not be helpful in the initial diagnosis of CTS.

On reflection the high positive predictive values are combined with low negative predictive values; patient-completed 40.43% and clinician-completed 41.30% (Tables 5.1 and 5.2) supported the fact that those presenting with atypical symptoms could well still present with CTS (false negatives) similar to the results obtained by Clark et al (2011).

### **5.6.6 Question 6**

#### **Has tingling and numbness presented when you were reading a newspaper, steering a car or knitting?**

Symptoms of CTS are often reported to be worse or exacerbated by holding a book or newspaper, steering a car or knitting as reflected in question 6 above.

When looking at the ergonomics of such activities it becomes clear that the wrist is held in a flexed position often for a sustained period of time.

Ultrasonography has been used to determine carpal tunnel pressure (CTP) and a relation between CTP and CTS has been established. Work carried out by Keir et al (2007) demonstrated how pressure within the carpal tunnel increases when wrist range deviates from neutral. Any sustained positioning of the wrist in flexion or extension can lead to an exacerbation of the symptoms associated with CTS. This is the basis upon which Phalen's test was developed (Phalen, 1966).

Within the study 84.93% sensitivity and 45.45% specificity was achieved through the patient-completed questionnaire and 85.339% sensitivity with 56% specificity through the clinician-completed (Tables 5.1 and 5.2). This item offers an ability to predict positive outcome (those who present with positive NCS) yet has little ability in discriminating those who would go on to have negative NCS.

### **5.6.7 Question 7**

**If applicable has the tingling and numbness in your hand been more severe during pregnancy?**

CTS is a well-known complication of pregnancy: a recent large prospective longitudinal cohort study carried out by Meems et al (2015) explored the prevalence of CTS in 639 pregnant women finding positive results in 219 (34%). A systematic review of pregnancy-related carpal tunnel syndrome carried out by Padua et al (2010) explored the reported incidence of pregnancy-reported CTS. 214 studies met their selection criteria with only six meeting the inclusion criteria. There was a varying reported incidence ranging from between 7% to 43% of NCS confirmed CTS and 31% to 62% of clinically diagnosed CTS.

When considering aetiopathogenesis we need to consider physical changes that occur during pregnancy. It is believed that processes during pregnancy lead to increasing pressure within the carpal tunnel as a result of fluid retention related to hormonal changes with increased levels of progesterone and renal hormones which in turn increases blood volume.

Increased reactivity of nerves (reported in pregnancy) may lead to subjects being more susceptible to CTS where mild compression which may not be perceivable in non-pregnant subjects. This is thought to be a similar process that is observed in those presenting with diabetic neuropathy.



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Results obtained within this study demonstrated a very low response rate. With the clinician-completed questionnaire 88% reported N/A and the patient-completed 84%. Specificity was 100% for both questionnaires however this was based on just one subject's response on each questionnaire and therefore does not represent any statistical significance. Sensitivities were low with 26.67% and 45.45% for the patient-completed and clinician completed questionnaires respectively although once more numbers were low and of little value.

There is considerable evidence reporting pregnancy being a risk factor in the development of CTS, however with response rates so low this question adds little to the clinical usefulness of this questionnaire and may well be reasonably omitted from the questionnaire pending further analysis.

It may need to be considered whether or not different questionnaires need to be offered for male and female participants. This question can only be answered by female participants and therefore male participants can respond between +10 and -1 yet female participants between +11 and -2. The methodology of this study is limited; it did not note participant's gender therefore there is no way of knowing whether there are differences between the results obtained by male and female participants. The very low response rate for this question may well lead one to believe that this is not a validity issue however it may be that further analysis of the questionnaire needs to be carried out assessing sensitivity and specificity of the CTQ with two separate cohorts of participants defined by their gender.

### **5.6.8 Question 8**

#### **Has it helped the tingling and numbness on wearing a splint on your wrist?**

Splinting is one of the most common conservative managements of CTS. The purpose of splinting is to limit motion of the wrist, when the wrist deviates from a neutral position pressure within the carpal tunnel increases (Keir et al, 2007) therefore with splinting a neutral position is maintained with the hope of reducing pain together with numbness. Page et al (2012) carried out a systematic review exploring the effectiveness of splinting for CTS. Selection criteria included all those randomised and quasi-randomised trials comparing splinting to no treatment (and placebo) and/or any other non-surgical treatment. Studies comparing non-surgical management and surgical management were not included within the study.

The review included results from 19 studies with a total of 1190 participants with CTS. Quality of the studies was questioned with results only demonstrating small improvements gained through the use of wrist splints. In general more research is needed to analyse the potential benefit of using a splint at night in patients suffering with CTS.

Anecdotally wrist splints are often offered, as they are cheap, generally well accepted with little or no potential side effects. The results from the questionnaires indicate that response rates were low with 55% of the clinician-completed questionnaires answering N/A and 53% of the patient-completed.

With this in mind percentage agreements were low with 27% and 25% respectively for clinical and patient-completed questionnaires.

### **5.6.9 Question 9**

#### **Do you have neck pain?**

There are many causes of pins and needles/numbness within the hand: three of the most common would be CTS, Cervical radiculopathy and generalised neuropathy. Diabetic patients were excluded from this study due to that cohort's risk of presenting with a generalised neuropathy. The median nerve originates from medial and lateral cords of the brachial plexus any compression along its route can lead to paraesthesia being felt within the median nerve territory. The double crush syndrome initially reported by Upton and Upton (1973) was based on a hypothesis of the likely association between neck injury and peripheral nerve entrapment syndromes (including CTS) in the upper limb; in essence, when a patient presents with a cervical radiculopathy at the appropriate levels they maybe more susceptible to developing CTS.

In this case it is important to quantify how much each of these separate nerve lesions are indeed contributing to the symptoms with which the patient presents. This is indeed very difficult even with the benefit of NCS and potential Magnetic Resonance Imaging (MRI) of the neck. Investigations are important in such cases but they do not provide direct correlation to symptom severity, for example there are times where results of NCS can come as a surprise as tests may well reveal a moderate or indeed severe compression of a nerve yet the patients symptoms may well be relatively mild. These

## Chapter 5: Item Analysis

investigations are an adjunct to detailed history taking and clinical examination and when all these parts are put together provide the clinician with the necessary information to provide reasonable insight as to how beneficial a surgical procedure may be.

Patient-completed questionnaires demonstrated a sensitivity 63.89% and specificity 47.62% when comparing results of question 9 to NCS (Table 5.2). Clinician-completed questionnaires demonstrated 64% Sensitivity and 40% specificity (Table 5.1). What is important to consider is the context in which this questionnaire will be used. As a screening tool, those with co-existing neck pain are more likely to require confirmatory tests even if presenting with an otherwise classical history of CTS; hence the negatively scored algorithm.

### **5.7 Conclusion**

It is clear that no single question alone that can offer a confident prediction of the results of NCS in patients with suspected CTS. However anecdotally this does not come as a surprise: CTS is defined by a collection of signs and symptoms. Components of the questionnaire can only be considered as a piece of the jigsaw and it is not until numerous pieces are in place that the picture becomes clear. This study aims to provide reasoning behind the selection of these component.

Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

**Chapter 6: Study 2**

**6.1 Target Journal:**

Hand Surgery <http://www.bssh.ac.uk>

**6.2 Title**

**Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample**

**6.3 Abstract**

Nerve conduction studies (NCS) are commonly used in the diagnosis of carpal tunnel syndrome (CTS). A carpal tunnel questionnaire (CTQ) developed by Kamath and Stothard (2003) demonstrated high specificity in predicting positive outcome from NCS (Bridge et al 2011; Edwards and Frampton 2014). This CTQ uses a scoring algorithm the development of which is not clear from the original study. The current study aims to explore this algorithm and through binary logistic regression to explore its validity and if indeed improvements could be made through statistical analysis. Beta values acquired from the regression were analysed and used to form a new algorithm, values were adjusted to two decimal places. The revised algorithm did little to improve the

## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

specificity or the positive predictive value. We suggest therefore that the questionnaire with its original scoring algorithm offers a valid method for predicting the outcome of positive NCS in those patients with suspected CTS.

### **6.4 Introduction**

Carpal Tunnel Syndrome (CTS) accounts for 90% entrapment neuropathy presenting to the Orthopaedic outpatient department (Aroori and Spence, 2008). Reported incidence varies depending on diagnostic criteria however a review by Atroshi et al (1999) explored the prevalence of CTS in a general population. This study, which randomly recruited 3000 subjects, used a diagnostic criterion similar to that, adopted within this current study. Prevalence was reported at 3.8%. Assessment of CTS depends on detailed history taking, clinical examination and nerve conduction studies (NCS). NCS carry a cost and often delay treatment due to additional waiting times. Nerve conduction studies (NCS) have traditionally been viewed as the effective method of assessment for CTS. NCS however have their limitations and there is no single 'gold standard' test in the diagnosis of CTS.

Kamath and Stothard (2003) developed a questionnaire in order to assess the likelihood of a patient presenting with CTS this has been subsequently explored and shown to have high levels of sensitivity when used to predict outcomes of NCS in those with suspected CTS (Bridge, 2011; Edwards and Frampton 2014). The 9-item questionnaire is scored using an algorithm with

## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

items being weighted differently. It is not clear is how this algorithm was originally derived.

The aim of the present study is to explore how the algorithm performs in a newly recruited sample in predicting those patients who subsequently have positive NCS. This in order to see whether indeed the algorithm is valid or whether alternatives derived through statistical analysis could improve the function of the questionnaire and consequently its clinical usefulness.

### **6.5 Research Methods**

#### **6.5.1 Participants**

100 consecutive patients attending the orthopaedic hand clinic with suspected Carpal Tunnel Syndrome (CTS) who met the inclusion criteria were selected for the study. Power was determined through reviewing previous studies including the original study carried out by Levine et al (1993) that explored the use of a questionnaire in the assessment of CTS (n=67). The questionnaire developed and assessed by Kamath and Stothard (2003) included 107 consecutive patients referred into a hand clinic with suspected CTS of whom 74 met the inclusion criteria and 16 were lost to follow up, giving a total sample size in that study of 58.

The cohort of patients for this study was acquired through direct referral from either primary care (usually their own General Practitioner) or through

## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

secondary care via other specialist clinics. These patients were referred with the direct question as to whether they did, or did not have CTS.

### **6.5.2 Inclusion Criteria**

- Those able to offer informed consent
- Patients having been referred with suspected Carpal Tunnel Syndrome
- Patient aged over 18 year (no upper age limit)
- Those patients who are suitable for NCS

### **6.5.3 Exclusion Criteria**

- Peripheral Neuropathy including those diagnosed with Diabetes Mellitus
- Pregnancy
- Patients who have undergone renal transplant
- Previous Carpal Tunnel Decompression on the same side
- Those unable to give informed consent
- Those under the age of 18 years

Diagnosis of CTS in patients with diabetic neuropathy is difficult as the two conditions may affect the median nerve in a similar way. Renal transplant patients (often requiring more involved surgery including the removal of amyloid tissue) and pregnant patients will be also excluded. Carpal tunnel syndrome can recur but it is rare and this may well complicate matters, all patients returning to an orthopaedic clinic with recurrence of symptoms would require NCS.



## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

Prior to the commencement of the clinic notes were triaged and those meeting the inclusion criteria were selected. Those patients deemed appropriate for the study were provided with a patient information leaflet and questionnaire upon their attendance (see Appendix 8). Sufficient time was offered in order for the patients to decide whether or not they wished to participate in the study. It was made specifically clear at this point that being included within the study would have no effect on the outcome of their clinic appointment.

### **6.5.4 Procedure**

Consecutive patients who consented and who met the inclusion criteria underwent subjective/objective examination by the hand specialist. The hand specialist then completed the CTQ and NCS were carried out. CTQ was not analysed until a later date and had no influence over the clinical management of the patient's symptoms.

Criteria for the interpretation of NCS were based on the Kamath and Stothard (2003) study. Criteria for normal values were matched, with terminal latency to abductor pollicis brevis less than 4.0ms and a sensory conduction from digit 2 to wrist greater than 47m/s. Further routine tests included transpalmar recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

### **6.5.5 Materials**

The CTQ consists of nine questions related to the common symptoms reported by patients suffering with CTS. The questions are differentially weighted and a possible scoring range of between -2 and +11 is possible.

### **6.5.6 Data Analysis**

Total CTQ scores for each participant were computed using the original weighting algorithm. Using the original threshold of CTQ weighted score  $>5$ , specificity and sensitivity together with positive and negative predictive values in relation to obtained positive NCS results were compared.

Raw scores on each item of the CTQ for each participant were then entered into a binary logistic model predicting NCS outcome (positive or negative).

Beta coefficients were extracted for each item in the questionnaire and applied as a weighting.

Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

## 6.6 Results

Of the 100 participants included within the study who were tested for CTS, 75 (75%) went on to have positive (abnormal) NCS, 25 (25%) having negative (normal NCS).

Question	Original Algorithm		Beta Scores following Initial Logistic Regression		Beta Scores following Subsequent Logistic Regression	
	Yes	No	Yes	No	Yes	No
Has Pain in your wrist woken you at night?	1	0	0.32	0	0.17	0
Has tingling and numbness in your hand woken you during the night?	1	0	1.07	0	1.20	0
Has tingling and numbness in your hand been more pronounced first thing in the morning?	1	0	1.83	0	1.89	0
Do you have any trick movements to make the tingling, numbness go from your hands?	1	0	1.14	0	0.94	0
Do you have tingling of numbness in your little finger at any time?	0	3	0	2.46	0	2.24
Has tingling and numbness presented when you were reading a newspaper, steering the car or knitting?	1	0	1.16	0	1.32	0
If applicable, has the tingling and numbness in your hand been severe during pregnancy?	1	-1	20.08	0	-	-
Has it helped the tingling and numbness on wearing a splint on your wrist?	2	0	1.51	0	1.80	0
Do you have any neck pain?	-1	0	-0.23	0	-0.10	0

Table 6.1 Beta values obtained through regression modelling

Table 6.1 demonstrates the original scoring system algorithm with the adjusted values gained through carrying out the binary logistic regression. Initial beta values demonstrated an outlier in question 7 related to pregnancy with the beta score being calculated at 20.08; this was due to very low response rate.

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Subsequent analysis was carried out removing results from question 7 from the equation. Using the beta values, specificity and sensitivity together with negative and positive predictive, values were re-evaluated using the cut-off scores between 5-6 (Table 8.2).

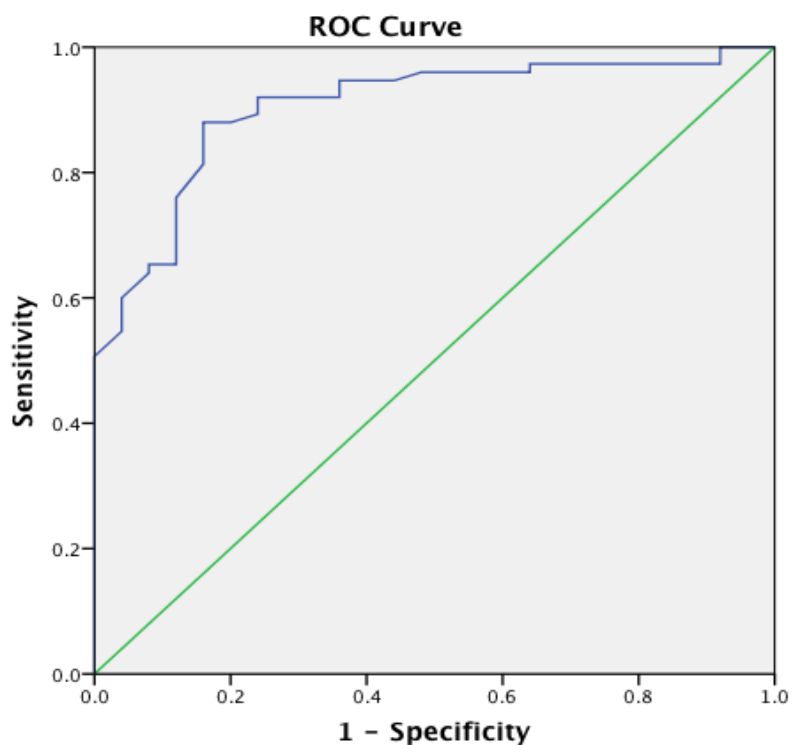
Cut-off score	Specificity (%)	Sensitivity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
5.0	88.00	84.00	94.29	70.00
5.1	88.00	84.00	94.29	70.00
5.2	88.00	84.00	94.29	70.00
5.3	86.67	84.00	94.20	67.74
5.4	86.67	84.00	94.20	67.74
5.5	81.33	84.00	93.85	60.00
5.6	76.00	88.00	95.00	55.00
5.7	76.00	88.00	95.00	55.00
5.8	74.67	88.00	94.92	53.66
5.9	70.67	88.00	94.64	50.00
6.0	70.67	88.00	94.64	50.00

Table 6.2 Sensitivity/specificity, positive predictive value and negative predictive values using threshold score ranging from 5-6 with the new algorithm derived from logistic regression

Cut-off score	Specificity (%)	Sensitivity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
≥5	80	92	96.77	60.53
≥6	70.67	96	98.15	52.17

Table 6.3 Sensitivity/specificity, positive predictive value and negative predictive values using threshold score of ≥5 and ≥6 with the original scoring algorithm using the same cohort

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Diagonal segments are produced by ties.

