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Current review of the SarQoL®: a health-related quality of life questionnaire specific to sarcopenia

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ABSTRACT
Introduction: Sarcopenia, defined by a progressive and generalized loss of muscle mass and muscle function, is associated with many harmful clinical consequences. Several studies have reported the impact of sarcopenia on health-related quality of life (HRQoL) using generic quality of life (QoL) questionnaires. The results of these observational studies are quite heterogeneous. Indeed, generic tools may not be able to detect subtle effects of sarcopenia on QoL. Recently, a sarcopenia-specific HRQoL questionnaire was developed and validated in a population of sarcopenic subjects to more accurately assess the impact of sarcopenia on QoL. Areas covered: The purpose of this review is to present evidence regarding the impact of sarcopenia on QoL and to introduce a new specific HRQoL questionnaire, the SarQoL®. Expert commentary: The self-administered SarQoL®, initially developed in French, comprises 55 items translated into 22 questions. The questionnaire has been shown to be understandable, valid, consistent, and reliable and can therefore be recommended for clinical and research purposes. The questionnaire is now available in 11 different languages with another 20 translations in progress. The instrument’s sensitivity to change still needs to be assessed in future longitudinal studies.

1. Introduction
After the age of 25 years, the size and number of type II muscle fibers progressively declines, resulting in a progressive decrease in total muscle mass of approximately 40% between the ages of 25 and 80 years [1]. Beyond a certain defined threshold, this age-related phenomenon is considered abnormal; it was first defined by Rosenberg [2] in 1989 using the term ‘sarcopenia’. This first definition only addressed the notion of decreased muscle mass and was the start of many attempts to establish a clinically approved and applicable definition. The definition of sarcopenia has since evolved to include decreased muscle function (i.e. decreased muscle strength and/or physical performance). At present, there is still no universal diagnostic criteria and definition of sarcopenia available in literature; instead, several operational definitions of sarcopenia are available and are used across studies [3–10]. These definitions differ in terms of muscle mass indicators; the cut-off points used to define low muscle mass, low muscle strength and low physical performance; and the proposed tools for measuring these parameters. Sarcopenia, which has been shown to be prevalent in about 10% of community-dwelling subjects aged 65 years or older [11,12], is prospectively associated with several adverse outcomes, such as functional decline, loss of mobility, hospitalization, falls, fractures and mortality [13]. Sarcopenia is now recognized as a major clinical problem for older people and as a significant public health issue [14]. Because of the association of these outcomes with sarcopenia, the impact of this condition [15] on HRQoL, defined by the World Health Organization (WHO) as an ‘individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns’, seems intuitively evident but has yet to be shown with well-designed studies. The purpose of this study was to review evidence regarding the impact of sarcopenia on QoL and to introduce a new, specific HRQoL questionnaire, the SarQoL®.

2. Assessment of health-related quality of life in sarcopenia
2.1. How to assess HRQoL?
Two main approaches, namely generic and disease-specific instruments, can be used to measure HRQoL [16]. By definition, a generic QoL questionnaire can be designated for all types of populations of any age with any type of health trouble. The generic questionnaires are therefore widely used in observational and clinical studies since they allow comparisons between, for example, different populations with the same disease or comparisons of a disease’s impact on QoL based on the stage of the disease.

Currently, links between QoL and muscle function have been investigated using generic health-related questionnaires. The three questionnaires most commonly used in the
literature are (1) the Short-Form 36 questionnaire (SF-36) [17], composed of 36 items measuring eight health-related QoL domains (physical functioning [PF], role limitation due to physical problems [RP], bodily pain [BP], general health [GH], vitality [VT], social functioning [SF], role limitation due to emotional problem [RE], and mental health [MH]); (2) the EuroQoL 5-dimension (EQ-5D) [18] questionnaire, which records the level of self-reported problems in five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression); and (3) the EQ visual analog scale (EQ-VAS) questionnaire [18,19], which records the patient’s self-rated health on a scale ranging from 0 (worst imaginable health) to 100 (best imaginable health).

