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Core outcomes in nerve surgery: development of a core outcome set for common peroneal (fibular) neuropathy

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OBJECTIVE Common peroneal (fibular) neuropathy is the most common mononeuropathy of the lower extremity. Despite this, there are surprisingly few studies on the topic, and a knowledge gap remains in the literature. As one attempts to address this knowledge gap, a core outcome set (COS) is needed to guide the planning phases of future studies to allow synthesis and comparability of these studies. The objective of this study was to develop the COS—common peroneal neuropathy (CoPe) using a modified Delphi approach.

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

RESULTS The Core Outcomes in Nerve Surgery (COINS) Consortium comprised 23 participants, all neurological surgeons, representing 13 countries. The final COS-CoPe consisted of 31 data points/outcomes covering domains of demographics, diagnostics, patient-reported outcomes, motor/sensory outcomes, and complications. Appropriate instru-

ABBREVIATIONS BPUE = brachial plexus and upper extremity nerve injuries; COINS = Core Outcomes in Nerve Surgery; COMET = Core Outcome Measures in Effectiveness Trials; CoPe = common peroneal neuropathy; COS = core outcome set; CRPS = complex regional pain syndrome; LEFS = Lower Extremity Functional Scale; MMT = manual motor testing; MRC = Medical Research Council; NRS = numeric rating scale; PRO = patient-reported outcome; ROM = range of motion; SF-36 = Short Form-36; STAD = STAndards for Development; UNE = ulnar neuropathy at the elbow; VAS = visual analog scale.

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ments, methods of testing, and definitions were set. The consensus minimum duration of follow-up was 12 months. The consensus optimal time points for assessment were preoperatively and 3, 6, 12, and 24 months postoperatively.

CONCLUSIONS The COINS Consortium developed a consensus COS and provided definitions, methods of implementation, and time points for assessment. The COS-CoPe should serve as a minimum set of data that should be collected in all future neurosurgical studies on common peroneal neuropathy. Incorporation of this COS should help improve consistency in reporting, data synthesis, and comparability, and should minimize outcome reporting bias.

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KEYWORDS common fibular nerve; common fibular neuropathy; common peroneal nerve; common peroneal neuropathy; core outcome set; lower extremity; peripheral nerve

COMMON peroneal (fibular) neuropathy is the most common mononeuropathy of the lower limb.¹ Despite this, there are few, if any, large outcomes studies in the literature.² This lack demonstrates the need for additional studies to best understand and optimize the treatment of common peroneal neuropathy. Common peroneal neuropathy affects multiple domains of life, including motor function, sensation, pain, gait, vocational activities, and athletic pursuits. These effects on multiple domains raise the issue of how best to assess outcomes associated with the natural history or treatment of common peroneal neuropathy. This is a common problem in medicine and has been one of the impetuses to develop core outcome sets (COSs). COSs ensure that we are assessing a broad array of the dimensions that are affected by a given disorder, unify data reporting, and allow synthesis and comparison of data across studies. One of the strongest initiatives pushing the development of COSs is the Core Outcome Measures in Effectiveness Trials (COMET) initiative.^{3,4} There is a need to develop COSs across medicine, across peripheral nerve surgery, and specifically for common peroneal neuropathy. We have formed the Core Outcomes in Nerve Surgery (COINS) Consortium to accomplish the task of developing COSs across peripheral nerve surgery. We have already developed the COS–ulnar neuropathy at the elbow (COS–UNE) and the COS–brachial plexus and upper extremity nerve injuries (COS–BPUE).^{5,6} The goal of the current study was to develop a COS for common peroneal neuropathy (COS–CoPe). In this paper, we report the results of our modified Delphi approach to developing the COS–CoPe.

Methods

Study Overview

At the outset, the scope of the COS–CoPe was defined. The COS–CoPe is intended to be used for all future neurosurgical studies on common peroneal neuropathy, inclusive of entrapment neuropathy, traumatic injuries, inflammatory/autoimmune, and peroneal intraneural/extraneural ganglion cysts. The COS–CoPe is designed to be integrated into everyday clinical practice by all neurological surgeons treating common peroneal neuropathy. The study was submitted for registration in the COMET database (<https://www.comet-initiative.org/About/SubmitNewStudy>) and will be added at the time of publication.