**Figure 6.1** ROC curve demonstrating Sensitivity and Specificity of the CTQ using the revised algorithm

**Area Under the Curve**

Test Result Variable(s): CTQ\_Score

<i>Area</i>	<i>Std. Error<sup>a</sup></i>	<i>Asymptotic Sig.<sup>b</sup></i>	<i>Asymptotic 95% Confidence Interval</i>	
			<i>Lower Bound</i>	<i>Upper Bound</i>
<b>.905</b>	<b>.032</b>	<b>.000</b>	<b>.841</b>	<b>.968</b>

The test result variable(s): CTQ\_Score has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

**Table 6.4** Represents the area under the curve acquired from the ROC analysis.

Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

Observed		Predicted		
		NCS		Percentage Correct
		Negative	Positive	
NCS	Negative	0	25	0
	Positive	0	75	100
	Overall Percentage			75

Table 6.5 Demonstrates the predictive capability without using the CTQ assuming all patients referred into the service will present with positive NCS

Table 6.5 reflects the incidence of positive and negative nerve conduction studies within the cohort of patients (n=100). Prior to applying the model, if positive NCS were predicted on all patients there would be an overall percentage agreement of 75. 100% of those presenting with positive NCS would be predicted correctly yet 0% with negative NCS predicted correctly.

Observed		Predicted		
		NCS		Percentage Correct
		Negative	Positive	
NCS	Negative	17	8	68
	Positive	4	71	94.7
	Overall Percentage			88

Table 6.6 Demonstrates the predictive capability of the CTQ following regression modelling

Table 6.6 reflects the effect of applying the regression model on predicted outcomes of NCS. This demonstrates that the model can predict 68% of those who presented with negative NCS and 94.7% of those who went on to have positive NCS. The overall prediction percentage correctly predicted (as positive or negative) increased from 75% to 88% after the model was applied.

## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

### **6.7 Discussion**

In a study exploring the scoring algorithm of the Carpal Tunnel Questionnaire (CTQ) in 100 participants binary logistic regression was applied to ascertain what effect this may have upon sensitivity, specificity and positive/negative predictive validity coefficients. When considering the CTQ as a screening tool for NCS in those with suspected CTS, binary logistic modelling did not improve the effectiveness of the original questionnaire algorithm derived by Kamath and Stothard (2003).

Clarification of the role of this questionnaire needs to be explored in order to interpret the significance of the obtained results. Through analysing the scores of the questionnaire against NCS, the questionnaire can be deemed as a screening tool: those scoring above a predetermined threshold are so likely to present with positive NCS that the studies (and consequent costs) could potentially be avoided.

#### **6.7.1 Sensitivity**

Sensitivity reflects the percentage of those who scored above the questionnaire threshold as a fraction of the total number who subsequently had positive NCS (true positives).

An increase in the threshold score increases both the sensitivity and positive predictive value. In clinical terms all those scoring above the predetermined

## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

threshold would potentially avoid NCS. There are two important points to be considered when reflecting on 'false positive' questionnaire scores: firstly it is known that there is a false negative rate for NCS and furthermore decision to treat will not be based upon the results of this questionnaire alone, but upon the subjective and objective examination carried out by the hand specialist and if in doubt patients could still be referred for further tests.

### **6.7.2 Specificity**

Specificity reflects the percentage of those who scored below the questionnaire threshold as a fraction of all those who subsequently had negative NCS (true negatives).

As threshold scores increase specificity reduces as the negative predictive value falls. This has a few potential connotations; firstly if this tool were to be used within a clinical environment all those scoring below the threshold would proceed to NCS. Those still presenting with CTS despite scoring below the scoring threshold would be captured and not inappropriately discharged. Our primary aim when considering a screening tool is that it is 'clinically safe', so the fact that specificity falls has no impact upon the safety of the tool. However a fall in specificity leads to more patients being referred for NCS reducing the potential resource-saving impact of the screening tool.

ROC analysis has revealed significantly positive results for the questionnaire when considering its use as a screening tool for NCS using the revised



## Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

algorithm. Figure 8.1 demonstrates the ROC curve with the green line depicting the null hypothesis of zero sensitivity/specificity. The blue line depicts the ROC curve. Each point along the curve represents the sensitivity/specificity corresponding to a particular questionnaire score. When analysing ROC the area under the curve is a measure of how well the questionnaire can distinguish between the two diagnostic groups (positive NCS/negative NCS). Table 8.4 demonstrates the area under the curve rated as 0.905 using a confidence interval of 95% this would indicate the CTQ to be an excellent predictive test for NCS in those presenting with CTS.

The original scoring is simple: easy to be carried out in a clinic setting and produces a high level of specificity. The revised scoring algorithm did not improve the function of the CTQ. The revised algorithm is far more complex and would likely need some form of software implementation in order to input the questionnaire scores. This would be more time consuming and present with some considerable logistical considerations for negligible gain in diagnostic accuracy.

### **6.8 Conclusion**

Through binary logistic regression a revised algorithm has been derived, although this ultimately has not improved the function of the questionnaire. This study adds further validity for the use of the CTQ as developed by Kamath and Stothard (2003) as a screening tool for patients with suspected CTS.

Chapter 6: Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample

Through statistical analysis of this algorithm it has been demonstrated that the original scoring system is effective, achieving a high level of sensitivity with significant potential for both cost-saving and shortening waiting lists without compromising patient care and safety.

Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

## **Chapter 7: Study 3**

### **7.1 Target Journal:**

Hand Surgery <http://www.bssh.ac.uk>

### **7.2 Title**

Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Complete Version.

### **7.3 Abstract**

Carpal Tunnel Syndrome (CTS) accounts for 90% of entrapment neuropathy presenting to the orthopaedic outpatient department (Aroori and Spence, 2008). Reported incidence varies depending on diagnostic criteria however a review by Atroshi et al (1999) explored the prevalence of CTS in a general population. Debate remains as to how best assess and diagnose this condition. Nerve conduction studies (NCS) are an effective way of objectively measuring the presence of CTS yet they are often costly and lead to an increase in waiting times; they are also not always necessary. Kamath and Stothard (2003) devised the Carpal Tunnel Questionnaire (CTQ) and went on to compare sensitivities between the CTQ and NCS for the diagnosis of CTS. The CTQ has been subsequently explored and shown to have high levels

## Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

of sensitivity when used to predict outcomes of NCS in those with suspected CTS (Bridge, 2011; Edwards and Frampton 2014). This questionnaire however has only been assessed when being completed by a hand specialist and not used as a patient-completed questionnaire, thus limiting its potential application within primary care. This study has the aim of replicating these previous studies in an extended population to assess the sensitivity and specificity of the CTQ in predicting outcomes of NCS with the addition of exploring whether the CTQ could reliably be used as a patient-completed version.

Results of the clinician-completed version demonstrate high levels of sensitivity (92%) using the original devised cut-off score of  $\geq 5$  and increased sensitivity (96%) when the threshold score was raised to  $\geq 6$ . If incorporated into clinical practice using this cohort of patients and the original scoring threshold 62% of patients could have potentially avoided NCS.

The patient-completed version demonstrated reasonable levels of sensitivity (72%) using the original devised cut-off score of  $\geq 5$  and increased sensitivity (92%) when the threshold score was raised to  $\geq 6$ . Results demonstrate that the CTQ could potentially be used as a patient-complete questionnaire (using a cut-off score  $\geq 6$ ) in primary care. Economic evaluation of the potential impact of using this tool within the clinical setting will be explored in a further study.

#### **7.4 Introduction**

Carpal Tunnel Syndrome (CTS) is the most common entrapment neuropathy presenting to the Orthopaedic outpatient department affecting between 5-16% of the population (Priganc and Henry, 2003). Assessment of CTS depends on detailed history taking, clinical examination and nerve conduction studies (NCS). NCS have traditionally been viewed as the most effective method for the assessment of CTS; however, they carry a cost and often delay treatment due to additional waiting times. In any case, NCS however have limitations (such as false positive and false negative results) and so need to be interpreted alongside other clinical data; there is no single 'gold standard' test in the diagnosis of CTS.

A questionnaire developed by Kamath and Stothard (2003) based on original work by Levine et al (1993) has been shown to demonstrate a high sensitivity when compared to positive results from NCS (Bridge et al 2011; Edwards Frampton 2014) and outcome from carpal tunnel decompression surgery (Kamath and Stothard, 2003). The 9-item questionnaire is scored using an algorithm with items being weighted differently. This questionnaire however has only been assessed when being completed by a hand specialist and not used as a patient-completed questionnaire, thus limiting its potential application within primary care settings as a component of screening for CTS.

## Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

The aim of this study is to explore the positive and negative predictive validity of a clinician and patient-completed version of the CTQ against the outcome of subsequent NCS.

### **7.5 Research Methods**

#### **7.5.1 Participants**

100 consecutive patients attending an orthopaedic hand clinic with suspected Carpal Tunnel Syndrome (CTS) who met the inclusion criteria were selected for the study.

Power was determined through reviewing previous studies including the original study carried out by Levine et al (1993) exploring the use of a questionnaire in the assessment of CTS (n=67). The original questionnaire developed and evaluated by Kamath and Stothard (2003) included 107 consecutive patients referred into a hand clinic with suspected CTS, of whom 74 met the inclusion criteria and 16 were lost to follow up, giving a total sample size in that study of 58.

The cohort of participants for the current study was acquired through direct referral from either primary care (usually their own General Practitioner) or through secondary care via other specialist clinics. These patients were referred with the direct question as to whether they did, or did not have CTS.

### **7.5.2 Inclusion Criteria**

- Those able to offer informed consent
- Patients having been referred with suspected Carpal Tunnel Syndrome
- Patient aged over 18 year (no upper age limit)
- Those patients who are suitable for NCS

### **7.5.3 Exclusion Criteria**

- Peripheral Neuropathy including those diagnosed with Diabetes Mellitus
- Pregnancy
- Patients who have undergone renal transplant
- Previous Carpal Tunnel Decompression on the same side
- Those unable to give informed consent
- Those under the age of 18 years

Diagnosis of CTS in patients with diabetic neuropathy is difficult as the two conditions may affect the median nerve in a similar way. Renal transplant patients (often requiring more involved surgery including the removal of amyloid tissue) and pregnant patients were also excluded. Carpal tunnel syndrome can recur but it is rare and this may well complicate matters; in any case all patients returning to an orthopaedic clinic with recurrence of symptoms would normally require repeat NCS.

Prior to the commencement of the clinic notes were reviewed and those meeting the inclusion criteria were selected. Those patients deemed

## Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

appropriate for the study were provided with a patient information leaflet and questionnaire. It was made specifically clear at this point that their decision to consent to the study would have no bearing on the outcome of their clinic appointment.

### **7.5.4 Procedure**

Patients meeting the inclusion criteria were provided with the patient information leaflet and questionnaire upon their attendance. Sufficient time was offered in order for the patients to decide whether or not they wished to participate in the study. It was made specifically clear at this point that being included within the study would have no effect on the outcome of their clinic appointment. Sufficient time was determined by the patient with them being offered flexible appointment times with assurances that they would not miss their appointment. If more time was needed to consider the implications further appointments were offered on another day at the patient's convenience.

Patient-completed questionnaires were posted into a sealed box and were not seen by the hand specialist. Participants then underwent a standard clinical examination and completion of the CTQ administered by the hand specialist. NCS were carried out on all patients. Questionnaire responses were not analysed until a later date and had no influence over the clinical management of the patient.

Criteria for the interpretation of NCS were based on the Kamath and Stothard (2003) study. Criteria for normal values were matched, with terminal latency to



## Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

abductor pollicis brevis less than 4.0ms and a sensory conduction from digit 2 to wrist greater than 47m/s. Further routine tests included transpalmar recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

Completed questionnaires were posted into a sealed box and were not seen by the hand specialist. Participants then underwent a standard clinical examination and completion of the CTQ by the hand specialist administered. NCS were carried out on all patients. Questionnaire responses were not analysed until a later date and had no influence over the clinical management of the patient.

Criteria for the interpretation of NCS were based on the Kamath and Stothard (2003) study. Criteria for normal values were matched, with terminal latency to abductor pollicis brevis less than 4.0ms and a sensory conduction from digit 2 to wrist greater than 47m/s. Further routine tests included transpalmar recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

### **7.5.5 Materials**

The CTQ consists of nine questions related to the common symptoms reported by patients suffering with CTS. The questions are differentially weighted giving a possible scoring range of between -2 and +11.

### **7.5.6 Data Analysis**

Total clinician completed and patient-completed CTQ scores for each participant was computed using the original weighting algorithm described by Kamath and Stothard (2003). Using the original threshold of CTQ weighted score  $\geq 5$ , specificity and sensitivity together with positive and negative predictive values in relation to obtained positive NCS results were derived. Based on the results of Edwards and Frampton (2014), the effect of raising the threshold to  $\geq 6$  were analysed in the same way. Receiver operator characteristic (ROC) analysis was used to derive a single optimum cut off questionnaire score, in order to establish the positive and negative predictive validity of the patient-completed questionnaire in relation to the outcome of subsequent NCS.

## **7.6 Results**

### **7.6.1 Clinician-Completed Version**

Clinician-completed CTQ weight total scores were calculated for 100 patients, of whom 75 (75%) subsequently tested positive for CTS on NCS, 25 (25%) tested negative. Inspection of the results (Figure 6.1) suggests that all those patients scoring 7 or over ( $n=31$ ) on the questionnaire had positive NCS for

Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

CTS. Of those who scored  $\geq 6$  (n=54) only one patient subsequently obtained negative NCS.

Using the original Kamath and Stothard (2003) cut-off score of  $\geq 5$ , 60% (n=60) scored  $\geq 5$  with seven of those (11.7%) with negative NCS and 53 (88.3%) had positive NCS. Table 6.1 records the sensitivity, specificity and positive/negative predictive validity of these thresholds

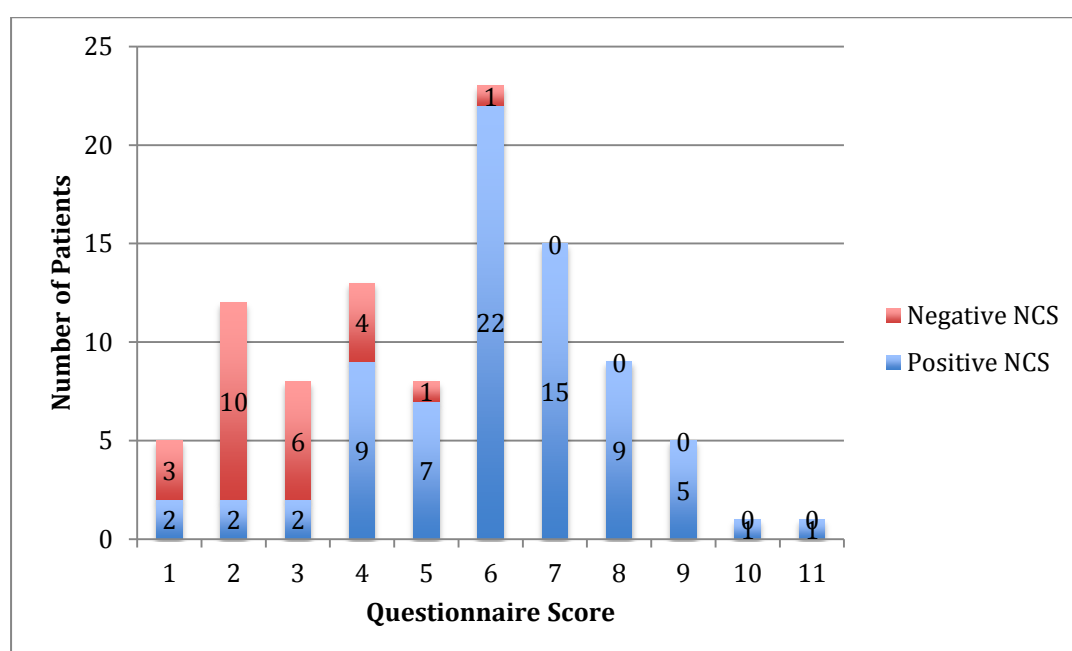


Figure 7.1 The distribution of weighted total clinician-completed Carpal Tunnel Questionnaire scores obtained.