2.2. QoL and muscle function

Several studies have shown that lower grip strength is associated with reduced HRQoL. In 2012, Silva Netto showed that handgrip strength correlated positively and significantly with all of the SF-36 dimensions except vitality and mental health [20] in a population of 56 subjects aged 64.92 ± 5.74 years. A significant association between reduced grip strength and reduced QoL was also shown in 2987 community-dwelling men and women aged 59–73 years from the Hertfordshire study in the UK [21], in 764 older adults in the ISCOPE study [22], in 432 hospitalized elderly people [23] and in 117 elderly people with heart failure [24].

Links between QoL and muscle mass have been less frequently investigated. In 2002, Ianuzzi et al. [25] published data showing a significant correlation between low muscle mass and reduced QoL but only for the general health score of the SF-36 questionnaire and only for men, not for women. Bekfani et al. [24] also showed that higher appendicular lean mass (ALM) values were associated with a better QoL in 117 elderly people with heart failure. It should be pointed that none of these studies are prospective studies.

2.3. QoL and sarcopenia

No fewer than 11 different studies investigating QoL in a sarcopenic population were identified through a systematic literature search performed on PubMed (MEDLINE) and Web of Science until March 2016. Results shown that sarcopenia was diagnosed using different methods (the definitions of the European Working Group on Sarcopenia in Older People (EWGSOP) or Baumgartner, specific ALM indexes, the SARC-F screening tool). All these studies used generic QoL questionnaires (seven used the SF-36, three used the EQSD, three used the EQVAS and one used the CASP-12 scale [26]). The results were quite heterogeneous (Table 1), showing either no difference in QoL between sarcopenic and non-sarcopenic participants or poorer QoL for sarcopenic patients, but generally only for specific QoL domains.

These results highlight the fact that only specific domains of QoL are impacted by sarcopenia and, therefore, that generic tools may not be able to detect the subtle effects of sarcopenia on QoL. Moreover, in generic questionnaires, only a restricted number of questions will be relevant to sarcopenia; therefore, it is more difficult to observe a difference between sarcopenic and non-sarcopenic subjects with such a tool than with a specific questionnaire in which all questions are related to sarcopenia. After a treatment that increased muscle function, for example, all responses to a specific questionnaire are likely to vary, and the general score of the scale will be impacted; however, since only a restricted number of questions on a generic questionnaire will vary, variation in the global score will be low. A specific tool would thus be better able to accurately assess the impact of sarcopenia on QoL.

3. The SarQoL®, a specific tool to assess QoL in sarcopenia

3.1. Interest in the development of a specific tool to assess QoL in sarcopenia

Recently, the Department of Public Health, Epidemiology and Health Economics of the University of Liège, Belgium, in collaboration with (1) the Division of Bone Diseases, Faculty of Medicine, Geneva University Hospitals, Geneva, Switzerland; (2) Clinical Gerontology, CHU Toulouse, Toulouse, France; (3) the Frailty in Aging Research Department, Vrije Universiteit Brussel, Brussels, Belgium; and (4) the Geriatric Department, CHU Liège, Liège, Belgium, developed a specific HRQoL questionnaire for sarcopenia, the SarQoL® [41,42]. The purposes of this questionnaire are to create a tool to clinically characterize QoL in subjects with sarcopenia; to enhance the accuracy of clinicians’ assessments of well-being and the physical, psychological and social impacts of sarcopenia; to assess changes in QoL over time in this population and, finally, to assess the relevance of therapeutic interventions in the field of sarcopenia by measuring their effectiveness in terms of changes in QoL.

This questionnaire comprises 55 items transcribed into 22 questions. All these questions are specific to muscle mass and muscle function. Therefore, this questionnaire can be used for sarcopenia patients and for any population with impaired muscle function.

