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Core outcomes in nerve surgery: development of a core outcome set for ulnar neuropathy at the elbow

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OBJECTIVE Ulnar neuropathy at the elbow (UNE) is common, affecting 1%–6% of the population. Despite this, there remains a lack of consensus regarding optimal treatment. This is primarily due to the difficulty one encounters when trying to assess the literature. Outcomes are inconsistently reported, which makes comparing studies or developing meta-analyses difficult or even impossible. Thus, there is a need for a core outcome set (COS) for UNE (COS-UNE) to help address this problem. The objective of this study was to utilize a modified Delphi method to develop COS-UNE.

METHODS A 5-stage approach was utilized to develop COS-UNE: stage 1, consortium development; 2, literature review to identify potential outcome measures; 3, Delphi survey to develop consensus on outcomes for inclusion; 4, Delphi survey to develop definitions; and 5, consensus meeting to finalize the COS and definitions. The study followed the Core Outcome Set-STAndards for Development (COS-STAD) recommendations.

RESULTS The Core Outcomes in Nerve Surgery (COINS) Consortium comprised 21 participants, all neurological surgeons representing 11 countries. The final COS-UNE consisted of 22 data points/outcomes covering the domains of demographic characteristics, diagnostics, patient-reported outcomes, motor/sensory outcomes, and complications. Appropriate instruments, methods of testing, and definitions were set. The consensus minimum duration of follow-up was 6 months, with the consensus optimal timepoints for assessment identified as preoperatively and 3, 6, and 12 months postoperatively.

CONCLUSIONS The authors identified consensus data points/outcomes and also provided definitions and specific scales to be utilized to help ensure that clinicians are consistent in their reporting across studies on UNE. This COS

ABBREVIATIONS COINS = Core Outcomes in Nerve Surgery; COMET = Core Outcome Measures in Effectiveness Trials; COS = core outcome set; COS-UNE = core outcome set for ulnar neuropathy at the elbow; COS-STAD = Core Outcome Set-STAndards for Development; DASH = Disabilities of the Arm, Shoulder, and Hand Questionnaire; NRS = Numeric Rating Scale; UNE = ulnar neuropathy at the elbow.

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should serve as a minimum set of data to be collected in all future neurosurgical studies on UNE. The authors hope that clinicians evaluating ulnar neuropathy will incorporate this COS into routine practice and that future studies will consider this COS in the design phase.

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KEYWORDS core outcome set; cubital tunnel syndrome; peripheral nerve; ulnar nerve; ulnar neuropathy

Ulnar neuropathy at the elbow (UNE), commonly referred to as cubital tunnel syndrome, can lead to a variety of symptoms, including weakness, pain, paresthesias, and numbness. UNE is common, affecting between 1%–6% of the population and making this the second most common upper-extremity nerve entrapment behind only carpal tunnel syndrome.[1] Despite this, no consensus exists on the outcomes to be reported in natural history or interventional studies on UNE. Surprisingly, there remains a lack of agreement regarding the optimal treatment for one of the most common surgically treated pathologies that a nerve surgeon encounters. This is primarily due to the difficulty one encounters when trying to assess the literature. Outcomes are inconsistently reported, which makes comparing studies or developing meta-analyses difficult or even impossible. Thus, there is a need for a core outcome set (COS) that can be used in guiding the design and reporting of future studies.

Although a COS is desperately needed for UNE, this is additionally true across all of nerve surgery. Especially for pathologies that occur less frequently, the ability to combine and analyze data across studies is paramount for evidence-based practice. The Core Outcome Measures in Effectiveness Trials (COMET) initiative is trying to address this by promoting the creation of COSs.[2,3] This initiative has been taken up by multiple fields, and there is an increasing number of COSs available. However, nerve surgery has been deficient to this point. To address this deficiency, we developed an international consortium of nerve neurosurgeons, the Core Outcomes in Nerve Surgery (COINS) Consortium, to develop COSs for the pathologies encountered in nerve surgery. The goal of the current study was to develop a COS for UNE (COS-UNE) using a modified Delphi approach.