Cut-off score	Specificity	Sensitivity	Positive Predictive Value	Negative Predictive Value	False Positive Rate
5 or over	80%	92%	96.77%	60.53%	2%(n=2)
6 or over	70.67%	96%	98.15%	52.17%	1%(n=1)
7 or over	41.33%	100%	100%	36.23%	0%

Table 7.1 Sensitivity/Specificity and Positive/Negative Predictive Values of the CTQ relative to results of NCS using  $\geq 5, \geq 6$  and  $\geq 7$  as cut-off scores

Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

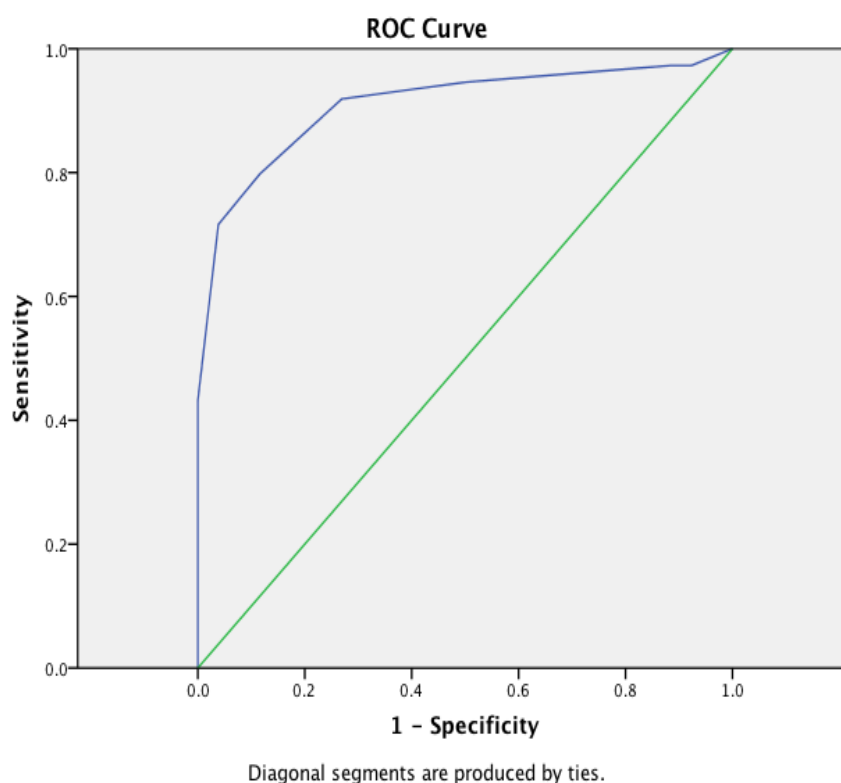


Figure 7.2 Receiver Operating Characteristic (ROC) analysis of alternative cut-off scores on hand clinician-completed Carpel Tunnel Questionnaire for predicting outcome of nerve conduction studies.

ROC analysis demonstrated significantly positive results for the questionnaire when considering its use as a screening tool for NCS.

### **7.6.2 Patient-Completed Version**

Patient-completed CTQ weighted total scores were calculated for the same 100 patients, of who 75 (75%) subsequently tested positive for CTS on NCS, 25 (25%) tested negative. Inspection of the results (Figure 7.3) suggests that all but one of those patients scoring 7 or over (n=26) on the questionnaire had

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positive tests for CTS. Of those who scored  $\geq 6$  (n=43) only two patients subsequently obtained negative NCS.

Using the original Kamath and Stothard (2003) cut-off score of  $\geq 5$ , 60% (n=60) scored  $\geq 5$  with seven of those (11.7%) negative NCS and 53 (88.3%) had positive NCS. Table 7.1 records the sensitivity, specificity and positive/negative predictive validity of these thresholds.

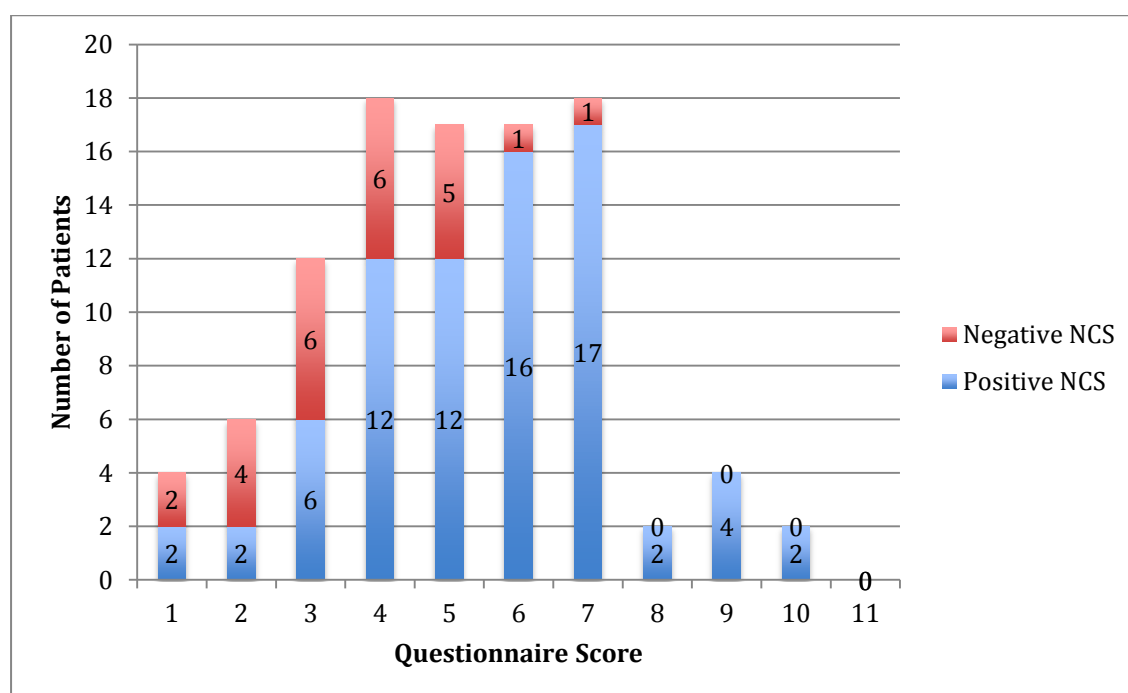
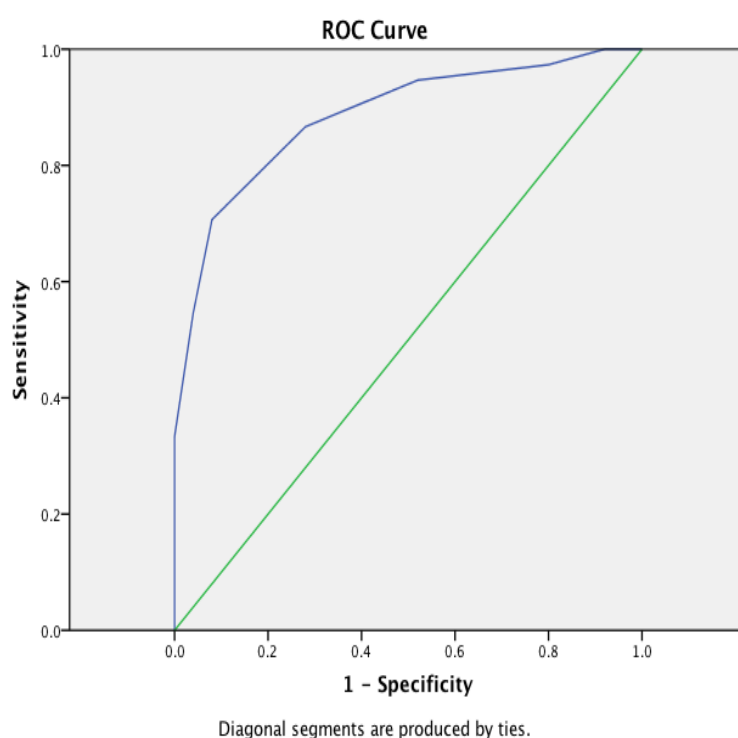


Figure 7.3 Distribution of weighted total Patient-completed Carpal Tunnel Questionnaire scores obtained.

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Cut-off score	Specificity	Sensitivity	Positive Predictive Value	Negative Predictive Value	False Positive Results
5 or above	70.67%	72%	88.33%	45.00%	7%(n=7)
6 or above	54.67%	92%	95.35%	40.35%	2%(n=2)
7 or above	33.33%	96%	96.15%	32.43%	1%(n=1)

**Table 7.2:** Sensitivity/Specificity and Positive/Negative Predictive Values of the Patient-complete CTQ relative to results of NCS using  $\geq 5$ ,  $\geq 6$  and  $\geq 7$  as cut-off scores



**Figure 7.4** ROC analysis of alternative cut-off scores Patient-completed version of the CTQ

ROC analysis demonstrated significantly positive results for the questionnaire when considering its use as a screening tool for NCS. Figure 6.2 shows the ROC curve. The area under the curve was calculated depicting how well the questionnaire can distinguish between the two diagnostic groups (positive NCS/negative NCS) based on a range of possible threshold scores. The total

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area under the curve (0.885, 95% confidence interval 0.816 to 0.953) indicates that the predictive validity of the questionnaire is statistically significant ( $p < 0.001$ ).

### **7.7 Discussion**

In a study of the clinician-complete and patient-completed versions of the Carpal Tunnel Questionnaire (CTQ) in 100 participants, sensitivity, specificity and positive/negative predictive validity coefficients were derived for three cut-off thresholds for weighted totals, based on Kamath and Stothard (2003). ROC analyses confirmed that all reviewed potential cut-off thresholds (5-7) were significantly better than chance at predicting the outcome of nerve conduction studies (NCS). Inspection of the ROC curve indicates the optimum balance between sensitivity and specificity, such that false negatives (those who are below threshold for the screening questionnaire but subsequently test positive on NCS) are equally important as false positives (those above the threshold for the screening questionnaire who subsequently test negative on NCS).

In clinical practice, the relative balance between false positives and false negatives depends on the consequences of subsequent investigations and ultimately surgical intervention. If a patient were to score below the questionnaire threshold they will go on to have confirmatory NCS and therefore the false negative rate is not of a clinical concern. The sensitivity/true positive rate is of significance; when relying on the questionnaire as a potential screening tool it is crucial that those scoring above the threshold would

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definitely have subsequent positive NCS (if questionnaire results are being used to omit these studies). The results of the current study suggest that false positive rates vary depending upon the threshold score. Rates of 2, 1 and 0% were obtained for the clinician-complete version and 7, 2, 1% for the patient-completed version with respective cut-off scores of 5, 6 and 7. Sensitivity increased as cut off scores were raised as depicted in tables 7.1 and 7.2. Bridges et al (2011) demonstrated a sensitivity of 87% when using this questionnaire (cut-off  $\geq 6$ ) in predicting the outcome of NCS in a cohort of patients with suspected CTS. The cohort of patient in this current study demonstrated a sensitivity of 96% (clinician-completed version) and 92% (patient-completed version) using the same cut-off ( $\geq 6$ ).

The participants in this study are already at high risk of presenting with positive NCS as they have all been referred into an orthopaedic clinic having been examined usually in a primary care setting and the suspicion of CTS has been raised. This is reflected in the high positive percentage rate (75%) of the results of the NCS. This will have implications when considering the optimum cut-off point and results of this study would not be transferable to a general population.

The results suggest that if this screening tool was implemented into clinical practice 54% (using a threshold score of  $\geq 6$ ) of those referred with suspected CTS could have avoided onward referral for NCS using the clinician-completed version and 43% for the patient-completed version. Economic evaluation of this will be explored in future studies.



## Chapter 7: Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a Clinician and Patient Completed Version.

Whilst the results of this study highlight higher sensitivity rates at all three of the evaluated threshold scores using the clinician-completed questionnaire we need to consider why one may wish to use the Patient-completed version over the clinician-completed.

An important point to stress is that sensitivity rates using the patient-completed versions were very high suggesting a clinical value in its use as a screening tool. The benefit of being able to use this as a patient-completed questionnaire is the improved flexibility, it would allow for its use within primary care. The questionnaire is not designed to be a stand alone tool in the assessment of CTS it does however add another string to the bow for general practitioners and physiotherapists as an adjunct to their assessment.

If the CTQ was used within primary care, it could be completed prior to referring into specialist services. This would offer potential benefits to both patients and the orthopaedic department. Firstly, time would be saved during the clinic appointment, as the questionnaire would have already been completed. If NCS was offered in house on the day, patients scoring over the threshold could be triaged into short appointment slots, as NCS are not likely to be necessary. This would have an impact upon waiting lists improving the efficiency of the service (the impact of this will be explored further within the economic evaluation). In some circumstance NCS may well be requested at the point of triaging, as hand specialists may well want NCS to be carried out prior to their appointment. Having questionnaire scores on the referral letter will

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provide the hand specialist further information to indicate which patients should or should not require NCS prior to considering a CTD. The impact of this would potentially reduce the number of referrals for NCS, reducing waiting times, saving money and reducing the potential of the patient being exposed to potentially uncomfortable and unnecessary investigations.

### **7.8 Conclusion**

Sensitivities obtained within this study for both the patient and clinician completed version of the CTQ strongly support its role as a screening tool for NCS in those patients with suspected CTS. This study increases the flexibility of the tool, providing validity for its use as a patient-completed questionnaire within primary care.

The results obtained from the ROC analysis demonstrate an excellent diagnostic accuracy for both versions furthering the support for the usefulness and practical value of the questionnaire. The potential use of this tool has only been tested on a cohort of patients who have been deemed as high risk of having CTS having already received a preliminary diagnosis of CTS by their GP or another medical practitioner. The generic use of this tool on a low risk population (such as patients presenting with a wide range of functional hand problems in primary care) cannot be judged through the data that have been obtained in this study.

## **Chapter 8: Study 4**

### **8.1 Target Journal:**

Journal of Hand Therapy <http://www.jhandtherapy.org>

### **8.2 Title**

**Exploring the potential for using a Carpal Tunnel Questionnaire as a Patient-Reported Measure – An Inter-rater Reliability Study**

### **8.3 Abstract**

The Carpal Tunnel Questionnaire (CTQ) was originally developed by Kamath and Stothard (2003) with the aim of being used as an adjunct to help in the diagnosis of carpal tunnel syndrome (CTS). This 9-item questionnaire is easy to implement into current practice and has been shown to have good correlation to both improvements gained from surgery (Kamath and Stothard 2003) and nerve conduction studies (Bridge, 2011; Edwards and Frampton, 2014). These studies have however relied upon a hand specialist completing the questionnaire. The aim of this study is to establish whether the CTQ could be used as a self-administered questionnaire to be completed by the patient. 100 patients having been referred into a hand clinic with suspected CTS patients completed the CTQ prior to their clinic appointment. A hand specialist

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who was blind to the results of the patient-completed questionnaire completed the questionnaire on the same cohort of patients with the patient in the clinic room prior to assessment and NCS. Results of the two questionnaires were carried out at a later date exploring the inter-rater reliability using Pearson's product-moment correlation. Results demonstrated a high degree of correlation between raters with Pearson's  $r = 0.81$ . The results obtained support the potential use of the CTQ as patient-reported questionnaire in patients who have a high suspicion of CTS.

### **8.4 Introduction**

The majority of measurements that we obtain involve a degree of measurement error; judgements made by humans are particularly susceptible to this problem. Measurement error inevitably significantly affects statistical analysis and subsequently interpretation that is why it is important to assess such error by calculating reliability (Shrout and Fleiss, 1979). Measurement error prevents us from being able to read a subject's true score exactly. There are many factors that can influence measurement error including issues with internal consistency (variance of a measurement tool when used on a subject over time), and the inter-rater reliability (IRR). Within this analysis we explore the IRR between clinician- and patient-rated questionnaires. The aim of establishing the IRR will be to attempt to demonstrate a degree of consistency among scores provided by multiple coders (Hallgren, 2012).