The methodology has been previously described.⁶ Briefly, the study was divided into 5 stages: 1) stage 1, consortium development; 2) stage 2, a literature review to identify potential outcome measures; 3) stage 3, a modified

Delphi survey to develop consensus on outcomes for inclusion; 4) stage 4, a modified Delphi survey to develop definitions; and 5) stage 5, a consensus meeting to finalize the COS and definitions.⁵ As with our previous work, the study followed the COS–STAndards for Development (COS–STAD) recommendations.³

Study Design and Process

Stage 1: Consortium Development

Development of the COINS Consortium has been previously described.⁶ Because Delphi studies rely on the expertise of the panel members, rather than on the size of the panel, we included international experts in nerve surgery.⁷ All members of the consortium are neurosurgeons. Similar to our previous work, while the members of the COINS Consortium were selected from other national and international organizations, including the leadership from the AANS/CNS 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, the COS generated in this study is not specifically endorsed by any of these organizations. The previous COINS Consortium comprised 23 expert nerve neurosurgeons.⁶ All 23 members agreed to participate in the current project.

Stage 2: Literature Review to Identify Potential Outcome Measures

We used a recent systematic review of outcomes reporting in common peroneal neuropathy to generate the preliminary list of potential outcome measures for consideration.² All outcomes identified in the systematic review were included. The preliminary list consisted of 56 outcomes to consider for inclusion in the COS–CoPe.

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

To adhere to the critical elements of the Delphi methodology, we used 3 rounds of anonymous survey, and we allowed participants to view the responses and change their responses between rounds.^{4,8,9} As a technique to build consensus, participants were provided a summary of responses between rounds, followed by an open period of discussion between each round of the survey.¹⁰

The survey process was conducted entirely electronically. During round 1, 56 potential outcomes were assessed. Respondents were also allowed to write-in additional outcomes for consideration in subsequent survey

rounds. All write-in outcomes were added to rounds 2 and 3. All suggested outcomes were included, and there were no specific criteria for consideration. During round 1, an additional 20 outcomes were suggested for evaluation, yielding 76 outcomes for consideration in rounds 2 and 3. For each outcome, participants were asked to rate the importance of the outcome on a Likert scale from 1 to 9: 1–3 being not important to include, 4–6 being important but not critical to include, and 7–9 being critical to include.

Following the same methodology as before, we agreed a priori that $\geq 70\%$ of participants rating that data point/outcome as critical to include (Likert score 7, 8, or 9) was the threshold for inclusion in the COS.^{5,6} All 23 members of the consortium were invited to complete round 1. We agreed that consortium members would be excluded from future rounds, if the member did not respond by the deadline in 2 consecutive rounds, although no consortium member was excluded based on this criterion.

Stage 4: Modified Delphi Survey to Develop Definitions

Definitions for each data point/outcome were generated during stage 4. A similar modified Delphi approach was used. As an example, patient satisfaction reached consensus. In stage 4, we defined what assessment scale would be used to evaluate patient satisfaction. The survey process was again conducted 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. Consortium members were provided a summary of responses between rounds, and an open discussion period was allowed between rounds. The definition/method of implementation was chosen by plurality, as defined a priori.

Stage 5: Consensus Meeting to Finalize COS and Definitions

Stage 5 consisted of comments and discussion via an online forum. Consortium participants were asked to comment on the COS and definitions and to provide data points/outcomes for reconsideration, for either inclusion or exclusion. Any consortium member could suggest any outcome for reconsideration. Only 1 member was required to list the data point/outcome for reconsideration. There were no other requirements for reconsideration. At the conclusion of the discussion, a vote was held on those data points/outcomes or definitions that were suggested by any member for reconsideration. Anonymity was maintained for the final vote but not during the comments and discussion. As for prior rounds, $\geq 70\%$ was used for inclusion of a data point/outcome, and a plurality was used to select a definition.

Statistical Analysis

Descriptive statistics are provided as number and percentage.

Results

Consortium Participants

The consortium comprised 23 participants, all neurological surgeons, representing 13 countries and 5 continents. The countries represented included the United

States ($n = 11$), Canada ($n = 1$), Argentina ($n = 1$), Australia ($n = 1$), Austria ($n = 1$), Brazil ($n = 1$), Germany ($n = 1$), India ($n = 1$), Israel ($n = 1$), Mexico ($n = 1$), the Netherlands ($n = 1$), Serbia ($n = 1$), and the United Arab Emirates ($n = 1$).