Methods

Study Overview

At the outset, the scope of the COS-UNE was defined. The COS-UNE is intended to be used for all future neurosurgical human clinical research studies focused on UNE, including natural history studies, retrospective cohort studies, prospective registries, and clinical trials. Correspondingly, the COS-UNE is intended to be incorporated into everyday clinical practice by all neurological surgeons commonly evaluating and treating UNE. The term "outcome" is used in this study to mean any preoperative or postoperative data points intended to be collected. The study was submitted for registration in the COMET database (https://www.comet-initiative.org) and will be added at the time of publication.

The study was divided into five stages: stage 1, consortium development; stage 2, literature review to identify potential outcome measures; stage 3, modified Delphi survey to develop a consensus on outcomes for inclusion; stage 4, modified Delphi survey to develop definitions; and stage 5, consensus meeting to finalize the COS and definitions. The study followed the Core Outcome Set-STAndards for Development (COS-STAD) recommendations.[2]

Study Design and Process

Stage 1: Consortium Development

The recommended panel size is between 10 and 18 members.[4] In many survey-based studies, sample size is one of the key features in determining generalizability and study quality. Studies using a Delphi approach do not rely on panel size but instead rely on the expertise of the members of the consortium.[5] Correspondingly, experts in the field of nerve surgery, representing multiple countries and continents and at various career stages, were invited to participate in the consortium. All invited participants were neurological surgeons. The leadership from the American Association of Neurological Surgeons/Congress of Neurological Surgeons Section on Disorders of the Spine and Peripheral Nerves Peripheral Nerve Division, World Federation of Neurosurgical Societies Peripheral Nerve Committee, and European Association of Neurosurgical Societies Peripheral Nerve Committee were included in the consortium. These individuals were queried for recommendations for other potential participants. Those who were recommended were invited to participate. There were otherwise no specific inclusion criteria. Note that the COS generated in this study was not specifically endorsed by any of these organizations. We assumed a 70% rate of agreement to participate and invited 26 potential expert participants, targeting a panel size of 18. After invitation, 21 experts agreed to participate and formed the consortium. The consortium is referred to as the COINS Consortium.

Stage 2: Literature Review to Identify Potential Outcome Measures

The literature was reviewed for any literature reviews, systematic reviews, or survey studies examining the use of outcome measures in research studies on UNE. Five studies were identified and used to generate the preliminary list of potential outcome measures.[6–10] The preliminary list consisted of 36 outcomes to consider for inclusion in the COS-UNE.

Stage 3: Modified Delphi Survey to Develop a Consensus on Outcomes for Inclusion

The survey was developed according to the modified Delphi methodology to have at least two rounds (we used three rounds), to allow participants to view the responses and change their responses between rounds, and to have the responses be anonymous.[3,4,11] The members of the con-

sortium were provided a summary of the responses between rounds. Use of this technique has been shown to build consensus.[12]

The survey process was carried out entirely electronically. The survey utilized in the first round consisted of the 36 outcomes identified during the literature review but also provided respondents the ability to write in additional outcomes for consideration in future survey rounds. During round 1, an additional 26 outcomes were suggested for evaluation. Rounds 2 and 3 assessed a total of 62 outcomes. For each outcome, participants were asked to rate the importance of the outcome by using a Likert scale from 1 to 9: 1–3, not important to include; 4–6, important but not critical to include; and 7–9, critical to include.

For outcomes, we agreed a priori that ≥ 70% of participants rating that outcome as critical to include (Likert scale score 7, 8, or 9) would be the threshold for inclusion in the COS. All 21 members of the consortium were invited to complete round 1 of the survey. We agreed that if any consortium member did not respond by the deadline in two consecutive rounds, they would be excluded from future participation. No consortium member was excluded on the basis of this criterion.