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Total scores were analysed comparing the results obtained between the patient-completed and clinician completed CTQ. Individual and mean scores were analysed together with Pearson's Correlation Coefficient using SPSS (version 22).

### **8.5 Research Methods**

100 consecutive patients attending the orthopaedic hand clinic with suspected Carpal Tunnel Syndrome (CTS) who met the inclusion criteria were selected for the study. Power was determined through reviewing previous studies including the original study carried out by Levine et al (1993) exploring the use of a questionnaire in the assessment of CTS (n=67). The questionnaire developed and evaluated by Kamath and Stothard (2003) included 107 consecutive patients referred into a hand clinic with suspected CTS of whom 74 met the inclusion criteria and 16 were lost to follow up giving a total sample size of 58.

The cohort of patients for this study was acquired through direct referral from either primary care (usually their own General Practitioner) or through secondary care via other specialist clinics. These patients were referred with the direct question as to whether they did, or did not have CTS.

#### **8.5.1 Inclusion Criteria**

- Those able to offer informed consent
- Patients having been referred with suspected Carpal Tunnel Syndrome

## Chapter 8: Exploring the potential for using a Carpal Tunnel Questionnaire as a self-reported measure – An Inter-rater Reliability Study

- Patient aged over 18 year (no upper age limit)
- Those patients who are suitable for NCS

### 8.5.2 Exclusion Criteria

- Peripheral Neuropathy including those diagnosed with Diabetes Mellitus
- Pregnancy
- Patients who have undergone renal transplant
- Previous Carpal Tunnel Decompression on the same side
- Those unable to give informed consent
- Those under the age of 18 years

Diagnosis of CTS in patients with diabetic neuropathy is difficult as the two conditions may affect the median nerve in a similar way. Renal transplant patients (often requiring more involved surgery including the removal of amyloid tissue) and pregnant patients will be also excluded. Carpal tunnel syndrome can recur but it is rare and this may well complicate matters, all patients returning to an orthopaedic clinic with recurrence of symptoms would require NCS.

Prior to the commencement of the clinic notes were triaged and those meeting the inclusion criteria were selected. Those patients deemed appropriate for the study were provided with the patient information leaflet and questionnaire upon their attendance. Sufficient time was offered in order for the patients to decide whether or not they wished to participate in the study. It was made specifically

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clear at this point that being included within the study would have no effect on the outcome of their clinic appointment.

### **8.5.3 Procedure**

Once the patient had agreed to participate and had been consented (by the lead researcher) they were coded and asked to complete the questionnaire. This questionnaire, once completed was put into a box file with the lead researcher being kept blind to the results.

Detailed subjective history was taken. This involved questioning regarding duration and nature of the symptoms; aggravating and relieving factors; past medical history; medication and social history. Physical examination was carried out. Sensory and motor assessment together with brief examination of the cervical spine was completed.

Following the examination but prior to the neurophysiological testing the clinician-rated questionnaire was completed with the hand specialist asking the questions and documenting the responses in the questionnaire. The questionnaire was coded as per the patient-completed questionnaire and entered into a separate box file to be scored at a later date.

Criteria for the interpretation of NCS were based on the Kamath and Stothard (2003) study. Criteria for normal values were matched, with terminal latency to abductor pollicis brevis less than 4.0ms and a sensory conduction from digit 2 to wrist greater than 47m/s. Further routine tests included transpalmar

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recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

Clinical decision-making was made entirely with the benefit of the history; examination and NCS. Questionnaires were not scored until the completion of the study and therefore had no bearing upon clinic outcome.

### 8.5.4 Materials

The CTQ consists of nine questions related to the common symptoms reported by patients suffering with CTS. The questions are differentially weighted giving a possible scoring range of between -2 and +11.

## 8.6 Results

### 8.6.1 Scatter Plot Distribution

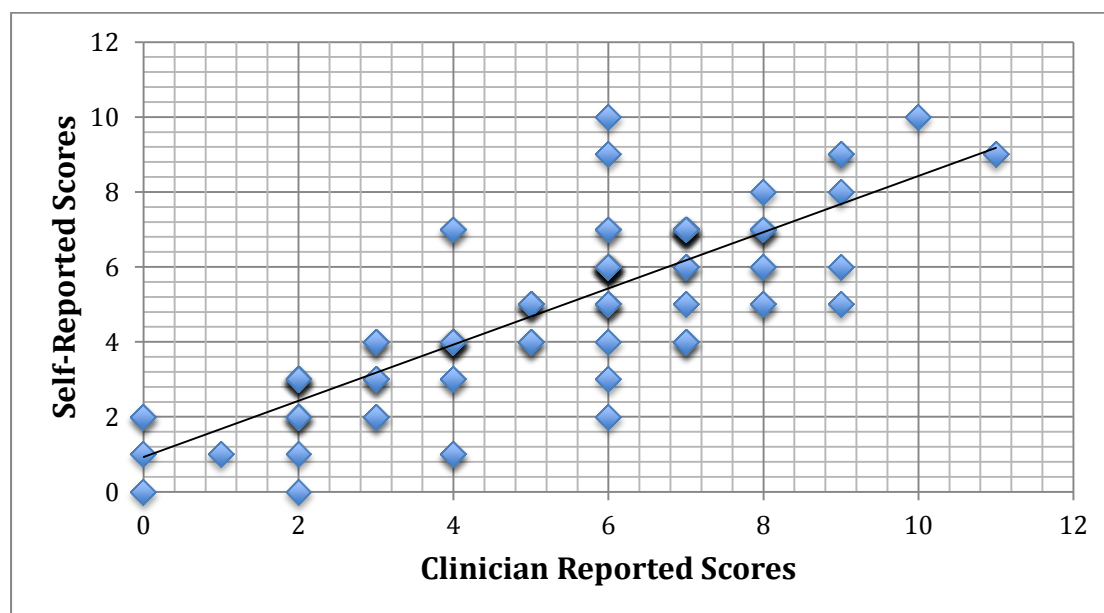


Figure 8.1 Scatter plot depicting the correlation between patient-reported scores and clinician-reported scores from the CTQ questionnaire.



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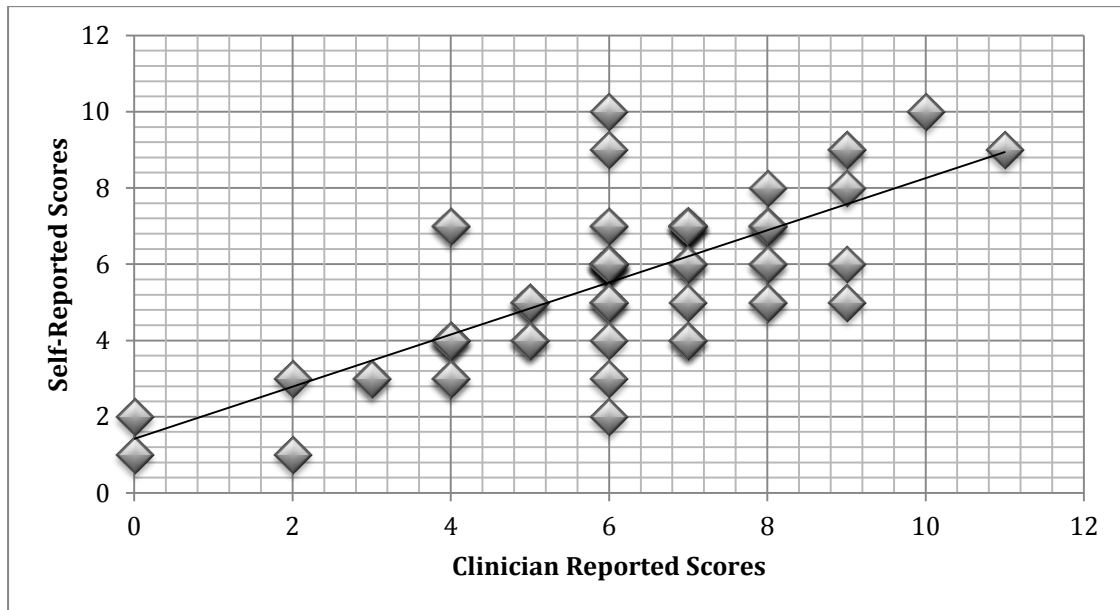


Figure 8.2 Scatter plot depicting the correlation between patient-reported scores and clinician-reported scores from the CTQ questionnaire who went on to have positive NCS

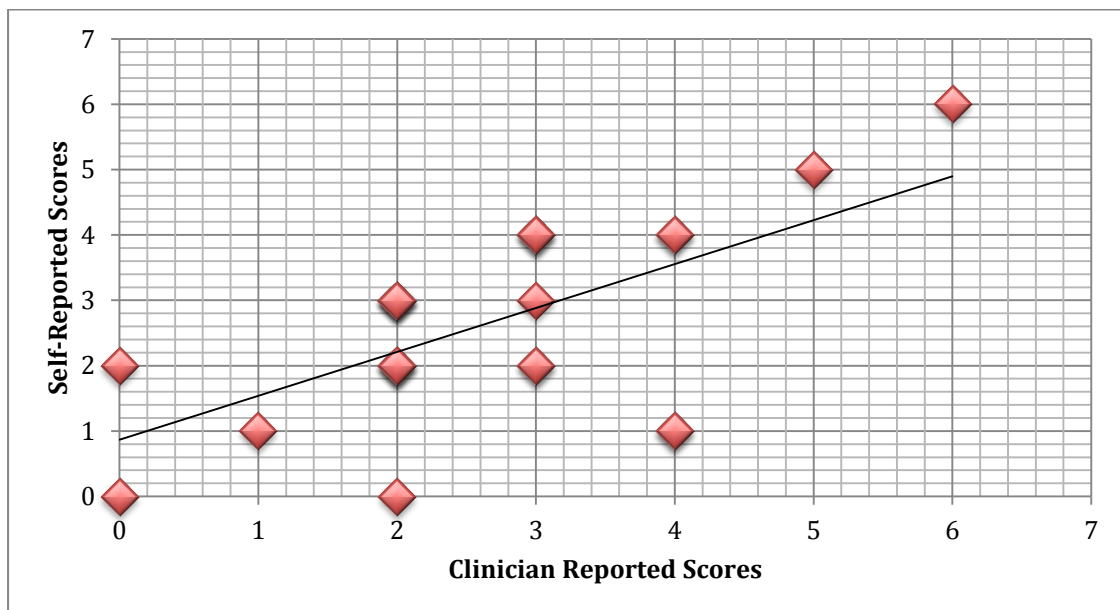


Figure 8.3 Scatter plot depicting the correlation between patient-reported scores and clinician-reported scores from the CTQ questionnaire who went on to have negative NCS

### **8.6.2 Pearson’s Product Moment Correlation Coefficient**

In order to establish the strength of correlation in particular the linear relationship between the two-raters; in this case the hand specialist and the patient, Pearson’s product-moment correlation coefficient was calculated as 0.81 ( $p < 0.001$ ), suggesting a statistically high level of agreement between clinician and patient-completed versions of the CTQ.

### **8.6.3 Mean Scores**

Total mean scores were calculated and depicted in the table below.

	Mean	Std. Deviation	Number of Subjects
Clinician Completed	5.2400	2.42928	100
Patient-Completed	4.8500	2.22645	100

Table 8.1 Mean Total Scores of the CTQ

## **8.7 Discussion**

In a study of the inter-rater reliability (IRR) of the Carpal Tunnel Questionnaire (CTQ) mean scores, Pearson’s product moment correlation coefficient was derived using the algorithm based on Kamath and Stothard (2003). Mean scores demonstrate that the patient-completed CTQ scores were lower than the clinician-completed demonstrating that the patient-reported questionnaires are scored a little more conservatively than those completed by the hand

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specialist. This is reassuring when considering the use of the CTQ as a screening tool, while higher scores may well lead to fewer subjects needing to go for further testing (NCS) lower scores will capture more patients below the threshold and likely provide a higher sensitivity at the potential expense of a reduced specificity at any given cut-off score. The clinician may well have a lower threshold to answer positively on the questionnaire based on past experience and expanding upon the questions asked. For example, with the questionnaire being delivered by the hand specialist he/she would have the opportunity to expand upon the question and potentially re-word it if the patient needed some clarification.

Figure 8.1 demonstrates a clear linear relationship between the CTQ scores obtained from the patient-reported (y-axis) and clinician-reported (x-axis) further analysis of this relationship was carried out using Pearson's product moment correlation coefficient. The resultant score of 0.8 represents very high correlation between the raters when using the CTQ. Figure 9.2 demonstrates those patients who went on to have positive NCS and Figure 9.3 negative NCS.

Two-way measures were analysed in order to assess the level of error due to both rater and subject. What were evaluated were the consistent differences between raters,

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What these results suggest is that 89% of the observed variance is due to true score variance with 11% due to error variance or variation in scoring between raters.

Results demonstrate that scores obtained between the patient and clinician completed CTQ show a high degree of consistency. What has already been established is that the CTQ provides high sensitivity when used as a screening tool for onward referral to NCS (Bridge 2011; Edwards and Frampton 2014). Previous studies using the CTQ (Kamath and Stothard 2003; Bridge 2011; Edwards and Frampton 2014) have used clinicians to complete the questionnaire; if this could reliably be completed by the patient then this could be carried out prior to the orthopaedic appointment and appropriate appointments be offered with or without NCS. This would potentially streamline the service reducing the number of face-to-face contacts needed which would have benefits in reducing unnecessary appointments, reducing pressure on orthopaedic departments and improving the patient journey.

The potential implication of this study will vary depending upon the availability of NCS. When NCS is not available within the orthopaedic department patients would be referred elsewhere for confirmatory studies, involving inevitable waits, and the patient will have to return to the referring clinician to discuss these results before a surgical decision can be made. There are times when this process is unavoidable for example when there is a suspicion of other contributing factors to the symptoms such as a generalised neuropathy of whatever aetiology or when the symptoms are less than classical. However

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there is a 'classic' cohort of patients where these tests may not be necessary, if we can predetermine those likely not to need NCS then a more direct pathway can potentially be established.

When considering this cohort of patients they have all been seen either by a GP or another member of the orthopaedic team and the suspicion of CTS has been raised therefore these subjects are already at a high risk of having CTS. 75% of the subjects did have positive neurophysiological evidence of CTS; any inferences gained from this study regarding the CTQ can only be applied to patients who already have a working diagnosis of CTS.

### **8.8 Conclusion**

Whilst it is clear that the correlation between the two raters is not perfect the study does demonstrate significant statistical support that the CTQ could well be used as a patient-completed questionnaire providing comparable results to those completed by the clinician. Further studies are needed to explore the potential health economic benefits of the patient-completed version of the CTQ.

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Chapter 9: Economic implications of the use of a clinician and self-completed screening questionnaire in the assessment of Carpal Tunnel Syndrome: a preliminary study.

## **Chapter 9: Study 5**

### **9.1 Target Journal:**

Hand Surgery <http://www.bssh.ac.uk>

### **9.2 Title**

**Economic implications of the use of a clinician and patient-completed screening questionnaire in the assessment of Carpal Tunnel Syndrome: a preliminary study.**

### **9.3 Abstract**

Carpal Tunnel Syndrome (CTS) is the most common entrapment neuropathy presenting to the Orthopaedic outpatient department affecting between 0.125%-1% and 5-16% of the population (Aroori and Spence, 2008; Priganc and Henry, 2003). With this in mind management of CTS is of significant economic concern to all Orthopaedic outpatient departments. Debates remain as to how best assess and diagnose this condition (Clark et al 2011). Nerve conduction studies are an effective way of objectively identifying the presence of CTS yet they are often costly and lead to an increase in waiting times. A blinded, prospective study with the objective of comparing clinical assessment to results of NCS was carried out by Graham (2008), this study on 143 patients demonstrated significant correlation between assessment and NCS. It was

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suggested that NCS might well just add inconvenience; delay, discomfort and expense and that in many if not most cases NCS are not necessary. Kamath and Stothard (2003) developed a clinician-completed questionnaire in order to assess the likelihood of a patient presenting with CTS. This has been subsequently explored and shown to have high levels of sensitivity when used to predict outcomes of NCS in those with suspected CTS (Bridge, 2011; Edwards and Frampton 2014). This study has the aim of exploring the financial implications of implementing the clinician-completed CTQ into management of CTS as a screening tool for NCS. The implications of use of a parallel patient-completed version are also explored. Results suggest that purely based on cost savings made through not referring on to NCS, using a clinician completed questionnaire with an annual referral rate of 750 patients implementing the CTQ as a screening tool for NCS could potentially save £73,305.00 Using the CTQ as a patient-completed questionnaire could save £58,372.50. Economic advantages and disadvantages of using the clinician and patient-completed versions of the CTQ are explored together with implications on waiting lists and compliance with the UK NHS 18-week wait target.