Outcomes

Table 1 summarizes the outcomes considered for inclusion and the final results from the Delphi survey. Among the 76 outcomes considered, 28 met the threshold for inclusion. During stage 5, the Lower Extremity Functional Scale (LEFS), EQ-5D-5L, and Neuro-QOL—lower extremity were reconsidered. The LEFS (15/21, 71%) and EQ-5D-5L (15/20, 75%) were voted to be critical to include. At the definitions stage, infection was split into superficial infection and deep infection. Thus, 31 data points/outcomes were included in the final COS-CoPe.

Definitions

The modified Delphi process was used to provide definitions for the following outcomes: 1) medical comorbidities (what comorbidities to include); 2) manual motor testing (MMT; what scale to use); 3) lumbar radiculopathy (definition); 4) patient satisfaction (what scale/metric to use); 5) infection (definition); 6) hematoma (definition); 7) seroma (definition); 8) complex regional pain syndrome (CRPS; what criteria to use); and 9) wound dehiscence (definition). The agreed upon definitions and methods of implementation are reflected in the final COS-CoPe. For MMT, the modified Medical Research Council (MRC) scale was selected.¹¹ The Valencia criteria were selected for the diagnosis of CRPS.¹² The consensus minimum postoperative follow-up for any study on common peroneal neuropathy was 12 months. The optimal time points for assessment were preoperatively and 3, 6, 12, and 24 months postoperatively.

Final COS-CoPe

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

Discussion

COSs improve research in numerous ways. Because of these recognized benefits, there has been a strong push across fields of medicine to develop COSs. We formed the COINS Consortium to address the need for COSs in nerve surgery. We previously published COSs for ulnar neuropathy at the elbow (COS-UNE) and brachial plexus and upper extremity nerve injuries (COS-BPUE).^{5,6} The current project developed the COS-CoPe.

Common peroneal neuropathy is the most common mononeuropathy in the lower extremity and third most common mononeuropathy overall, trailing only carpal tunnel syndrome and UNE;¹ despite this, there are few large studies focused on common peroneal neuropathy.² To address this knowledge gap, multicenter registries are

TABLE 1. Potential outcomes rated on the Likert scale

Outcome	Vote to Include (%)			Include/Exclude
	Round 1	Round 2	Round 3	
Electrodiagnostics	100	100	100	Include
Imaging: MRI or ultrasonography	NA	90	96	Include
MRI	65	62	57	Exclude
Ultrasonography	52	55	52	Exclude
Age	91	95	100	Include
Sex	74	86	83	Include
Race	17	14	17	Exclude
Occupation	48	43	30	Exclude
Symptom duration	100	100	100	Include
Medical comorbidities	91	100	100	Include
Mechanism of injury	91	95	100	Include
Scratch collapse test	0	0	0	Exclude
Tinel test	61	62	69	Exclude
BMI	NA	52	73	Include
Hx of knee surgery	NA	80	100	Include
Hx of knee trauma	NA	86	100	Include
Leg crossing	NA	48	39	Exclude
Hx of weight loss	NA	45	30	Exclude
Neurofibromatosis/schwannomatosis	NA	67	78	Include
Lumbar radiculopathy	NA	76	96	Include
CPRS	NA	71	87	Include
MMT	100	100	100	Include
Active ROM	61	62	65	Exclude
Passive ROM	57	67	74	Include
Dynamometry	13	13	4	Exclude
Formal gait analysis	41	24	9	Exclude
Orthotic use	NA	71	91	Include
Walking time	NA	19	4	Exclude
Walk on heels	NA	43	39	Exclude
Semmes-Weinstein monofilament	14	0	0	Exclude
2-point discrimination	27	10	0	Exclude
Ten test	9	0	4	Exclude
Pin prick	36	10	0	Exclude
Thermal testing	5	0	0	Exclude
Sensation (anesthesia, hypesthesia, normal)	NA	76	96	Include
PRO on sensation	NA	33	22	Exclude
Presence/absence of hyperalgesia, hypersensitivity, allodynia	NA	62	78	Include
Light touch	NA	38	35	Exclude
VAS for pain	41	30	13	Exclude
NRS for pain (overall)	76	95	96	Include
NRS for pain (common peroneal distribution)	NA	95	96	Include
Wong-Baker Faces Pain Rating Scale	0	0	0	Exclude
BPI	0	0	0	Exclude
MPQ	0	0	0	Exclude
Body diagram of pain	10	5	4	Exclude
LANSS	0	0	4	Exclude
PROMIS-pain	5	5	4	Exclude