Stage 4: Modified Delphi Survey to Develop Definitions

Each outcome that reached consensus in stage 3 was examined for whether it needed to be further defined. A modified Delphi survey was used again for those outcomes that needed further definition. For example, how would a postoperative hematoma be defined or what scale would be used to assess manual motor testing? The survey process was carried out entirely electronically. In round 1, participants were asked to provide write-in answers. For rounds 2 and 3, the responses from round 1 were voted on. Respondents were asked to choose their preferred definition. Consortium members were provided a summary of responses between rounds. A plurality was required to select a definition/method of implementation.

Stage 5: Consensus Meeting to Finalize the COS and Definitions

At the conclusion of the Delphi surveys (stages 3 and 4), an online forum was provided to all participants for comments and discussion. Consortium participants were asked to comment on the COS and definitions and to provide agenda items for a consensus meeting. They were asked to indicate any included outcomes or definitions that they would like to argue against inclusion, as well as any excluded outcomes or definitions that they would like to argue in favor of inclusion. At the end of the public discussion, no agenda items were requested. As a result, the final COS and definitions generated through the Delphi process were considered final in lieu of a meeting.

Statistical Analysis

Descriptive statistics are provided as number (%).

Results

Consortium Participants

The consortium comprised 21 participants, all neurological surgeons representing 11 countries. The countries represented included the United States (n = 10), Canada (n = 2), Argentina (n = 1), Australia (n = 1), Austria (n = 1), Brazil (n = 1), Germany (n = 1), Israel (n = 1), Mexico (n = 1), the Netherlands (n = 1), and Serbia (n = 1).

Outcomes

Table 1 summarizes the outcomes considered for inclusion and the final results of the Delphi survey. Among the 62 outcomes considered, 18 met the threshold for inclusion. It was agreed upon a priori to include age, sex, and race, in addition to the 18 outcomes that met the inclusion threshold. At the definitions stage, infection was split into superficial infection and deep infection. Thus, 22 data points/outcomes were included in total.

Definitions

The modified Delphi process was used to provide definitions for the following outcomes: 1) electrodiagnostics, i.e., what electrodiagnostic parameters to include; 2) McGowan classification, whether to use the original[13] or the modification proposed by Goldberg et al.;[14] 3) ulnar nerve subluxation, definition; 4) medical comorbidities, what comorbidities to include; 4) manual motor testing, what scale to use and what muscles to be tested; 5) 2-point discrimination, whether to use static 2-point discrimination, dynamic 2-point discrimination, or both; 6) patient satisfaction, what scale/metric to use; 7) infection, definition; 8) hematoma, definition; 9) seroma, definition; 10) medial antebrachial cutaneous nerve injury, definition; 11) wound dehiscence, definition; and 12) complex regional pain syndrome, what criteria to use. The agreed upon definitions and methods of implementation are reflected in the final COS-UNE. The Goldberg modification of the McGowan classification was selected.[14] For manual motor testing, the modified Medical Research Council scale was selected.[15] The Budapest criteria were selected for the diagnosis of complex regional pain syndrome.[16,17] The consensus minimum postoperative follow-up for any study on UNE was 6 months, with the optimal timepoints for assessment being preoperatively, 3 months postoperatively, 6 months postoperatively, and 12 months postoperatively.

Final COS-UNE

Tables 2–4 present the final COS-UNE, including definitions, in three parts: part 1) preoperative outcomes/data (Table 2); part 2) preoperative and postoperative outcomes/data (Table 3); and part 3) postoperative outcomes/data (Table 4). Table 5 presents a timeline for evaluation and outcome assessment based on the final COS-UNE.