## **9.4 Research Methods**

### **9.4.1 Participants**

100 consecutive patients attending an orthopaedic hand clinic with suspected Carpal Tunnel Syndrome (CTS) who met the inclusion criteria were selected for the study. Power was determined through reviewing previous studies including the original study carried out by Levine et al (1993) exploring the use



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of a questionnaire in the assessment of CTS (n=67). The questionnaire developed and evaluated by Kamath and Stothard (2003) included 107 consecutive patients referred into a hand clinic with suspected CTS, of whom 74 met the inclusion criteria and 16 were lost to follow up, giving a total sample size in that study of 58.

The cohort of participants for this study was acquired through direct referral from either primary care (usually their own General Practitioner) or through secondary care via other specialist clinics. These patients were referred with the direct question as to whether they did, or did not have CTS.

#### **9.4.2 Inclusion Criteria**

- Those able to offer informed consent
- Patients having been referred with suspected Carpal Tunnel Syndrome
- Patient aged over 18 year (no upper age limit)
- Those patients who are suitable for NCS

#### **9.4.3 Exclusion Criteria**

- Peripheral Neuropathy including those diagnosed with Diabetes Mellitus
- Pregnancy
- Patients who have undergone renal transplant
- Previous Carpal Tunnel Decompression on the same side
- Those unable to give informed consent
- Those under the age of 18 years

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Diagnosis of CTS in patients with diabetic neuropathy is difficult as the two conditions may affect the median nerve in a similar way. Renal transplant patients (often requiring more involved surgery including the removal of amyloid tissue) and pregnant patients were also excluded. Carpal tunnel syndrome can recur but it is rare and this may well complicate matters; in any case all patients returning to an orthopaedic clinic with recurrence of symptoms would normally require repeat NCS.

Prior to the commencement of the clinic notes were reviewed and those meeting the inclusion criteria were selected. Those patients deemed appropriate for the study were provided with a patient information leaflet and questionnaire. Sufficient time was offered in order for the patients to decide whether or not they wished to participate in the study. It was made specifically clear at this point that their decision would have no effect on the outcome of their clinic appointment.

#### **9.4.4 Procedure**

Consecutive participants who consented and who met the inclusion criteria completed the CTQ prior to entering the clinic room. Completed questionnaires were posted into a sealed box and were not seen by the hand specialist. Upon entering the clinic room the hand specialist completed a duplicate clinician-rated CTQ with the patient (Edwards & Frampton, 2014).

Participants then underwent a standard clinical examination by the hand specialist and NCS were carried out. Questionnaire responses were not

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analysed until a later date and had no influence over the clinical management of the patient.

Criteria for the interpretation of NCS were based on the Kamath and Stothard (2003) study. Criteria for normal values were matched, with terminal latency to abductor pollicis brevis less than 4.0ms and a sensory conduction from digit 2 to wrist greater than 47m/s. Further routine tests included transpalmar recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

#### **9.4.5 Materials**

The CTQ consists of nine questions related to the common symptoms reported by patients suffering with CTS. The questions are differentially weighted (using an algorithm developed by Kamath and Stothard, 2003) giving a scoring range of between -2 and +11.

#### **9.4.6 Data Analysis**

Threshold scores for the CTQ were derived from Edwards and Frampton (2014). A cut-off score of  $\geq 6$  was used as this demonstrated high level of specificity (94.44%) and positive predictive value (96.97%) in a previous sample of 68 patients when piloting the questionnaire as a screening tool for NCS (Edwards and Frampton, 2014). Specificity and sensitivity together with positive and negative predictive values in relation to obtained positive NCS results were derived. Results were used to evaluate the economic implication

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of introducing the CTQ into current practice distinguishing between the patient-complete version and clinician completed depending upon operational organisation.

## 9.5 Results

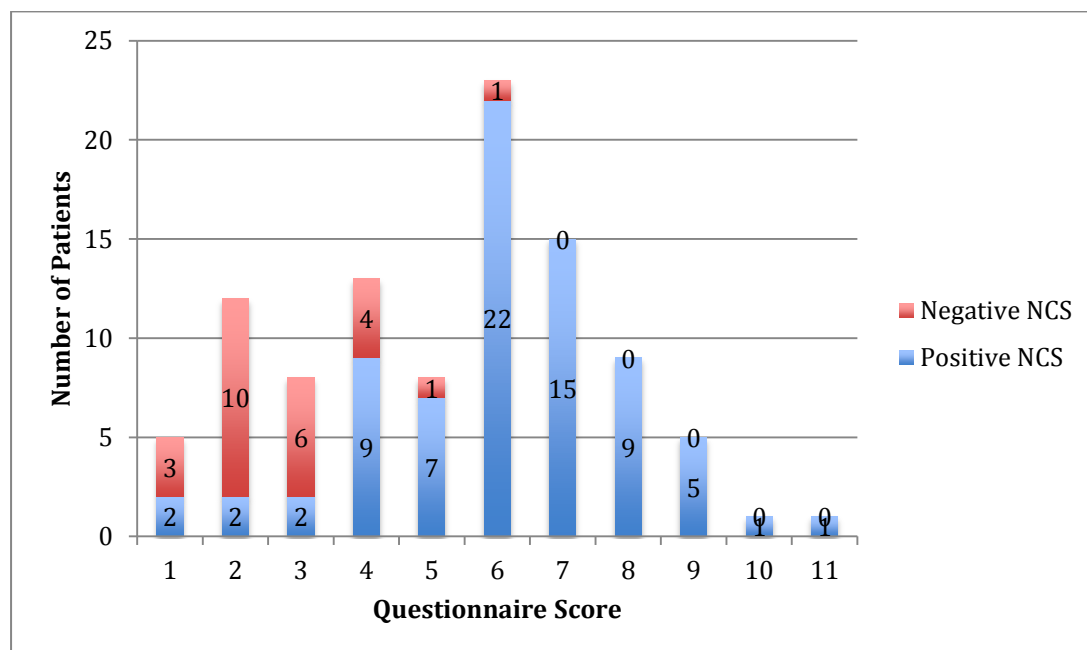


Figure 9.1 The distribution of weighted total clinician-completed Carpal Tunnel Questionnaire scores obtained.

Cut-off score	Specificity	Sensitivity	Positive Predictive Value	Negative Predictive Value	False Positive Rate
6 or over	70.67%	96%	98.15%	52.17%	1%(n=1)

Table 9.1 Sensitivity/Specificity and Positive/Negative Predictive Values of the clinician-completed CTQ relative to results of NCS using  $\geq 6$  cut-off

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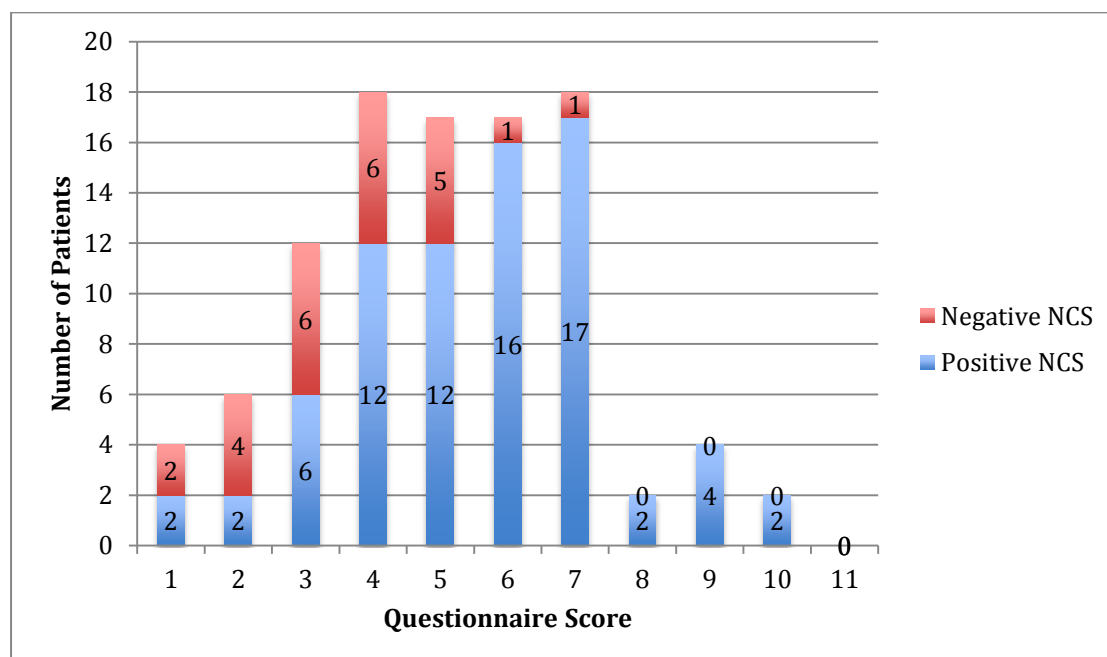


Figure 9.2 Distribution of weighted total patient-completed Carpal Tunnel Questionnaire scores obtained.

Cut-off score	Specificity	Sensitivity	Positive Predictive Value	Negative Predictive Value	False Positive Results
6 or above	54.67%	92%	95.35%	40.35%	2%(n=2)

Table 9.2 Sensitivity/Specificity and Positive/Negative Predictive Values of the patient-completed CTQ relative to results of NCS using  $\geq 6$  cut-off

## 9.6 Discussion

Validity of the CTQ as a screening tool for patients with potential CTS has been demonstrated (Kamath and Stothard, 2003; Edwards and Frampton, 2014; Bridges et al, 2011) but to date the cost implications of its use have not been explored.

Chapter 9: Economic implications of the use of a clinician and self-completed screening questionnaire in the assessment of Carpal Tunnel Syndrome: a preliminary study.

A traditional model of managing those with potential CTS will be to refer patients for neurophysiological testing externally carrying a tariff cost. In the UK this tariff is negotiated locally and does fluctuate year on year (at the time of print our local tariff charge is £181 per study; this figure will be used to calculate potential cost savings). CTS is the most common peripheral nerve entrapment being the most common referral into specialist hand services. If we consider a hypothetical referral rate of 750 patients annually into Orthopaedics via Primary Care, if all of these patients were referred for confirmatory studies this would incur an annual cost of £135,750.

Fifty-four percent of patients in this study scored above threshold on the clinician-completed questionnaire (specificity of 96%; table 10.1) and therefore would have been screened out of needing NCS, saving £73,305. Forty three percent scored above threshold on the patient-completed version of the questionnaire (specificity of 92%; table 10.2) and therefore would have been screened out of needing NCS saving £58,372.5.

The availability of NCS has improved over recent years with the development of hand held NCS devices that can be used within the orthopaedic clinic by a clinician with minimal training. However there are costs involved, disposables are expensive costing around £60 (variable) per patient to assess both hands for potential CTS. When considering this operational model savings of £24,000 or £19,350 could be achieved per annum when implementing the clinician completed and patient-complete version of the CTQ as a screening tool for NCS respectively. Further costs are incurred if clarification of the results is

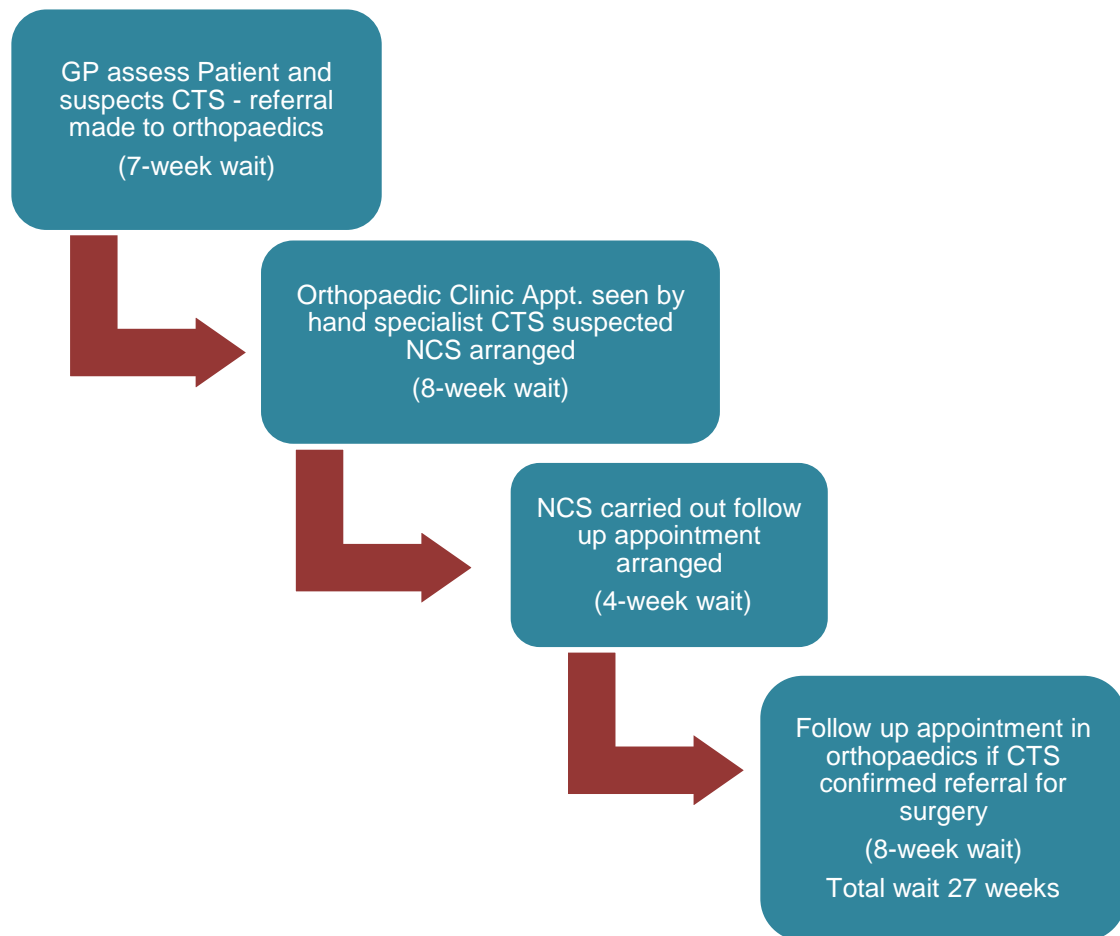
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required through the online assessment by a neurophysiologist. As well as the costs, time also needs to be considered when carrying out fewer tests more patients can be seen in any given clinic improving waiting times.

In-house NCS may take around 20 minutes, considering the above scenario saving 54% of the 750 referrals needing NCS would save 405 (clinician completed) and 323 (patient-completed) referrals for NCS in turn saving 135/107.5 hours of clinic time respectively. Assuming an orthopaedic outpatient session lasts 3.5 hours 135 hours equates to over 38 orthopaedic sessions over a year and 107.5 hours or 30 sessions.