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TABLE 1. Potential outcomes rated on the Likert scale

Outcome	Vote to Include (%)			Include/Exclude
	Round 1	Round 2	Round 3	
Pain Catastrophizing Inventory	9	5	0	Exclude
SCL-10	5	0	0	Exclude
SMDDS	5	0	0	Exclude
Zung Self-Rated Depression Scale	9	5	4	Exclude
Neuro-QOL anxiety	5	0	4	Exclude
Neuro-QOL depression	5	0	4	Exclude
HADS	5	5	4	Exclude
BDI	0	0	0	Exclude
VAS for depression	0	0	4	Exclude
DASS	NA	10	4	Exclude
LEFS	32	10	13	Exclude*
SF-36	14	5	0	Exclude
EQ-5D-5L	27	19	30	Exclude*
Neuro-QOL-lower extremity	NA	10	4	Exclude
Stanmore assessment	5	10	0	Exclude
Kitaoka assessment	0	0	0	Exclude
AOFAS assessment	0	0	0	Exclude
FAAM	5	0	0	Exclude
Patient satisfaction	82	90	91	Include
Would the patient have surgery again? yes/no	NA	62	69	Exclude
Return to work	91	95	100	Include
Pain medication use	73	90	100	Include
Terzis/Kostas grade	0	0	4	Exclude
Infection	91	100	100	Include
Hematoma	82	100	100	Include
Seroma	55	67	74	Include
Complication-CPRS	95	100	100	Include
Wound dehiscence	82	100	100	Include
Thromboembolic event	NA	57	61	Exclude

AOFAS = American Orthopedic Foot & Ankle Society; BDI = Beck Depression Inventory; BPI = Brief Pain Inventory; DASS = Depression, Anxiety, Stress Scale; FAAM = Foot and Ankle Ability Measure; HADS = Hospital Anxiety and Depression Scale; Hx = history; LANSS = Leeds Assessment of Neuropathic Symptoms and Signs; MPQ = McGill Pain Questionnaire; NA = not applicable; PROMIS = Patient-Reported Outcomes Measurement Information System; SCL-10 = Symptom Checklist-10; SMDDS = Symptoms of Major Depressive Disorder Scale.

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 “critical to include” for the outcome measure to be included in the final COS. Gray shading indicates value > 70% threshold for inclusion.

* The outcome was reconsidered during stage 5 and ultimately included in the final COS.

planned. Given that common peroneal neuropathy has effects on gait and motor function, sensation, pain, and the ability to participate in vocational and avocational activities, there would be numerous ways that outcomes could be assessed. This is one of the major drivers for developing a COS for common peroneal neuropathy. The COS will allow us to better design multicenter studies and will hopefully allow consistent design of future studies to improve data synthesis and comparability. The development of the COS-CoPe will allow for reduced research waste

and outcome reporting bias, while ensuring that outcomes are broadly evaluated in a way that the assessment is relevant to both clinician and patient.^{13,14}

As with the previous COSs developed by the COINS Consortium, the COS-CoPe is intended to be used for all future neurosurgical studies on the specific pathology under investigation (in this case, common peroneal neuropathy). This is intended to be inclusive of entrapment neuropathy, traumatic injuries, inflammatory/autoimmune, and peroneal intraneural/extraneural ganglion cysts. This

TABLE 2. The final COS-CoPe comprised 31 outcomes/data points: part 1 includes the 13 data points to be collected preoperatively