Discussion

Within nerve surgery, there is a strong need to be able to combine data across surgeons and across institutions in order to allow evidence-based decisions. There is also a need to develop prospective registries to help us better understand prognostic factors and to improve surgical decision-making. The major issue preventing the combination of data in a retrospective fashion, either into a database or in a meta-analysis, is that there is no consensus on the

TABLE 1. Potential outcomes rated on the Likert scale

Outcome*	Total Respondents	Vote to Include	Vote to Exclude	Include/ Exclude
Electrodiagnostics	19	19 (100)	0 (0)	Include
McGowan classification	19	15 (79)	4 (21)	Include
Ulnar nerve subluxation	19	17 (89)	2 (11)	Include
Duration of symptoms	19	19 (100)	0 (0)	Include
Medical comorbidities	19	18 (95)	1 (5)	Include
Ultrasound	19	5 (26)	14 (74)	Exclude
MRI	19	0 (0)	19 (100)	Exclude
Dellon classification	19	0 (0)	19 (100)	Exclude
Wilson-Krout classification	19	0 (0)	19 (100)	Exclude
Tinel sign	19	7 (37)	12 (63)	Exclude
Assessment for double crush	19	6 (32)	13 (68)	Exclude
Family history of neuropathy/neurocutaneous disorder	19	5 (26)	14 (74)	Exclude
Patient diagram of symptom distribution	19	3 (16)	16 (84)	Exclude
LSUMC grade	19	1 (5)	18 (95)	Exclude
Elbow flexion test	19	1 (5)	18 (95)	Exclude
Scratch collapse test	19	0 (0)	19 (100)	Exclude
Occupation	19	10 (53)	9 (47)	Exclude
Modified Bishop score	19	0 (0)	19 (100)	Exclude
Manual motor testing	19	19 (100)	0 (0)	Include
Dynamometry	19	8 (42)	11 (58)	Exclude
Independent motor evaluation	19	3 (16)	16 (84)	Exclude
2-point discrimination	19	18 (94)	1 (6)	Include
Semmes-Weinstein monofilament	19	1 (5)	18 (95)	Exclude
NRS				
Overall pain	19	11 (58)	8 (42)	Exclude
Ulnar distribution pain	19	18 (95)	1 (5)	Include
Visual analog scale				
Overall pain	19	3 (16)	16 (84)	Exclude
Ulnar distribution pain	19	11 (58)	8 (42)	Exclude
McGill pain questionnaire	19	0 (0)	19 (100)	Exclude
LANSS	19	0 (0)	19 (100)	Exclude
PROMIS–pain	19	1 (5)	18 (95)	Exclude
DN4 questionnaire	18	0 (0)	18 (100)	Exclude
Pain Catastrophizing Inventory	19	1 (5)	18 (95)	Exclude
Neuropathic Pain Inventory	19	0 (0)	19 (100)	Exclude
BPI	19	1 (5)	18 (95)	Exclude
Zung Self-Rating Depression Scale questionnaire	19	1 (5)	18 (95)	Exclude
SCL-10	19	1 (5)	18 (95)	Exclude
SMDDS	19	1 (5)	18 (95)	Exclude
Neuro-QOL				
Anxiety	19	1 (5)	18 (95)	Exclude
Depression	19	1 (5)	18 (95)	Exclude
Upper extremity	18	1 (6)	17 (94)	Exclude
HADS	19	1 (5)	18 (95)	Exclude
Beck's Depression Inventory	19	0 (0)	19 (100)	Exclude
PRUNE	18	2 (11)	16 (89)	Exclude
DASH	19	16 (84)	3 (16)	Include
QuickDASH	19	3 (16)	16 (84)	Exclude
MHQ	19	0 (0)	19 (100)	Exclude
Novak Survey	19	0 (0)	19 (100)	Exclude
UNEQ	19	1 (5)	18 (95)	Exclude
EQ-5D-5L	19	2 (11)	17 (89)	Exclude
BCTQ	19	0 (0)	19 (100)	Exclude
PREE	19	2 (11)	17 (89)	Exclude
Patient satisfaction	19	19 (100)	0 (0)	Include
Patient satisfaction w/ wound appearance	19	3 (16)	16 (84)	Exclude
Return to work	19	19 (100)	0 (0)	Include
Narcotic use	19	14 (74)	5 (26)	Include
Brief resiliency score	19	0 (0)	19 (100)	Exclude
Complication				
Infection	19	19 (100)	0 (0)	Include
Hematoma	19	19 (100)	0 (0)	Include
Seroma	19	17 (89)	2 (11)	Include
Medial antebrachial cutaneous nerve injury	19	19 (100)	0 (0)	Include
Wound dehiscence	19	18 (95)	1 (5)	Include
Complex regional pain syndrome	19	19 (100)	0 (0)	Include