In the UK, Patient-centred delivery of healthcare has been a central focus within the NHS since the NHS Plan in 2000 and subsequent NHS Improvement Plan in 2005. In order to reduce patient waiting times 18-week pathways were developed with the aim that all patients receive treatment within 18 weeks of their initial referral (Reid et al, 2009). Fines are implemented on an Orthopaedic department when this 18-week target is breached. Although difficult to specify, implementing the CTQ as a screening tool for NCS in those with suspected CTS will reduce pressure on Orthopaedic waiting lists and inevitably reduce the number of breaches. This will have financial benefits as well as improving the reputation of the department for meeting its targets

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**Figure 9.3** Depiction of current practice for patients attending Orthopaedic Clinic with suspected CTS being referred for NCS



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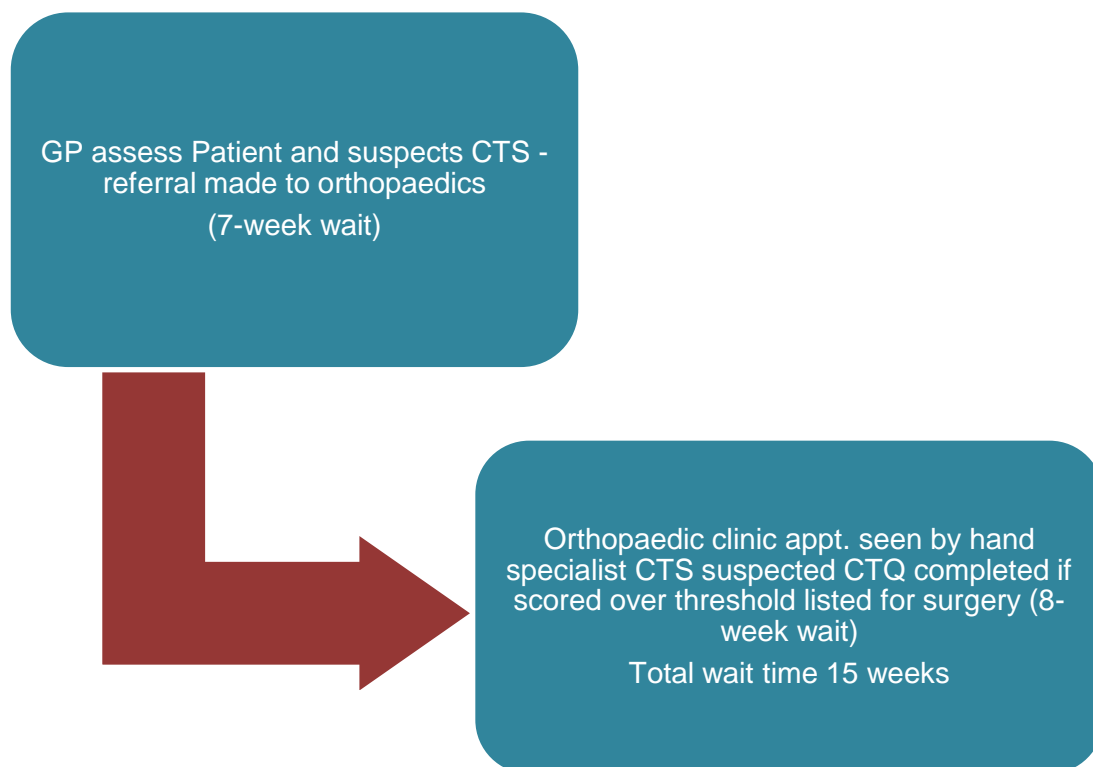


Figure 9.4 Potential impact of introducing clinician-completed version of CTQ into practice

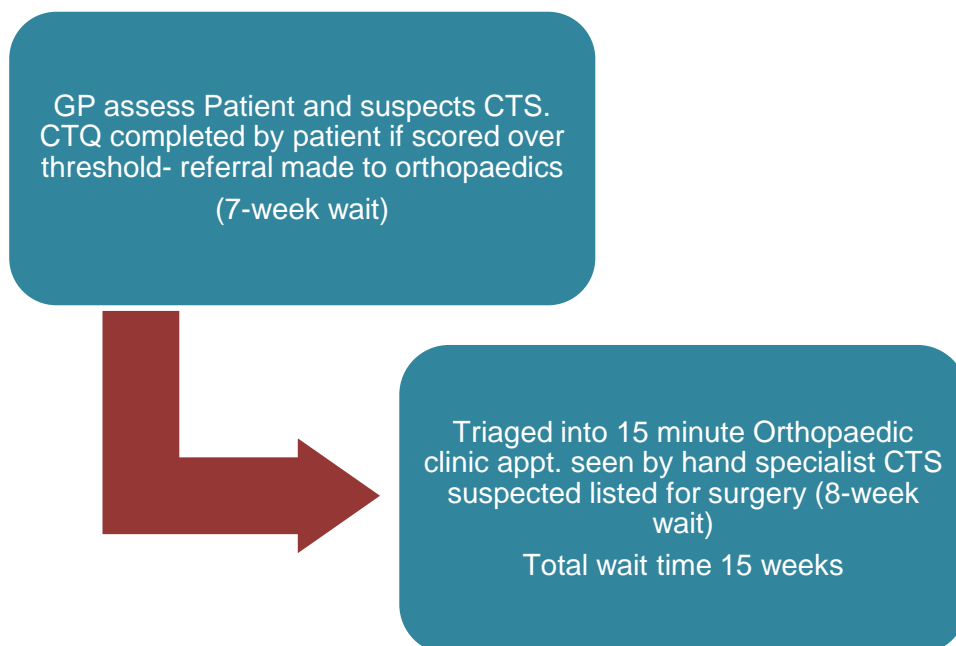


Figure 9.5 Potential impact of introducing patient-complete version of CTQ into practice

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Current practice as demonstrated in figure 9.3 includes waiting times and whilst these will obviously vary between provider organisation they do provide an example of the problems faced by orthopaedic department when trying to meet 18-week targets. Wait times from GP to the hand specialist in orthopaedics is currently 7-weeks; if a preliminary diagnosis of CTS is suspected patients will often be referred on for confirmatory NCS (currently 8-week wait). A follow up appointment is made with the hand specialist to discuss the results and subsequent management (4-weeks) if CTS is diagnosed then waiting times for surgery is 8-weeks. This gives a total waiting time of 27 weeks and significantly breaches the 18-week wait target. Fines are implemented of £150 per patient (who is not treated within 18-weeks of being referred to specialist services), however this is due to increase from 1<sup>st</sup> October 2015 to £300 per patient for every month that the 18-weeks are breached. With this in mind from October there could potentially be a £600+ fine for every patient who undergoes surgery for their CTS.

Figure 9.4 demonstrates the impact of using the CTQ as a screening tool when completed by the hand specialist during their orthopaedic appointment. Waiting times from first appointment with the hand specialist will remain the same (7 weeks) however those scoring over the threshold could (if the clinical assessment supports diagnosis of CTS) bypass NCS and are listed directly, leading to a total weight of 15-weeks.

Figure 9.5 depicts the pathway when using the patient-completed version of the CTQ at the point of triage the orthopaedic team will be aware of the CTQ

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score and would be able to allocate a shorter clinic appointment – waiting times would initially remain the same however it could be surmised that as the appointment times are shorter more patients can be seen and therefore waiting times for first appointments within orthopaedics would reduce.

There is a further point to be considered - would those who complete the CTQ but score below the threshold benefit in any way from the implementation of this screening tool? With potentially 56% of those referred scoring above the threshold and bypassing NCS, pressures on neurophysiology services would inevitably be reduced and whilst it would be difficult to quantify, waiting time for NCS would reduce. Furthermore with those scoring above the threshold not needing follow up orthopaedic appointments waiting times for those that do need to be reviewed will also be reduced. One could hypothesise that if this screening tool was implemented that all patients with suspected CTS whether they did or did not require NCS could be seen within the 18-week target.

Commissioners who pay for the orthopaedic services would also save money on those patients who score over the CTQ threshold. By bypassing NCS the subsequent follow up appointment would be unnecessary - these appointments at time of print are charged at £76.

“Patient choice” has become increasingly central to healthcare policy in the UK over the past four decades. Successive governments have prioritised patient choice in their manifestos and healthcare policies. The recent UK coalition

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government viewed patient choice as means to increasing competition as well as improving the patient experience (BMA, 2013).

In 2012 a new commissioning approach (Any Qualified Provider) was introduced in the UK, allowing any provider to offer a particular service so long as they met the minimum standards of care and are able to provide this within a nationally or locally agreed tariff. Patients are provided a list of the providers that have been approved by local commissioners and offered choice as to where they wish to be referred.

The focus of this competition is based on quality and not cost. National tariff (or locally agreed tariff if there is no set national guideline) has been fixed across the board so all providers effectively receive the same per patient. (BMA, 2013).

Increasing competition has a significant bearing upon all affected services. With basic supply and demand theory (assuming demand remains the same) increasing competition increases supply. This potentially reduces the numbers of patients seen by each of the providers and reducing tariff costs. What each provider needs to ensure is that they are cost efficient, lean yet able to maintain the quality of the service.

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## **9.7 Conclusion**

This study suggests that the use of the CTQ as a screening tool confers improvements in efficiency without sacrificing patient care. Since waiting lists have a significant influence upon patient choice when considering which provider they wish to attend, the introduction of the CTQ would have the potential to improve the patient journey reducing wait-lists, avoiding unnecessary and uncomfortable tests and reducing costs to the service provider, in turn making the service seem more attractive to the patient and provider. When considering competition this may well influence patient choice in selecting the provider increasing the number of patients coming through the service and therefore increasing revenue.

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## **Chapter 10: Discussion and Overview**

### **10.1 Summary of Studies in the Thesis**

In a thesis exploring the CTQ originally devised by Kamath and Stothard (2003) to predict the outcome of NCS in those with suspect CTS the validity, reliability, flexibility and potential economic impact has been analysed through five separate studies.

#### **10.1.1 Study 1 Predicting the Outcome of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Using an Existing Carpal Tunnel Assessment Tool**

Explored the ability of the CTQ to predict the outcome of NCS in a cohort of 68 patients with suspected CTS. This acted as a pilot study the results of which showed a sensitivity of 86% and specificity of 84%. This prompted further work on a new cohort of patients.

Studies 2-5 used a new cohort of 100 patients.

#### **10.1.2 Study 2 Exploring the predictive validity of a scoring algorithm for a carpal tunnel syndrome questionnaire in determining outcome of nerve conduction studies in a clinical sample**

Using data from the clinician-completed questionnaires the scoring algorithm was explored using binary logistic regression. Clinician-completed data was used, as it was this version upon which the original algorithm was devised by Kamath and Stothard (2003).

Results supported the validity of the original algorithm as the revised version obtained through regression modelling did not improve the function of the questionnaire.

**10.1.3 Study 3 Exploring the Potential of a Questionnaire in Predicting Results of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Exploring a clinician-completed and patient-completed version.**

In a high-risk population both clinician and patient-completed versions of the CTQ provided levels of sensitivity and PPV which convincingly supported the use of either version in predicting the results of NCS in patients with suspected CTS.

Clinician-completed questionnaires achieved higher levels of both sensitivity and PPV than the patient-complete version. The decision about which version should be adopted will be determined by the individual Orthopaedic department and accessibility to NCS,



#### **10.1.4 Study 4 Exploring the potential for using a Carpal Tunnel**

##### **Questionnaire as a patient-reported measure – An Inter-rater Reliability**

###### **Study**

Inter-rater reliability was explored which demonstrated a statistically high level of agreement between clinician and patient raters using Pearson's product moment correlation. This supported the use of the CTQ by both clinician and patient.

#### **10.1.5 Study 5 Cost Analysis and Modelling**

Explored the potential economic impact if the CTQ was implemented as a screening tool for NCS in patients with suspected CTS. Different care pathways were explored and savings calculated dependant upon delivery of care within an Orthopaedic department. Both clinician and patient-completed versions of the questionnaire conferred significant savings to both primary and secondary care together with benefitting the patient in reducing waiting times and reducing the need for unnecessary and uncomfortable tests.

### **10.2 Discussion overview**

The original development of the CTQ (Kamath and Stothard, 2003) explored the tool as a diagnostic measure for CTS. Outcome of surgery was used as the diagnostic gold standard for CTS and results of NCS were compared to those of the CTQ. Sensitivity of 85% was achieved for the CTQ compared to 92% for NCS. Bridge et al (2011) compared results of the CTQ to those of NCS in 211 consecutive patients presenting with suspected CTS with a sensitivity of 87% being reported. Bland and Rudolpher (2011) developed a questionnaire with

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125 variables with a complex scoring system; they reported 88% sensitivity and 50% specificity in predicting abnormal NCS in those with suspected CTS.

Results achieved within these reported studies compare favourably with available research. Both the patient-completed and clinician-completed questionnaires demonstrated very high sensitivity when predicting results of NCS in patients with suspected CTS. Direct comparison of the results with the original Kamath and Stothard (2003) study cannot be made in view of different proposed application of the CTQ. Kamath and Stothard (2003) looked at the potential use of the CTQ as a diagnostic tool for CTS, not as a screening tool for NCS as in the current studies. Increased sensitivity achieved within the current work may well be due to the increase suggested in the threshold of the CTQ, Kamath and Stothard (2003) suggested the cut-off point for a positive CTQ as 5 or more whereas the optimum cut-off point from this study was deemed as 6 or more.

This study has explored the potential use of the CTQ/revised CTQ as a screening tool for patients with suspected CTS. As a screening tool the proposed application will be to identify those patients who present with very typical signs and symptoms of CTS and potentially negate the use of NCS, saving time money and potential discomfort experienced through the tests. This study has not explored the potential for a questionnaire to replace NCS.

There will always be times when objectivity is required to be sure about the surgical decision-making. Factors other than those addressed within the

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questionnaire itself need careful thought before deciding whether or not to proceed to NCS. Through the author's own clinical experience one has developed a 'gut feeling' whereby NCS are carried out despite the results of the questionnaire or indeed the history and clinical examination; this may be based on a number of factors, for example those patients who have responded poorly to steroid injections into the Carpal Tunnel. Much work has been carried out exploring the effect of injections for CTS. Peters-Veluthamaningal et al (2010) explored the use of Carpal Tunnel injections in general practice, this multicentre trial of 69 patients from 20 general practices found that cortisone injections provided effective short-term relief of symptoms.

Further work by Jenkins et al (2012) further supported the use of injections in the short-term management of CTS. A Cochrane review by Marshall et al (2009) that included twelve studies concluded that cortisone injections did provide good symptomatic relief in the short-term. This indicates that injections could potentially provide the clinician with a useful diagnostic indicator - as those who have had an injection should obtain short-term relief from their symptoms if they do indeed present with CTS.

Patients who have had poor results from previous hand surgery, or those who are below the expected age for developing the condition may well be presenting with numerous pathologies within the hand such as trigger fingers, Osteo-arthritis, Rheumatoid Arthritis etc. In such cases, classifying the degree of nerve impairment may be helpful in determining how much the CTS is contributing to the overall picture.

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The use of NCS in such situations provides an objective measure of the condition of the nerve. Recording conduction velocities, latencies and amplitudes provides useful information indicating potential demyelination and axonal degeneration therefore enabling the hand specialist to quantify the severity of the CTS. This is something that the CTQ is unable to achieve. In those with very severe CTS subjective complaints can actually reduce; night waking ceases, aggravating and relieving factors stop as the symptoms of intermittent paraesthesia are replaced by persistent anaesthesia, which does not vary in intensity. In such cases despite there being marked median nerve compression, low scores are likely to be achieved on the CTQ. In the context of this study this is not of concern as those patients scoring low on the CTQ would go onto the have NCS however it does highlight that the questionnaire is not sensitive to severity of CTS - but is this important?

Severity of CTS can often be judged with reasonable confidence through clinical examination, through subjective questioning regarding the longevity of the condition, frequency and irritability. In addition, looking objectively at signs of thenar wasting, autonomic disturbances, sensory loss and response to provocative tests can aid in the classification of CTS. Having a clinical classification of CTS as mild, moderate or severe enables the clinician to provide a prognosis from surgery. Those presenting with more severe compression are less likely to do well and recovery of sensation often takes more time and is likely to be incomplete. Patient expectation inevitably relates to patient satisfaction; if we can provide accurate prognosis then patients know

## Chapter 10: Discussion and overview

what to expect especially when it comes to the likelihood of the incomplete resolution of the symptoms.

In the author's experience NCS results relating to CTS rarely come as a surprise, however there are times when the severity of the compression is greater than expected. Potentially in the absence of NCS unrealistic expectations could be provided if the classification of the CTS is wrongly assumed.

This series of studies has enhanced the validity of the CTQ when used as a screening tool for NCS in patients with suspected CTS. Exploration of the scoring algorithm through binary logistic regression showed that the original scoring system of the questionnaire is an effective model and was not improved through regression modelling.

The results of the studies show that the most statistically significant means of delivery of the CTQ is by the hand specialist; what further benefit is conferred by adopting a patient-completed version? Results of the studies reported in this thesis show that, whilst higher rates of both sensitivity and PPV were established when comparing clinician-completed to patient-completed versions, the patient-complete were still highly significant. This supports the use of either version; the decision about which version to adopt will depend upon local care pathways for the management of CTS. This added flexibility significantly increases the potential use of the CTQ within primary care.

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When used within primary care, in General Practice or Physiotherapy department, the completion of the CTQ could act as an adjunct to assessment providing a reliable indication as to whether the patient would likely have positive or negative NCS if tested for CTS. This may well influence potential onward referral and prompt reassessment if results were not as expected.