COS-CoPe Part 1: Preop Outcomes/Data	
Data Element/Outcome	Definition or Scale
Age	
Sex	
Duration of symptoms/time from injury	
Medical comorbidities	
Diabetes	
Coagulopathy	
Spinal cord injury	
Smoking (tobacco)	Pack-year Hx Current/former/never smoker
Autoimmune condition	Any autoimmune condition requiring systemic immunosuppression
Polyneuropathy	
Connective tissue disorder	
Alcohol abuse	
Peripheral vascular disease	
Electrodiagnostics	
Imaging: MRI or ultrasonography	
Mechanism of injury	
Hx of knee surgery	
Hx of knee trauma	
Obesity	BMI
Neurofibromatosis	NF1, NF2-related schwannomatosis, non-NF2-related schwannomatosis
Lumbar radiculopathy	Symptoms & signs in any lumbar nerve root distribution verified on MRI or electrophysiology
CPRS	Valencia criteria (present preop)

NF = neurofibromatosis.

The minimum duration of follow-up is 12 months. The optimal time points for assessment include preoperatively and 3, 6, 12, and 24 months postoperatively.

TABLE 3. The final COS-CoPe comprised 31 outcomes/data points: part 2 includes the 10 data points to be collected preoperatively and postoperatively

COS-CoPe Part 2: Preop & Postop Data	
Data Element/Outcome	Definition or Scale
MMT	Scale: modified MRC (0, 1, 2, 3, 4–, 4, 4+, 5)
Passive ROM	Degrees
Orthotic use	Yes/no Orthotic type
Sensation	Anesthesia/hypesthesia/normal
Altered sensation	Presence/absence of hyperalgesia, hypersensitivity, allodynia
Pain (overall)	Scale: NRS (range 0–10)
Pain (common peroneal distribution)	Scale: NRS (range 0–10)
Pain medication use	Morphine mg equivalents (MME)
EQ-5D-5L	
LEFS	

The minimum duration of follow-up is 12 months. The optimal time points for assessment include preoperatively and 3, 6, 12, and 24 months postoperatively.

Delphi methodology, and various definitions of consensus have been used throughout the literature. We previously used $\geq 70\%$ agreement in the COS-UNE and COS-BPUE. To be consistent, we agreed a priori that $\geq 70\%$ agreement would be required for data points/outcomes and that a plurality would be used for definitions.^{5,6,16} While the specific level of agreement is important, even more important to the methodology is defining the methods a priori, adhering to them, and transparently reporting them, especially the methods for generating consensus and for adding or dropping items to be considered.

The Delphi methodology is not a specific itemized guide, but rather a set of principles that must be adhered to. We strictly adhered to these principles throughout the study. First, responses were anonymous and independent. Second, participants were allowed to change their responses between rounds. Third, there was no rubric for decision-making. Participants were allowed to vote based on whatever criteria that they deemed important. As a result, each participant likely incorporated different factors into their individual votes, and the COS that was generated is not simply a list of data elements or outcomes with the strongest neurobiopsychometric properties. Instead, the COS incorporates popularity of the metric historically or in current clinical practice, ease of implementation, and neurobiopsychometric properties, among other factors.

The final COS-CoPe comprised 31 data points/outcomes (Tables 2–5). As with any good COS, these outcomes cover a broad range of domains, including motor function, sensation, pain, disability, and quality of life. This group feels strongly that one of the limitations to COSs is a lack of definitions for the outcomes and/or a lack of methods for implementation. To address this potential deficiency, we have agreed on definitions and methods of implementation, including assessment time points, as part of the process of generating the COS. The consensus was

COS was produced by neurosurgeons for use by neurosurgeons. As such, the focus is for the COS to be adopted among neurosurgeons, especially during the design phase of planned future prospective registries and multicenter studies. Despite this, we do believe the COS is applicable for all clinicians who regularly evaluate and treat common peroneal neuropathy. We hope to utilize the COS-CoPe as a baseline for discussion with our colleagues in other fields, as we seek to develop multidisciplinary consensus.