BCTQ = Boston Carpal Tunnel Questionnaire; BPI = Brief Pain Inventory; DN4 = Douleur Neuropathique 4; HADS = Hospital Anxiety and Depression Scale; LANSS = Leeds Assessment of Neuropathic Symptoms and Signs; LSUMC = Louisiana State University Medical Center; MHQ = Michigan Hand Outcomes Questionnaire; Neuro-QOL = Quality of Life in Neurological Disorders; PREE = Patient-Rated Elbow Evaluation; PROMIS = Patient-Reported Outcomes Measurement Information System; PRUNE = Patient-Rated Ulnar Nerve Evaluation; SCL-10 = Symptom Checklist-10; SMDDS = Symptoms of Major Depressive Disorder Scale; UNEQ = Ulnar Nerve at the Elbow Questionnaire.
* Outcomes were ranked as follows according to the Likert scale: 1–3, not important to include; 4–6, important but not critical to include; and 7–9, critical to include. A rating of 7–9 was considered a vote to include, whereas 1–6 was considered a vote to exclude. At least 70% of respondents had to vote to include the outcome measure in order for it to be included in the final core outcome set.

TABLE 2. The final COS-UNE comprised 22 outcomes/data points: part 1 included the following 8 data points to be collected preoperatively

COS-UNE Part 1: Preop Data	
Data Element/ Outcome	Definition or Scale*
Age	
Sex	
Race	
Duration of symptoms	
Medical comorbidities	Diabetes, peripheral neuropathy, vasculitis, tobacco smoking (pack-year history, current/ former/never smoker), obesity (body mass index), elbow trauma
McGowan classification	Goldberg modification of the McGowan Scale
Presence of ulnar nerve subluxation/ dislocation	Subluxation: determined by palpation or ultrasound, anterior movement of the ulnar nerve from the retrocondylar groove w/ elbow flexion Dislocation: determined by palpation or ultrasound, movement of the ulnar nerve anterior to the medial epicondyle w/ elbow flexion
Electrodiagnostics	Ulnar motor conduction velocity Ulnar sensory conduction velocity Ulnar nerve conduction velocity across elbow Ulnar nerve conduction velocity below elbow EMG of 1st dorsal interosseous muscle EMG of abductor digiti minimi muscle

EMG = electromyography.
* The minimum duration of follow-up is 6 months. The optimal timepoints for assessment include preoperatively and 3, 6, and 12 months postoperatively.

TABLE 3. The final COS-UNE comprised 22 outcomes/data points: part 2 included the following 5 data points to be collected preoperatively and postoperatively

COS-UNE Part 2: Preop & Postop Data	
Data Element/Outcome	Definition or Scale*
MMT	Modified Medical Research Council scale (0, 1, 2, 3, 4–, 4, 4+, 5) Muscles to be tested: Flexor digitorum profundus IV/V Flexor carpi ulnaris Adductor pollicis Dorsal interossei Abductor digiti minimi
2-point discrimination	Static 2-point discrimination (millimeters)
Ulnar nerve distribution pain	NRS (range 0–10)
DASH	
Narcotic use	Average MME/day

MME = morphine milligram equivalent; MMT = manual motor testing.
* The minimum duration of follow-up is 6 months. The optimal timepoints for assessment include preoperatively and 3, 6, and 12 months postoperatively.

outcomes to be tracked and/or reported. This lack of consistency makes meaningful combination of data difficult and in many cases impossible. One might think that this is only an issue for rare pathologies, but this is not true. UNE is the second most common upper-extremity entrapment neuropathy, affecting 1%–6% of the population.[1] Despite the high incidence of this condition, there remains a lack of consensus regarding treatment. As examples, should the primary operation be simple in situ decompression or some form of transposition, and what is the optimal surgical treatment when the ulnar nerve dislocates on examination? There is significant disagreement among experts in the field regarding these questions. Despite there being numerous published studies on the topic of UNE, inconsistency in outcomes reporting has made meta-analysis very difficult, and thus, there is a lack of consensus despite the volume of publications.[7,9,10] This has become clear as multiple nerve surgery societies have attempted to create guidelines for the treatment of UNE. This is a major issue facing our field and necessitates the development of COSs.