If the CTQ could be completed before referring the patient into secondary care this would offer the secondary care team advance notice as to whether the patient will likely require NCS or not. Using this as a basis upon which to triage into an appropriate appointment either with or without NCS thus saving time and money that has been extrapolated within chapter 9 (study 5).

It should be reiterated that the use of the CTQ as a stand-alone tool in the assessment of CTS has not been explored or indeed advocated by these studies. It has only been explored on a high-risk population having been previously assessed by a health professional and a provisional diagnosis of CTS has been made (75% of the population tested had positive NCS for CTS). Further research is needed to establish the potential use of the CTQ as a universal screening tool.

Integrating the CTQ into current practice would be straightforward and not incur any significant extra burden to either the patient or clinician. The point at which the CTQ should be completed will depend upon the organisational structure of the individual orthopaedic department. Results of the patient-completed version of the questionnaire (study 3) provides further flexibility of

use for the CTQ. Results suggest that CTQ could provide a reliable screening tool, which if adopted could have a significant impact through cost savings, and waiting list times in the management of this very common condition.

### **10.3 Limitations of the studies**

Results of the CTQ were compared to those of NCS. When comparing the results of the CTQ with NCS it is important to remember that NCS does not represent a perfect test. This would provide a significant limitation if the study was to infer that the CTQ was used to diagnose CTS. This is not the case as the CTQ will offer only an adjunct to assessment and should not be used as a stand-alone test in the diagnosis of CTS. Due to Research Ethics constraints questionnaires were anonymised and as a result it was not possible to follow the patients up to see if they went ahead with surgery and if so how they responded.

Demographic characteristics of the population were not explored within the study. Therefore no conclusions can be obtained as to whether the CTQ would be more sensitive in any particular cohort of patients.

The population within the study was at high risk of having CTS as they had already been seen by their GP who has made an onward referral for diagnosis. With this in mind results obtained within this study will only be representative for patients who have the preliminary diagnosis of CTS and are not transferable to the general population.

#### **10.4 Recommendations for further Study**

Exploring the demographics of a population with the suspected diagnosis of CTS who have completed CTQ would provide further information regarding the application of the CTQ in the management of CTS.

In the absence of a true gold standard in the assessment of CTS the addition of impact of surgery would provide further information regarding the potential use of the CTQ in the assessment of CTS and not just purely as a screening tool for NCS.

#### **10.5 Conclusion**

One could view the assessment of CTS as a jigsaw, each individual piece providing a clearer picture as to the diagnosis. These pieces may well be constructed of subjective history, clinical tests (phalens, tinels etc.), NCS and CTQ. It is clear that there is no one piece that is sufficient to make a diagnosis, however the picture may well become very clear without the necessity to complete every piece of the jigsaw. Results of the overall study would confidently suggest that if clinical examination and history supports the diagnosis of CTS, a positive CTQ provides a convincing picture of CTS without the addition of NCS. The potential resource savings and improvement in patient experience of appropriate use of the CTQ could be significant; future studies could explore its widespread implementation.



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**Appendix 1** – Email from Primal Pictures regarding copyright.

Hi Carl,

Please use this in your references.

3D anatomy images. Copyright of Primal Pictures Ltd. [www.primalpictures.com](http://www.primalpictures.com)

Many thanks,

Mark

**Mark Simmance**

Business Development Executive  
Primal Pictures

an **informa** business

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From: Simmance, Mark [Mark.Simmance@informa.com]

Sent: 24 April 2014 10:24

To: Edwards Carl (SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST)

Subject: RE: RE: copyright interactive hand



Hi Carl,

Thank you for getting in touch and you can certainly use the images within your Doctoral Research. Exeter university have an existing license and as you also have a DVD, the use of our images is free for non-commercial purposes. However, please ensure you reference Primal Pictures.

Best of luck!

Mark

Mark Simmance

Business Development Executive

Primal Pictures

an informa business

e: [mark.simmance@primalpictures.com](mailto:mark.simmance@primalpictures.com)<<mailto:mark.simmance@primalpictures.com>>

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[www.primalpictures.com](http://www.primalpictures.com)<<http://www.primalpictures.com/>>

[<cid:image001.png@01CF5FA7.6414DDE0>]<<http://www.anatomy.tv/>>

From: 'CSD IBI Books' [<mailto:books@informa.com>]

Sent: 23 April 2014 19:51

To: customerservice

Subject: Fw: RE: copyright interactive hand

Hi,

This customer would like permission to use some Primal images in his doctorate - please advise.

Many thanks,

Adam (Hudson).

----- Original Message -----

Subject :RE: copyright interactive hand

Date :23/04/14 11:27

From :Edwards Carl (SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST)<carl.edwards@nhs.net<mailto:carl.edwards@nhs.net>>

To :'CSD IBI Books' <books@informa.com<mailto:books@informa.com>>

Dear Chris,

Thank you for your response, what I am after is some guidance regarding the possibility of incorporating some images from your software within my Doctoral thesis. My thesis is based on Carpal Tunnel Syndrome - a condition of the hand, and there are some excellent images within 'interactive hand' which I would like to include within the anatomy section. These would obviously be referenced clearly within the text. What I do not want to do is breach any copyright restrictions which may well prevent publication of these images.

Kind Regards,

Carl

---

From: 'CSD IBI Books' [books@informa.com]

Sent: 03 April 2014 15:49

To: Edwards Carl (SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST)

Subject: Re: copyright interactive hand

Dear Carl,

Thank you for your email.

Can I please ask you to elaborate further as to what assistance we can provide.

If you have any queries or if I can be of any further assistance, please do not hesitate to contact me.

Kind Regards

Chris Davies

Adhoc Customer Operations Executive

Customer Operations

Sheepen Place, Colchester, Essex, CO3 3LP, UK

Tel: +44 (0)20 7017 6682

E-Mail:

adhoc@informa.com<mailto:adhoc@informa.com<mailto:adhoc@informa.com%3cmailto:adhoc@informa.com>>>

On 02/04/14 10:21, Edwards Carl (SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST) wrote:

Hello,

My name is Carl Edwards and I work as a Orthopaedic Physiotherapist at Torbay Hospital. I purchased a copy of your interactive hand some years ago (v1.1) and was looking to incorporate two maybe three of the images within my Doctoral Research run through Exeter University. I would obviously like you permission to do so if possible. The project is studying method of assessment of Carpal Tunnel Syndrome and the images would be used and referenced within the Anatomy and Physiology section.

Any advice would be gratefully received,

Kind Regards

Carl

Carl Edwards

Specialist Orthopaedic Physiotherapist

(

**Appendix 2** – Journal Article - Predicting the Outcome of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Using an Existing Carpal Tunnel Assessment Tool (Edwards, C., & Frampton, I. 2014)

# Predicting the Outcome of Nerve Conduction Studies in Patients with Suspected Carpal Tunnel Syndrome: Using an Existing Carpal Tunnel Assessment Tool

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## Abstract

This service evaluation and pilot study was designed to establish whether a clinical questionnaire could be incorporated within our Secondary Care Carpal Tunnel Service. The purpose of the questionnaire is to predict the positive and negative results of Nerve Conduction Studies (NCS) in those patients with suspected Carpal Tunnel Syndrome. The hand specialist, preceding NCS administered the questionnaire; it was then scored at a later date. Results showed a sensitivity of 86% and specificity of 84% referring to the ability to predict a positive NCS when using a predetermined cut-off score. When analysed with Receiver Operating Characteristics, a threshold score could be determined in order to obtain 100% sensitivity/specificity. This questionnaire can be used as a useful adjunct to assessment of those presenting with suspected Carpal Tunnel Syndrome. Using the questionnaire to identify those patients scoring outside a predetermined threshold range would reduce the need for NCS by nearly 50%, with significant cost and clinical practice implications.

## Keywords

Carpal Tunnel Syndrome, Questionnaire, Nerve Conduction Studies, Health Economics

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## 1. Introduction

Carpal tunnel syndrome (CTS) is the most common type of peripheral nerve entrapment [1]. Symptoms can be

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debilitating including loss of sensation in the fingers, pain, muscle wasting, weakness of grip and night waking. The condition is most commonly seen in females and in the age range 40 - 50 [2]. The pathology involves the compression of the median nerve passing through the carpal tunnel in the hand. The tunnel is exactly that, with the “floor and walls” composed of the carpus and the “roof” by the flexor retinaculum, a fibrous ligamentous structure attaching to the pisiform and hamate medially and scaphoid and trapezium laterally. Through the carpal tunnel, the tendons of flexor digitorum profundus, flexor digitorum superficialis, flexor pollicis longus and the median nerve pass [2].

Numerous studies have attempted to link occupational history with the development of this condition. These have been generally proved inconclusive with those in heavy construction as likely to develop the condition as those within office-based employment. Conolly and McKessar [3] suggest that most cases of CTS are constitutional, although some patients in occupations involving increased force and pressure within the carpal tunnel have an increased risk of developing CTS. Mechanical changes affecting either the structure of the “tunnel”, or its contents can affect the median nerve. For example, previous distal radius fractures with associated deformity, or flexor synovitis presenting commonly in inflammatory arthropathy.

CTS is by definition a collection of signs and symptoms that in combination make the clinical diagnosis relatively straightforward [4]. Clinical history and presentation are paramount in diagnosing this condition, however further investigative measures are available to help clarify the diagnosis and severity of compression.

Differential diagnosis is crucial. Paraesthesia in the hand is a common complaint and while it is easy to label a patient with CTS, other potential causes have to be considered. The median nerve originates from the C6/7 nerve roots, so any compression of the nerve or its roots could culminate in paraesthesia in the hand. More proximal compression of the median nerve may include the pronator teres or struthers arcade. Inflammatory conditions need to be considered such as mononeuritis and inflammatory demyelinating neuropathy. Radiculopathy, thoracic outlet, polyneuropathies are among other potential differential diagnoses thus stressing the importance of reaching a confident diagnosis before considering treatment [5].

If clinical diagnosis is in doubt, further investigative methods are available. The most widely researched and used are Nerve Conduction Studies (NCS), which are the best predictor of symptom severity [4]. Descatha *et al.* [6] showed that NCS together with clinical examination significantly improved detection rates for CTS compared to examination alone. They suggested that clinical examination is appropriate as an initial screening, and that NCS should be used as the confirmatory test in those who have less convincing signs and symptoms on examination. Although NCS are often considered to be the gold standard, they are open to both operator and interpreting error. Nevertheless, it does provide a useful adjunct to clinical assessment in localising potential nerve entrapments and assisting with surgical decision-making [7].

Questionnaires have been developed to help predict the likelihood of CTS [8]-[10]. These have typically included diagrams, which are annotated by the patient reflecting the distribution of their symptoms together with multiple choice and single answer questions. An assessment tool developed by Kamath and Stothard [9] based on work carried out by Levine *et al.* [8] and further studies by Bridges *et al.* [11] has proven to be a reliable adjunct to developing a diagnosis. It comprises a list of questions to be used within the assessment process by the clinician. Responses are scored using a simple algorithm with weighted scores for each answer. These have been based on six critical domains that were identified by a panel of hand surgeons, rheumatologists and patients [8]. These domains include pain, paraesthesia, numbness, weakness, nocturnal symptoms and over-all functional status and used to predict likelihood of CTS. Previous studies [9] have shown that this assessment tool has a sensitivity of 85% in predicting CTS compared with the result of subsequent surgery.

Since CTS can be diagnosed with this kind of systematic assessment, we wondered whether it is possible to predict whether or not a patient is so likely to be “classical” for CTS that NCS could be acceptably removed from the assessment process. If it is possible to identify those who do not need NCS in order to make a positive or negative diagnosis (because they have so many or so few of the “classic” symptoms respectively), there could be significant savings in clinic time, increased capacity and reduced costs.

The aim of the current study is therefore to explore the development and preliminary evaluation of a paper-based questionnaire based on Kamath and Stothard [9] in a clinical series of patients referred for assessment and diagnosis of CTS. The objectives of the study are to derive upper and lower threshold scores to predict positive and negative diagnosis of CTS and to compare these with current clinical diagnosis including examination and NCS.

## 2. Method

### 2.1. Participants

68 patients attending a local secondary care clinic for assessment of CTS consented to participate in the study. Exclusion criteria included any possible peripheral neuropathy (for example—those with diabetes mellitus, since diagnosis of CTS in patients with diabetic neuropathy is difficult as the two conditions may affect the median nerve in a similar way [12] [13]). Renal transplant patients (often requiring surgery including the removal of amyloid tissue) and pregnant patients were also excluded.

### 2.2. Materials

Participants were asked a series of standard questions (see [Appendix](#)) by the first author at the beginning of their appointment. Clinical assessment was then conducted as normal in order to make a clinical diagnosis of CTS. Tests included assessment of sensation, autonomic function, tinel, phalens and flick test. Cervical spine range was assessed and any resultant exacerbation of distal symptoms was recorded.

NCS was based on the Kamath and Stothard [9] study. Criteria for normal values were matched, with terminal latency to APB less than 4.0 ms and a sensory conduction from digit 2 to wrist greater than 47 m/s. Further routine tests included transpalmar recording to digit 3 with a 20% reduction in conduction velocity for the median nerve across the carpal tunnel compared to the palm to finger recording considered significant.

Following the appointment the questionnaires were scored and compared to the results of the NCS and clinical diagnosis.

### 2.3. Data Analysis

Questionnaire data were scored using the algorithm developed by Kamath and Stothard [9]. Cut-off thresholds for predicting positive and negative NCS were derived using Receiver Operating Characteristics (ROC) analyses [14].

## 3. Results

The questionnaire was completed on 68 patients, of whom 50 (73%) tested positive for CTS on NCS, 19 (27%) tested negative. [Figure 1](#) depicts the frequencies of questionnaire total scores for NCS-positive and NCS-negative diagnosis.

ROC analyses showed that of those testing NCS-positive 41 (82%) scored five or over on the questionnaire. Of those testing NCS-negative 15 (83.3%) scored below five on the questionnaire. All those scoring 7 or above went on to have a positive NCS, and those scoring 1 or less all presented with negative NCS.

20% of respondents (n = 14) indicated that they had previously received a carpal tunnel injection. All of these had had good, temporary, symptomatic relief of symptoms, and all proved to have positive NCS and Questionnaire scores.

Using the original cut off score as 5 or above as a positive questionnaire result [9] we can compare to the results of NCS using these two discrete dichotomous variables.

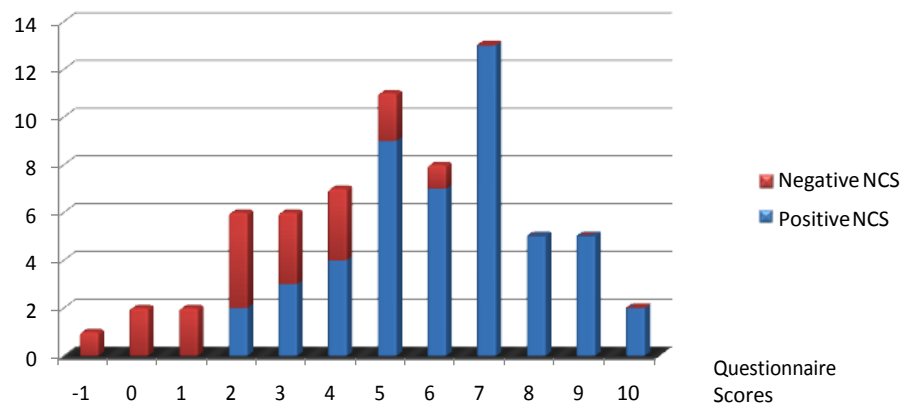
Positive NCS	41	9
Negative NCS	3	15

McNemar Change Tests: Pearson chi2: 3 (p = 0.0833); Yates chi2: 2.083; (p = 0.1489); Binomial (p ≥ 3|N = 12) = 0.9807.

## 4. Discussion

The aim of the present study was to explore the potential for a standardised questionnaire to predict outcome of nerve conduction studies (NCS) for patients referred for diagnosis of potential carpal tunnel syndrome (CTS). 68 participants attending a clinical diagnostic service for the assessment of CTS completed a brief standard clinician-administered questionnaire before undergoing routine clinical assessment and diagnosis. Using Receiver Operating Characteristic (ROC) analyses, a single threshold score was derived to predict the outcome of NCS





**Figure 1.** Questionnaire score by NCS positive and negative diagnosis.

with a sensitivity of 82% (*i.e.* 16 out of 20 patients with positive NCS were correctly identified by those scoring five or more on the questionnaire) and a specificity of 83.3% (*i.e.* 17 out of 20 patients with a negative NCS were correctly identified by those scoring less than five on the questionnaire).