We rigorously adhered to the important tenets of the Delphi methodology that make it a powerful technique, including anonymity in responses to avoid groupthink, iteration, feedback that is controlled, and generation of consensus.^{9,15} By using these tenets, the Delphi methodology emphasizes the collective intelligence and expertise of the group and helps guide the group toward consensus. There is no prescribed level of consensus according to the

TABLE 4. The final COS-CoPe comprised 31 outcomes/data points: part 3 includes the 8 data points to be collected postoperatively

COS-CoPe Part 3: Postop Data	
Data Element/Outcome	Definition or Scale
Patient satisfaction	Scale: NRS (range 0–10)
Return to work	Time (days)
Complications	
Superficial infection	Definition: local swelling, tenderness, redness, w/ or w/o discharge (i.e., clinical signs of infection) that requires antibiotic treatment
Deep infection	Definition: clinical signs of infection requiring reop for drainage/debridement
Hematoma	Definition: postop blood collection requiring reop or altered postop follow-up &/or care (e.g., increased pain medication)
Seroma	Definition: symptomatic seroma requiring drainage or reop
CPRS	Definition: CPRS as defined by the Valencia criteria
Wound dehiscence	Definition: wound opening requiring reop, wound management, or change in typical postop care

The minimum duration of follow-up is 12 months. The optimal time points for assessment include preoperatively and 3, 6, 12, and 24 months postoperatively.

for a minimum follow-up of 12 months, with the ideal time points for assessment being preoperatively and 3, 6, 12, and 24 months postoperatively.

For motor outcomes, we included MMT assessed on the modified MRC scale and passive range of motion (ROM). With the foot drop that ensues in many patients with common peroneal neuropathy, the Achilles tendon can become tight and passive ROM can become limited. Therefore, it is important to include passive ROM, because limitation of passive ROM can have a profound effect on overall outcomes. Several scales for MMT were considered, including the MRC scale, Smith-Wilson modification to the MRC scale, and the Louisiana State University Motor Grading Scale, but ultimately the modified MRC scale was selected. In a previous survey, the modified MRC scale was the scale most commonly used in clinical practice.¹⁷ While there are limitations to MMT, the MRC has strong interrater agreement. One study found that in the lower extremity, Gwet's AC₂ ranged from 0.87 to 0.93, suggesting near-perfect agreement.¹⁸ We believe that MMT combined with passive ROM provides a reliable, reproducible, and easy-to-administer assessment of motor function.

As with our previous COSs, we considered multiple options for assessment of pain, but ultimately settled on a simple pain metric, the numeric rating scale (NRS) for both overall pain and in the common peroneal distribution. This selection aligns with clinical practice, because simple pain metrics such as the visual analog scale (VAS) and NRS are most commonly used in clinical practice and the most commonly reported pain metrics in the literature.^{2,17} The consortium favored the NRS over the VAS due to its versatility, given that the NRS can be administered graphically or verbally, while the VAS can only be administered graphically. Importantly, despite being a simple metric, the NRS shows good sensitivity to change.¹⁹

Patient-reported outcomes (PROs) have not commonly been included in previous studies on common peroneal neuropathy;² thus, comparability with previous stud-

ies was not a major consideration when deciding which PROs to include. The consortium feels strongly that PROs should be included in every COS. Simple clinician-directed assessments are not enough to understand the impact on function—especially everyday function—and quality of life. The two main PROs included in the COS-CoPe were the LEFS and the EQ-5D-5L.^{20–22} The LEFS is an easy-to-administer 20-item questionnaire. Critical to being a good PRO, the LEFS has both a validated minimum detectable change and minimal clinically important difference (MCID), both 9 points.²⁰ The metric has strong test-retest reliability and internal validity and is more sensitive to change than the Short Form-36 (SF-36) physical function subscale.²⁰ Due to its ease of administration and strong neurobiopsychometric properties, the consortium elected to include the LEFS in the final COS-CoPe.

The EQ-5D-5L was also selected for inclusion. The EQ-5D-5L is a generic assessment tool for assessing function and quality of life. The EQ-5D-5L assesses 5 domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The generic nature of the tool offers the advantage of being able to compare the impact of common peroneal neuropathy on quality of life to other diseases and pathologies. With value-based care increasingly emphasized, it is critical to understand how a given disorder and the interventions we perform affect overall quality of life, including quality-adjusted life years, and how this compares to other disorders. Thus, the inclusion of the EQ-5D-5L allows us to have a metric for assessing the global impact of common peroneal neuropathy on our patients.