There have been multiple initiatives, including the COMET initiative, promoting the creation of COSs across fields of medicine. COSs exist or are in progress for a variety of neurological and neurosurgical conditions.[18–27] Peripheral nerve neurosurgery lags behind in this regard, with the current study representing the first effort to develop a COS. Multiple methods for developing COSs have been proposed. The current study adheres to the COS-STAD recommendations.[2] COSs are intended to be pathology specific and need to have a defined scope to be useful. In the current study, we developed the COS-UNE. The COS-UNE is intended to be used in all future neurosurgical human clinical research studies focused on UNE, including natural history studies, retrospective cohort studies, prospective registries, and clinical trials. Correspondingly, the COS-UNE is intended to be incorporated into everyday clinical practice by all clinicians commonly evaluating and treating UNE. Because the COINS Consortium consists of neurosurgeons, this is intended to be adopted by neurosurgeons for future studies, especially multicenter studies. However, this COS is broadly applicable for all clinicians (e.g., orthopedic surgeons, plastic surgeons, hand surgeons, physiatrists, neurologists, occupational therapists, physical therapists) evaluating or studying UNE. We hope that our colleagues in other fields will also consider adopting the COS generated in this study.

We formed an international group of neurological surgeons with significant expertise in UNE to develop the COS. The COINS Consortium plans to develop COSs across nerve surgery. We utilized a modified Delphi method to develop the current COS. Several features of the Delphi method are important. The responses are independent and anonymous, and participants are allowed to change their responses between rounds. The method's strength relies on the expertise, rather than the number, of the participants. The participants are not provided any guidance on how to rate each potential outcome. As a result, several factors likely go into the decision, including the neurobiopsychometric properties (e.g., sensitivity to change),

TABLE 4. The final COS-UNE comprised 22 outcomes/data points: part 3 included the following 9 data points to be collected postoperatively

COS-UNE Part 3: Postop Data	
Data Element/ Outcome	Definition or Scale*
Patient satisfaction	NRS (range 0–10)
Return to work	
Complications	
Superficial infection	Local swelling, tenderness, and/or redness, w/ or w/o discharge (i.e., clinical signs of infection) that requires antibiotic treatment
Deep infection	Clinical signs of infection requiring reoperation for drainage/debridement
Hematoma	Postop blood collection requiring reoperation or altered postop follow-up and/or care (e.g., increased pain medication)
Seroma	Symptomatic serous fluid collection requiring drainage or reoperation
MABC nerve injury	New postop pain, altered sensation (hypesthesia or hyperesthesia), or paresthesias along the medial forearm (MABC distribution)
Wound dehiscence	Wound opening requiring reoperation, wound management, or change in typical postop care
Complex regional pain syndrome	Complex regional pain syndrome as defined by the Budapest criteria

MABC = medial antebrachial cutaneous.
* The minimum duration of follow-up is 6 months. The optimal timepoints for assessment include preoperatively and 3, 6, and 12 months postoperatively.

