

**TITLE PAGE:**

**Title: Measuring patient-reported outcomes (PROs/PROMs) in people with Achilles tendinopathy: How useful is the VISA-A?**

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**Word count:** 767

**Key words:** Achilles tendon, tendinopathy, reliability and validity

## **Measuring patient-reported outcomes (PROs/PROMs) in people with Achilles tendinopathy: How useful is the VISA-A?**

It is important for clinicians and researchers to measure outcomes. Patient-reported outcome measures (PROMs) are short questionnaires, which are self-reported and designed to capture a person's perceptions of specified aspects of their health status.[1] Conceptually, PROMs can be viewed either as a 'tool for evaluation' or as a 'mechanism for improvement' suited to the many factors that characterise a person's health status that cannot be observed, measured with a device, or analysed with even the most sophisticated imaging methods.[2] Such questionnaires are ideally suited to areas such as tendinopathy where disease impact does not correlate consistently with biomarkers.

The Victorian Institute of Sport- Achilles (VISA-A) questionnaire is a widely-used PROM for Achilles tendinopathy and is available in seven different languages. The ability of the VISA-A to improve decision making is determined by its reliability, validity and responsiveness to change, as these are essential psychometric properties for any measure.[3,4] Here we critically review the evidence that exists for the VISA-A questionnaire.

### **Development**

The severity of Achilles tendinopathy is the construct of interest for the VISA-A, with validity and reliability first being examined by Robinson et al.[5] Content validity is defined as the degree to which the content of the PROM is an adequate reflection of the construct to be measured.[1,3] Content validity for the VISA-A was established from a pre-existing version of the questionnaire, interviewing colleagues, informally interviewing patients about their symptoms, and using a focus group of clinicians and subject experts. The inclusion of patients in this process is limited. Because the focus is on patient reported outcome, patients should be considered experts when judging the relevance of the items for the patient population.[3] As such, the relevance and comprehensiveness of the items in the VISA-A for the target population require further investigation, with additional consideration given to reflect current understanding of the multidimensional nature of the condition.[6]

Construct validity is the degree to which the scores of the PROM are consistent with predetermined hypotheses based on the assumption that the PROM validly measures the construct of interest.[1,3] The formulation and testing of such hypotheses are missing from the VISA-A development, and the potential for the VISA-A to be measuring more than one construct has been identified.[7] The physical activity section of the VISA-A weighs heavily in the overall scoring (40/100). Consequently, if a person with Achilles tendinopathy is functioning at a high level despite pain, the construct of the VISA-A may lead to the view that they are less affected. As high level function precedes pain, they may be simply 'pushing on'.

In addition to validity, reliability was also tested by Robinson et al,[5] but only in a sporting population; they used cases referred to a sports medicine clinic or awaiting surgery and controls representing active individuals from a University population or running club. Given that only 35% of the general population with Achilles tendinopathy may describe a relationship to sports activity,[8] the VISA-A lacks evidence of reliability not only in non-sporting populations, but also a heterogeneous sporting population. Robinson et al[5] suggest that the VISA-A only be used in homogenous populations, and recognise the limitations of its use in non-sporting populations; a non-active person's symptoms may resolve, yet they might only score 50/100.

Responsiveness is the ability of a PROM to detect change over time in the construct to be measured, thus referring to the validity of a change score.[3] As with evaluating criterion validity, a PROM responsiveness is required to be tested against hypotheses.[3] Whilst a minimum clinically important difference for the VISA-A has been cautiously suggested to be 6.5 points,[9] test-retest reliability has only been established at one week.[5] Pre-determined hypotheses require testing at longer-term follow up to ascertain responsiveness. Longer-term follow up needs to allow time for sufficient clinical improvement, but still be short enough to assume the patients would be able to recall whether any changes in their condition had occurred.[10]

In summary, the VISA-A was published in 2001, and has now been widely used, offering easy comparison between treatments from various clinics and research studies. In absence of an alternative PROM, clinicians and researchers might continue to use the VISA-A, despite the limited extent of evidence concerning the clinimetric properties for this PROM. However, since 2001 both our understanding of the multidimensional nature of tendinopathy and PROMs have developed, and as such the VISA-A requires updating. This critical review has highlighted the need for future research into the construct and content validity and responsiveness of the VISA-A. To ensure methodological rigor, this should follow the COnsensus-based Standards for selection of health Measurement Instruments (COSMIN) recommendations for terminology and research agenda.[3]

## STATEMENTS

**Competing interests:** There are no competing interests

**Contributorship:** All authors listed have made substantial contributions to the conception, design, acquisition, analysis and interpretation of data. All authors have revised it critically for important intellectual content and approved the final version. In doing so, we agree to be accountable for all aspects of the work.

**Acknowledgements:** There are no additional acknowledgments

**Funding info:** There are no funders to report

**Ethical approval information:** None

**Data sharing statement:** There are no unpublished data.

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