The consortium voted to include imaging, either MRI or ultrasonography, in the final COS. Imaging the common peroneal nerve prior to surgery is critical for identifying peroneal intraneural and/or extraneural ganglion cysts arising from the superior tibiofibular joint. The surgical technique differs for entrapment of the common peroneal nerve versus peroneal ganglion cysts.^{23–25} Peroneal ganglion cysts are common and probably still underrecognized.

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

Outcome/Data	Preop	Postop Mos			
		3	6	12*	24
Age	X				
Sex	X				
Duration of symptoms/time from injury	X				
Medical comorbidities	X				
Electrodiagnostics	X				
Imaging: MRI or ultrasonography	X				
Mechanism of injury	X				
Hx of knee surgery	X				
Hx of knee trauma	X				
Obesity	X				
NF	X				
Lumbar radiculopathy	X				
CPRS	X				
MMT	X	X	X	X	X
Passive ROM	X	X	X	X	X
Orthotic use	X	X	X	X	X
Sensation	X	X	X	X	X
Altered sensation	X	X	X	X	X
Pain					
Overall	X	X	X	X	X
Common peroneal distribution	X	X	X	X	X
Medication use	X	X	X	X	X
EQ-5D-5L	X	X	X	X	X
LEFS	X	X	X	X	X
Patient satisfaction		X	X	X	X
Return to work		X	X	X	X
Complication					
Superficial infection		X	X	X	X
Deep infection		X	X	X	X
Hematoma		X	X	X	X
Seroma		X	X	X	X
CPRS		X	X	X	X
Wound dehiscence		X	X	X	X

The optimal time points of assessment include preoperatively and 3, 6, 12, and 24 months postoperatively.

* Minimum recommended postoperative follow-up duration.

In fact, in a cohort supposedly with negative MR images, 64% were found to have a peroneal ganglion cyst upon re-assessment.²⁶ To appropriately track outcomes, it is important to accurately identify compressive common peroneal neuropathy versus common peroneal neuropathy secondary to peroneal intraneural/extraneural ganglion cysts. Thus, ultrasonography of the common peroneal nerve or MRI of the knee to evaluate the common peroneal nerve and the superior tibiofibular joint is important in the preoperative evaluation.

As we have discussed with our previous COSs, it is important to understand both what a COS is and what it is

not. The COS-CoPe should not be seen as a comprehensive set of outcomes that would allow an investigator to answer any research question on the topic of common peroneal neuropathy. Instead, the COS-CoPe should be seen as the minimum data that should be collected in every study. During the design phase of any specific research study, the investigators should consider what other elements may need to be included in addition to the COS to answer the specific research question. The mission of the COINS Consortium is to develop COSs across nerve surgery, and we as a group and the individual members are committed to using each of the COSs we develop in all future studies. There are several multi-institutional, prospective registries and at least 1 prospective clinical trial that are currently in the design phases, and the COS-CoPe will be used in those studies. To help disseminate the COS and to encourage broad adoption, the COS will be registered in the COMET database.

Limitations of the Study

The major limitation of the COS is that the COINS Consortium consists only of neurological surgeons. This was by design, and while it is a recognized limitation, it is also a strength. The impetus for the development of the COINS Consortium was the initial discussions regarding several neurosurgical multi-institutional prospective registries and the realization that the development of COSs was critical to the success of these registries. Thus, the goal of the COINS Consortium was to develop COSs to be used by neurosurgeons. Accordingly, neurosurgeons were included in the consortium. The strength of this inclusion is that it allows a more homogeneous approach to diagnosis, treatment, and postoperative evaluation that helped facilitate consensus. The limitation is that the COS would have a larger impact if it were adopted by all specialists treating common peroneal neuropathy, and adoption of the COS may be more likely if other specialties were included. We believe that the COS generated in this study is broadly applicable across fields and we plan to use this COS as a baseline for discussion with other specialties in the future. However, we emphasize that the primary purpose was creation of a COS for use by neurological surgeons and thus believe that the inclusion of only neurological surgeons is reasonable.

Conclusions

The COINS Consortium has developed a COS for common peroneal neuropathy comprising 31 data points/outcomes that has strong consensus. The COS-CoPe is broadly evaluative, including clinician-directed assessment and PROs that assess the many domains that common peroneal neuropathy affects. Importantly, we have both defined the COS and provided definitions, methods of implementation, and time points for assessment.

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