TABLE 5. Timeline for assessing each of the included outcomes/ data points

Outcome/Data	Preop	3 mos Postop	6 mos Postop*	12 mos Postop
Age	X			
Sex	X			
Race	X			
Duration of symptoms	X			
Medical comorbidities	X			
McGowan classification	X			
Presence of ulnar nerve subluxation/dislocation	X			
Electrodiagnostics	X			
MMT	X	X	X	X
2-point discrimination	X	X	X	X
Ulnar nerve distribution pain assessment	X	X	X	X
DASH	X	X	X	X
Narcotic use assessment	X	X	X	X
Patient satisfaction assessment		X	X	X
Return to work assessment		X	X	X
Complication				
Superficial infection		X	X	X
Deep infection		X	X	X
Hematoma		X	X	X
Seroma		X	X	X
Medial antebrachial cutaneous nerve injury		X	X	X
Wound dehiscence		X	X	X
Complex regional pain syndrome		X	X	X

MMT = manual motor testing.
* Minimum recommended postoperative follow-up duration.

popularity, ease of implementation, and personal experience. Owing to the expertise of each individual participant and ultimately the consortium coming to a consensus, all of these important factors are reflected in the final COS. Thus, it is important to recognize that the COS does not simply represent the list of outcomes with the strongest neurobiopsychometric properties because other factors are also considered in every individual's decision, which is ultimately reflected in the consensus.

UNE can present with a variety of symptoms, including weakness, numbness, pain, paresthesias, reduced dexterity, reduced sleep quality, reduced ability to complete daily tasks, and/or reduced ability to perform vocation-related tasks. Thus, an intervention's success could be judged in multiple ways. An optimal COS would address all of these facets of the pathology. Furthermore, it has been suggested that objective measures of strength and sensation complement patient-reported outcomes and utilization of both together is the best strategy for assessing outcomes.[8] The COS-UNE developed in this study achieves this by blending objective measures, such as manual motor testing and static 2-point discrimination, and patient-reported outcome measures, such as scores on the Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) and Numeric Rating Scale (NRS) for ulnar distribution pain. A high threshold was set for inclusion (≥ 70%), suggesting a strong consensus. All of the included outcomes had a very strong consensus, with only McGowan classification (79%) and narcotic use (74%) having less than 80% consensus. We also established definitions for the outcomes and the scales to be used for assessment. This is critical because outcomes are only comparable if the same metrics and scales are used and applied in a consistent fashion across studies.[6] The consensus was for a minimum follow-up of 6 months, with the ideal timepoints for assessment being preoperatively and 3, 6, and 12 months postoperatively.

The final COS-UNE comprised 22 data points/outcomes (Tables 2–5). The main patient-reported outcome included in the COS-UNE is score on the DASH questionnaire.[28] The DASH questionnaire score has been previously shown to correlate well with other evaluative measures in UNE.[29] However, the DASH questionnaire score was previously reported not to correlate with ulnar neuropathy severity, as assessed on the basis of compound muscle action potential amplitude.[30] Other measures, including the

Michigan Hand Questionnaire and Boston Carpal Tunnel Questionnaire, are more responsive than the DASH questionnaire for UNE, though the DASH questionnaire has been shown to be responsive to change.[8] The minimum clinically important differences in DASH score at 3, 6, and 12 months postoperatively for UNE have been shown to be 8, 7, and 7 points, respectively.[31] Although the DASH questionnaire has reasonable neurobiopsychometric properties, this is one example where the outcome measure with the strongest neurobiopsychometric properties was not chosen. The DASH questionnaire was chosen despite this for multiple reasons, including strong (though not the strongest) neurobiopsychometric properties, ease of implementation, current popularity, and historical popularity in the literature. In a survey of nerve specialists across specialties, DASH/QuickDASH was far and away the most used patient-reported outcome metric for the assessment of UNE.[6] Given that this COS is intended to be incorporated into everyday practice, the current use and popularity of an outcome metric is important. Furthermore, in the historical literature on UNE, DASH/QuickDASH is the most commonly reported patient-reported outcome.[7] One of the major goals of creating a COS is to allow synthesis and comparison of data across studies. This includes, when possible, allowing for comparison to and synthesis with previously reported studies. By including the DASH questionnaire, this allows future studies to be compared against or analyzed with the most previously reported studies. Thus, multiple factors went into the decision to include the DASH questionnaire over other options.