Adopting this single cut-off in the present sample led to 17% false positives and 18% false negatives. Nine patients scored below the questionnaire threshold yet went on to have positive NCS results, suggesting that a single cut-off threshold may not be sensitive enough in clinical practice. Correlation between NCS and questionnaire scores based upon the single cut-off was assessed using McNemar Chi-squared testing. The results do not show a significant correlation, however it is important to bear in mind the contents of the  $2 \times 2$  table used to evaluate this statistic. Relating once more to the clinical context, the important category is that of the patients which present having scored over 5 yet have negative NCS ( $n = 3$ ), it could be hypothesised that these patients may well be listed for surgery having bypassed NCS. It must be remembered however that CTS can still be present despite there being normal NCS. Those patients who presented with positive NCS yet scored below five ( $n = 9$ ) would be clinically “safe” as they would have proceeded to have NCS carried out as a result of their low scoring questionnaire and therefore “captured”.

One way of improving the results would be to devise threshold range, which could capture both the false negatives and positives. Looking specifically at the results of the present study all those scoring seven or over went on to have positive NCS and those scoring one or below all had negative tests.

Using this approach it would be reasonable to consider offering those scoring between 2 - 6 further confirmatory NCS and those outside of that range a shorter appointment without NCS (sensitivity and specificity 100%). 56% of the patients ( $n = 38$ ) fell within the threshold range of 2 - 6 and on this basis would require additional NCS tests in order to make a clinical diagnosis. The remaining 44% ( $n = 30$ ) were outside of the threshold and on this basis would not require NCS in order to make a clinical diagnosis.

The potential impact, if this model was used, could be very significant. Based on a notional annual referral rate of 600 patients with 44% not requiring studies this could save 66 hours of clinic time amounting to 19 whole orthopaedic clinics. This would provide more flexibility of the service, either to see more patients with CTS or to expand other existing services.

Patient expectation factors should also be considered. Patients often attend clinic with a clear expectation as to what they want to gain from their appointment. From their discussion with their family doctor or referring consultant a suspected diagnosis has often been discussed. With access to the Internet and other resources readily available patients may well look into the condition and the expected presentation, thus influencing their answers.

In order to justify any potential change in a service, the effect on both patient satisfaction and their journey through the system needs to be evaluated. Although not looked at within this study it would be reasonable to assume that a patient would rather wait to have the correct diagnosis rather than opt for a rapid assessment service. A study carried out by Khu *et al.* [1] looking at patients’ perceptions of carpal tunnel surgery and ulnar nerve decompression surgery found that satisfaction was clearly linked with clinical outcome, which in turn was dependant on the correct initial diagnosis. With this in mind rapid access to treatment may not be the only relevant factor.

Plans have been made to explore this further through a subsequent study. This will explore the potential of

using this tool as a self-completed questionnaire as a method of screening for nerve conduction studies in primary care before making an onward referral. Together with this item analysis and logistic regression will be carried out in order to maximise the potential of this useful assessment tool. The statistical analysis should optimise the algorithm to provide the most reliable results.

## 5. Conclusion

The results from this study demonstrate the potential for incorporating a standardised clinical questionnaire in the assessment of CTS. Further investigation of the psychometric properties of the questionnaire would help to establish whether it could be used in a self-completed format at the primary care stage to help referrers identify those patients who require further NCS in order to make an accurate diagnosis, and those who can reliably refer on for a clinical diagnosis and treatment without further investigation. Potential savings could be made within both primary care (where inappropriate referral may be avoided), and secondary care (reducing number of onward referrals for NCS) together with benefits to patients reducing potential lengthy waits without compromising the quality of their journey.

## Acknowledgements

Dr Ian Frampton and Dr Karen Knapp Department of Psychology, University of Exeter; Mrs Frances Hunt and Mrs Roberta Ainsworth Physiotherapy Department Torbay Hospital for their help and guidance and time.

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**Appendix 3 – NRES Proportionate review approval**

Wales REC 6  
Floor 8  
36 Orchard Street  
Swansea  
SA1 5AQ

Telephone : 01792 607416  
Fax : 01792 607533  
E-mail : penny.beresford@wales.nhs.uk  
Website : www.nres.nhs.uk

Dear Mr Edwards

**Study title:** Exploring the use of a questionnaire in the assessment of carpal tunnel syndrome  
**REC reference:** 13/WA/0054  
**IRAS project ID:** 111923

The Proportionate Review Sub-committee of the South West Wales REC reviewed the above application on 13 February 2013.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Ms Penny Beresford, penny.beresford@wales.nhs.uk.

## Ethical opinion

The sub-committee agreed that this study presented no material ethical issues, however, would like to make one suggestion of an inclusion in the information sheet under the heading ***Who has reviewed this study*** to be followed by ***This study has been reviewed by the South West Wales Research Ethics Committee.***

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

## Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.*

*Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

***Sponsors are not required to notify the Committee of approvals from host organisations.***

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.**

## Approved documents

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of insurance or indemnity		01 August 2012
Investigator CV	-	23 January 2013
Letter from Sponsor		23 October 2012
Other: Gantt Chart	1	
Other: letter from Zurich Municipal		13 July 2012
Participant Consent Form	1	23 January 2013
Participant Information Sheet	1	23 January 2013
Protocol	1	23 January 2013
Questionnaire: Carpel Tunnel Patient Questionnaire		
Questionnaire: Carpal Tunnel Questionnaire Scoring		
REC application	1	30 January 2013

## Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

## After ethical review

### Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial
- amendments Adding new sites
- and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

information is available at National Research Ethics Service website > After Review

**13/WA/0054**

**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project. Yours sincerely



**Roy L. Evans**  
**Chair**

Email: penny.beresford@wales.nhs.uk

*Enclosures: List of names and professions of members who took part in the review  
“After ethical review – guidance for researchers” [SL-AR2]*

*Copy to: Gail Seymour, Exeter Universtiy  
Dr Fiona Roberts, South Devon Health Care Foundation Trust*



**Appendix 4 – Letter of sponsorship – Exeter University**



**RESEARCH & KNOWLEDGE  
TRANSFER**

The Innovation Centre  
Rennes Drive  
University of Exeter  
Exeter EX4 4RN

Telephone +44 (0)1392 262393  
Fax +44 (0)1392 263686  
Email [res@ex.ac.uk](mailto:res@ex.ac.uk)  
Web [www.exeter.ac.uk](http://www.exeter.ac.uk)

23<sup>rd</sup> October 2012

Project title                    Can a validated clinical assessment tool be used in primary care in the diagnosis of carpal tunnel syndrome?

Chief Investigator            Mr Carl Edwards, College of Life and Environmental Sciences, University of Exeter

Dear Sir/Madam,

The University of Exeter will act as sponsor for the proposed clinical study titled 'Can a validated clinical assessment tool be used in primary care in the diagnosis of carpal tunnel syndrome?' The University will undertake its responsibilities in this role as outlined in the Department of Health's Research Governance Framework for Health and Social Care (second Edition, 2005). In addition the University will ensure that the necessary ethical approval and cover for indemnity and insurance are in place before the study commences.

Yours sincerely,

A handwritten signature in black ink that reads 'G Seymour'.

Gail Seymour  
Research & Knowledge Transfer

University of Exeter  
Tel: 01392 726621  
Email: [g.m.seymour@exeter.ac.uk](mailto:g.m.seymour@exeter.ac.uk)

## **Appendix 5 – Letter of insurance**

# HENDERSON

C O R P O R A T E

Henderson Insurance Brokers Limited  
No. 1 Whitehall Riverside  
Leeds  
West Yorkshire  
LS1 4BN

01 August 2012

Tel 0132615088  
Fax 0132615099

[www.hibl.co.uk](http://www.hibl.co.uk)

To Whom it May Concern

Dear Sirs,

EVIDENCE OF INSURANCE  
UNIVERSITY OF EXETER AND/OR EXETER ENTERPRISES

We are writing to confirm that we act as Insurance Brokers to the above client and that we have arranged liability insurance on their behalf as detailed below:

## PROFESSIONAL INDEMNITY

Indemnity in respect of the Legal Liability to Third Parties for breach of professional duty due to negligent act, error or omission in connection with your business.

INSURER	Markel (UK) Limited
POLICY NUMBER	SC1919X i IOVR/422
PERIOD OF INSURANCE	1st August 2012 – 31st July 2013
LIMIT OF INDEMNITY	£10,000,000 each occurrence and in the aggregate any one insurance period

Subject to the policy terms, conditions, limitations, exclusions and cancellation provisions.

If you should require any further information or the above please do not hesitate to contact us.

Yours faithfully



Rachel Edwards  
Direct Dial: 01 13261 5097  
Fax: 01 13 261 5099  
Email: [Rachel.edwards@hibl.co.uk](mailto:Rachel.edwards@hibl.co.uk)

This document is issued as a matter of information only and confers no rights upon the document holder other than those provided by the policy. This document does not amend, extend or alter the coverage afforded by the policy or policies as described herein.

Notwithstanding any requirement, term or condition of any contract or other document with respect to which this document may be issued or relied upon, the insurance afforded by the policy (policies) described herein is subject to all terms, conditions or exclusions of such policy (policies). Limits shown may have been reduced by paid claims.



**To Whom It May Concern**

Our ref: VP/IND

13 July, 2012

**Zurich Municipal Customer: University of Exeter**

This is to confirm that University of Exeter have in force with this Company until the policy expiry on 31 July 2013 Insurance incorporating the following essential features:

**Policy Number:** NHE-05CA01-0013

**Limit of Indemnity:**

Public Liability: £ 50,000,000

Products Liability: £ 50,000,000

Pollution:

any one event  
for all claims in the  
aggregate during  
any one period of  
insurance  
any one event  
inclusive of costs

Employers' Liability: £ 50,000,000

Zurich Municipal  
Zurich House  
2 Gladiator Way  
Farnborough  
Hampshire  
GU14 6GB

Telephone 0870 2418050  
Direct Phone: 01252 387859  
Direct Fax: 01252 375893  
E-mail alison.cliff@zurich.com

Communications will be monitored  
regularly to improve our service and  
for security and regulatory purposes

Zurich Municipal is a trading name of  
Zurich Insurance plc

A public limited company  
incorporated in Ireland. Registration  
No. 13460

Registered Office: Zurich House,  
Ballsbridge Park, Dublin 4, Ireland.

UK branch registered in England and  
Wales Registration No. BR7985.  
UK Branch Head Office: The Zurich  
Centre, 3000 Parkway, Witley,  
Fareham, Hampshire PO15 7JZ

Authorised by the Central Bank of  
Ireland and subject to limited  
regulation by the Financial Services  
Authority. Details about the extent of  
our regulation by the Financial Services

**Excess:**

Public Liability/Products Liability/Pollution: £250 any one event

Employers' Liability: Nil any one claim

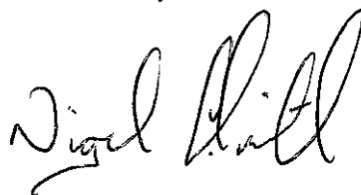
**Indemnity to Principals:**

Covers include a standard Indemnity to Principals Clause in respect of contractual obligations.

**Full Policy:**

The policy documents should be referred to for details of full cover.

Yours faithfully



Underwriting Services  
Zurich Municipal  
Farnborough

**Appendix 6 – Carpal Tunnel Questionnaire used within the study**

# Carpal Tunnel Patient Questionnaire

In order to help us to assess the symptoms in your hand, we would be grateful if you could take a few moments to complete this form. Please put a cross in the box which applies to your answers to the following questions.

For office use only:

Patient's Code

--	--	--	--	--	--	--	--

	Yes	No	Not applicable
Has pain in the wrist woken you up at night?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has tingling and numbness in your hand woken you during the night?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has tingling and numbness in your hand been more pronounced first thing in the morning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have any trick movements to make the tingling, numbness go from your hands? Such as shaking your hand or hanging it out of bed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have any tingling or numbness in your little finger at any time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has tingling and numbness presented when you were reading a newspaper, steering a car or knitting?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If applicable, has the tingling and numbness in your hand been severe during pregnancy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has it helped the tingling and numbness on wearing a splint on your wrist?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you have any neck pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Office use only:

Nerve conduction study performed?

Yes

No

Result of conduction test?

Positive

Negative

## **Appendix 7 – Scoring algorithm for Carpal Tunnel Questionnaire**



**Carpal Tunnel Questionnaire Scoring**

HISTORY (circle yes/no number)

Has pain in the wrist woken you up at night?

Yes 1    No 0

Has tingling and numbness in your hand woken you during the night?

Yes 1    No 0

Has tingling and numbness in your hand been more pronounced first thing in the morning?

Yes 1    No 0

Do you have any trick movements to make the tingling, numbness go from your hands?

Yes 1    No 0

Do you have any tingling or numbness in your little finger at any time?

Yes 0    No 3

Has tingling and numbness presented when you were reading a newspaper, steering a car or knitting?

Yes 1    No 0

Do you have any neck pain?

Yes -1    No 0

If applicable has the tingling and numbness in your hand been severe during pregnancy?

Yes 1    No -1    N/A 0

Has it helped the tingling and numbness on wearing a splint on your wrist?

Yes 2    No 0    N/A 0

**Appendix 8 – Patient Information Leaflet**

## **Study Title – Exploring the use of a Questionnaire in the Assessment of Carpal Tunnel Syndrome**

### **Patient Information Sheet**

I work as a Specialist Orthopaedic Physiotherapist in the treatment of shoulder; elbow and hand conditions. This study forms part of my Doctoral Studies at Exeter University.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through the information sheet with you and answer any questions you have.** We'd suggest this should take about 5 minutes talk to others about the study if you wish. Ask us if there is anything that is not clear.

### **What are the aims of this study?**

The aim of this study is to look into the use of a questionnaire in the diagnosis of Carpal Tunnel Syndrome – a condition whereby a nerve comes squashed as it enters the hand. This often causes pins and needles in the fingers.

There are many ways to try to help diagnose Carpal Tunnel Syndrome. Our aim is to see how effective a simple questionnaire can be in helping decide whether a patient has Carpal Tunnel Syndrome.

Through this study we will be comparing the results of the questionnaire completed by yourself to that completed by the hand specialist and also comparing these to the results of the nerve test that you will have to diagnose the condition. These tests are helpful to show how a nerve is functioning and whether you do, or do not have Carpal Tunnel Syndrome.

### **Who will be involved in the study?**

All patients being referred into Orthopaedics with suspected Carpal Tunnel Syndrome will be invited to take part in the study. It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. Also participating in the study will not have any bearing upon what treatment may or may not be offered.

### **What are we asking of you?**

This study will involve the completion of one questionnaire once you arrive at the orthopaedic department before your appointment. This includes 9 questions with tick box answers. The aim will be to publish the information gathered within a Physiotherapy and Hand Surgery Journal. Any information that may be published will be anonymised; none of your personal details will be used in any way.

All information, which is collected, about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

We cannot promise the study will help you, but the information we get from this study could help improve the treatment of people with Carpal Tunnel Syndrome. We will follow ethical and legal practice and all information about you will be handled in confidence.

### **What if I am not happy or wish to make a complaint?**

If you have a concern about any aspect of this study, you should ask to speak to the researcher – Carl Edwards (01803) 655342 or alternatively contact PALS (Patient Advice Liaison Service) the who will do their best to answer your questions. A PALS Officer is available in person, Monday to Friday, between 9.00am and 4.00pm. You can contact them by calling 01803 655838 or on our 24 hour freephone number 0800 02 82 037.

### **Do I have to take part?**

Participation in this study is entirely voluntary. If you decide not to take part in the study your treatment will not be effected in any way.

If you have any questions or concerns about the study, you can contact myself or my field supervisor Dr Roberta Ainsworth. Thank you.

### **Contact Details**

Carl Edwards  
carl.edwards@nhs.net  
ESP Orthopaedics  
Physiotherapy Dept  
Lawes Bridge  
Torquay  
Devon  
TQ2 7AA

Dr Roberta Ainsworth  
Consultant Physiotherapist  
(01803) 655340

**Appendix 9 –Consent Form**

Patient Identification Number for this trial:

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**CONSENT FORM**

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Title of Project: **Exploring the use of a Questionnaire in the Assessment of Carpal Tunnel Syndrome**

Name of Researcher: Carl Edwards

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated **23/01/2013** (version **1**) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
  
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
  
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
  
4. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of person giving consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature