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Reply to: Revisiting the Functional Severity Scale of the Boston Carpal Tunnel Questionnaire, a comment concerning the use of digital communication technology.

Christina Jerosch-Herold

Faculty of Medicine and Health Sciences, University of East Anglia, Norwich Research Park, Norwich, UK

Email: c.jerosch-herold@uea.ac.uk

ORCID 0000-0003-0525-1282

Jeremy DP Bland

Dept of Neurophysiology

East Kent Hospitals University NHS Foundation Trust

Canterbury, Kent, CT1 3NG

Email: Jeremy.Bland@nhs.net

ORCID 0000-0001-5591-6022

Mike Horton

Psychometric Laboratory for Health Sciences, Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, UK.

E-mail: m.c.horton@leeds.ac.uk

ORCID 0000-0002-6675-7335

Corresponding author:

C Jerosch-Herold

School of Health Sciences

Faculty of Medicine and Health Sciences

University of East Anglia

Norwich

NR4 7TJ

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We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines."

517 words

Authors' reply:

We thank Lattré and van Holder for their letter in response to our article[1].

It is true that we live in a much more digitalised world than that in which Levine et al[2] first developed the BCTQ. Therefore, questions about writing and using a telephone in the Functional Status Scale (FSS) may hold a very different meaning today, along with a different operationalisation within the FSS.

Lattré and van Holder present research about possible associations between keyboard and mobile device use for writing or communicating and structural changes to the median nerve. However, the current literature on acute changes in median nerve morphology in response to activity, as assessed by ultrasound imaging, suffers from serious methodological problems with observer blinding and limitations posed by the resolving power of current ultrasound systems such that the results they describe cannot be accepted as proven so far. Also these factors are of very limited relevance to the validity of the FSS.

The crux of our argument centred around the content validity of FSS, that is, the question of whether the items that make up the FSS are relevant for assessing the functional impact of carpal tunnel syndrome (CTS), irrespective of proven or hypothesized associations. It is unclear from Levine et al's original paper[2] how the concepts and questionnaire items were first generated, and only by undertaking cognitive interviews[3] with patients could we really begin to understand how they interpret these items in today's context.

Lattré and van Holder's proposal to revise the FSS by adding questions about digital device use and activities risks oversimplifying the process involved in patient reported outcome (PRO) instrument development, and we would urge some caution for the following reasons:

Firstly, a complete revision of the FSS should ideally follow best practice as advocated by ISPOR [4, 5] and the FDA's Guidance toward standardizing methods for developing patient-reported outcome (PRO) instruments which emphasises the importance of directly eliciting the patient perspective through qualitative research[6]. The new FSS would then have to

undergo full testing of its content, construct and criterion-validity. This is no small undertaking and a process that often takes years.

Secondly, the total score from a revised FSS would not be directly comparable to the total score of the current FSS, as the scale would be comprised of different items. Although it would be theoretically possible to co-calibrate and equate the two versions, the risk remains of these FSS scores being treated as directly equivalent.

Finally and given the above caveats, we propose as an alternative that existing and more contemporary PROs which measure the impact on hand use in daily activities are chosen based on the strongest evidence for content and construct validity, thus complementing the symptom severity scale. For example in a recent trial on sensory relearning after surgery for CTS we used 3 subscales of the Michigan Hand Questionnaire (MHQ) and which showed statistically significant improvements in unilateral and bilateral hand activities[7]. A further advantage being that the MHQ generates separate scores for the left and right hand which is particularly important in CTS where it can have a unilateral or bilateral presentation.

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