Manual motor testing was selected as the motor outcome, with dynamometry considered the major alternative. Interrater reliability for manual motor testing of the hand has been shown to have substantial to near perfect agreement (kappa 0.72–0.93), though dynamometry performs even better with near perfect agreement (kappa 0.92–0.98).[32,33] The major consideration of the group, and one that has been pointed out by others, was that standard pinch and grip dynamometry is not a pure test of ulnar nerve function but rather is heavily influenced by median and radial nerve function as well.[34] Manual motor testing has been shown to have a good correlation with ulnar nerve motor conduction studies.[35] Thus, although there are advantages and disadvantages of manual motor testing compared with dynamometry, the consensus for manual motor testing was strong with 100% of the consortium voting to include this outcome.

We developed a strong consensus COS that covers multiple domains important to evaluating UNE. However, it is important to understand what a COS is and what it is not. It should be understood to be a minimum, consistent, core set of data that should be collected in all studies on UNE. Ideally, this would be incorporated into routine clinical practice. It should not be understood to be the totality of data that should be collected to answer any specific research question. Other data points or outcome measures may need to be layered on to this foundation to address specific research questions.

Despite the push to develop COSs broadly across medicine, a recent study suggested that only a minority of late phase clinical trials reference a COS. This was seen by the authors as a major limitation for data synthesis. The authors also suggest that this low uptake may be due to the lack of appropriate COSs.[36] This is certainly true within peripheral nerve neurosurgery. Thus, it is incumbent upon us to develop COSs for future use. There are currently multiple registries and clinical trials in the design phase for peripheral nerve pathologies, and these studies would benefit from using a COS. Furthermore, protocol approval and funding decisions, in the future, are likely to require the use of COSs, when available. Thus, these efforts are important not only for improving data synthesis but also to help with funding access for future studies.

Strengths and Limitations

The strengths of the study include adherence to a rigorous modified Delphi process, with strong consensus reached using an a priori 70% agreement threshold for inclusion, participation by multiple experts in nerve surgery representing 11 countries, incorporation of outcome measures that do not require the purchase of additional equipment, and clarification of outcome definitions and follow-up timepoints to allow for consistent application.

The limitations include the absence of surgeons from Asia and Africa and all participants being neurological surgeons. The COINS Consortium consists only of neurological surgeons, which is both a strength and limitation. The major purpose for developing the COS was to allow for it to be used in the design phase of multi-institutional studies on UNE that are in the planning phases by neurological surgeons and all other future studies on UNE conducted by neurological surgeons. As such, the opinions of neurological surgeons were sought. By including only neurological surgeons, there is a more homogeneous approach to diagnosis, surgical treatment, and postoperative evaluation. This makes developing consensus more straightforward. However, the inclusion of only neurological surgeons is also a weakness. The impact would be greater if our colleagues in other fields would also adopt the COS, and the lack of their inclusion in the consortium may make this less likely. We believe the COS generated in this study is applicable broadly across fields, but we want to emphasize that the primary purpose was to create a COS to be used in future neurosurgical studies. We plan to engage plastic, orthopedic, and hand surgery societies to develop a plan for generating a multispecialty COS and will utilize the strong neurosurgical consensus represented in this COS as a starting point. Despite the lack of involvement of plastic, orthopedic, and hand surgeons in the consortium, the COS is in line with what the majority of nerve surgeons, including those of other specialties, reported in a previous survey and is also in line with the most commonly reported outcomes in the previous literature, thereby suggesting that uptake by other specialties may be feasible.[6,7]

Conclusions

The COINS Consortium has developed a COS-UNE consisting of 22 data points/outcomes that have a strong consensus. The COS-UNE covers multiple domains important in the assessment of UNE. We have identified the

data points/outcomes and have also provided the definitions and specific scales to be utilized to help ensure that we are consistent in our reporting across studies. This COS should serve as a minimum set of data to be collected in all future human neurosurgical clinical research studies on UNE. We hope that clinicians evaluating ulnar neuropathy will incorporate this COS into routine practice and that future studies will consider this COS in the design phase. We also hope that reviewers of scientific manuscripts and editors of journals will consider this COS when assessing future manuscripts for suitability for publication.

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