The sarcopenic subjects used for the development and validation of the French version of the SarQoL® were recruited from the SarcoPhAge study (for Sarcopenia and Physical Impairments with Advancing Age – an ongoing Belgian prospective study that enrolled a convenience sample of older subjects with the main objective of assessing the health and functional outcomes of sarcopenia) [27]. Sarcopenia was diagnosed according to the algorithm developed by the EWGSOP [3]:

- An appendicular lean muscle mass/height² (SMI) <5.5 kg/m² for women and <7.26 kg/m² for men assessed using dual-energy X-ray absorptiometry and
- A muscle strength <20 kg for women and <30 kg for men assessed using a hydraulic hand dynamometer or a physical performance ≤8 points assessed with the Short Physical Performance Battery (SPPB) test.

In the whole sample of the SarcoPhAge study [27] (n = 534), 73 subjects were diagnosed with sarcopenia (25 men and 48
women). Some of them took part in the development and validation of the SarQoL®.

### 3.2. Development of the SarQoL®

The SarQoL® was first developed in French [41] in four different steps [43,44]. During the first step, a list of 67 items related to QoL in sarcopenia was generated through a literature review. This list was then augmented through qualitative interviews with five sarcopenic subjects and through a structured-questionnaire given to seven different experts in the field of sarcopenia and aging. The resulting list comprised 180 items. During the second step, this list was reduced by asking 21 sarcopenic subjects (median age 76.1 [71.6–80.1] years, 13 women and eight men) and the seven experts to rate the relevance of each item on a Likert scale. Finally, 55 items were included in the SarQoL® and were transformed into 22 questions. All the questions are presented using a Likert scale format. These items are organized into seven domains of dysfunction: physical and mental health, locomotion, body composition, functionality, activities of daily living, leisure activities and fears.

The SarQoL® is a self-administered questionnaire, which means that each patient must complete the questionnaire by himself. A pretest, performed on 20 sarcopenic subjects, indicated that the SarQoL® is comprehensible, easy to complete, independently, in approximately 10–15 min. The total possible score for the SarQoL® is 100 points. An individual score for each domain can also be determined.

### 3.3. Validation of the SarQoL®

Before using a questionnaire for clinical and research purposes, it is important to ensure that it has the appropriate psychometric properties for its intended application. The SarQoL® has therefore been tested for these proprieties among 296 subjects (median age of 73.3 [68.9–78.6] years, 57% of women) [42].

Several psychometric analyses were performed.

First, the discriminative power of the SarQoL® was tested. The results indicated that sarcopenic subjects (n = 43) presented a significantly reduced QoL compared to non-sarcopenic ones (n = 253) when the SarQoL® was used. Regarding the total score of the SarQoL®, the sarcopenic subjects showed a median QoL of 54.7 (45.9–66.3) compared with 67.8 (57.3–79.0) for non-sarcopenic subjects (p-value adjusted for age and BMI < .001). A significantly reduced QoL was observed for sarcopenic subjects on all seven domains of the QoL in the SarQoL®. These results indicate that the questionnaire has good discriminative power. Moreover, two generic QoL questionnaires (i.e. the SF-6 and EQ5D) were also completed by the study population. These generic questionnaires, which are not specifically related to sarcopenia, were unable to show a difference in QoL between the sarcopenic and non-sarcopenic subjects except on the SF-36 domain of physical functioning, which yielded lower scores for sarcopenic subjects than for non-sarcopenic subjects. These results reinforce the necessity of using a specific HRQoL tool instead of a generic one to assess QoL in a specific disease.

Second, we measured the internal consistency, which is the estimation of the questionnaire’s homogeneity. A Cronbach’s alpha of .87 was found. All individual domains were also significantly and positively correlated with the total score of the SarQoL® (p < .001 for all domains). These results indicated good internal consistency, which is an important psychometric property for the validation of HRQoL questionnaires.

Third, the SarQoL® was also tested for test-retest reliability. Indeed, when no health change is observed over
2 weeks among the population, the score of the SarQoL® is expected to be unchanged. This property is measured with an intra-class coefficient correlation (ICC). Validation analyses indicated excellent test-retest reliability after a 2-week interval, with an ICC of .91 (95% CI .82–.95).

Fourth, construct validity was measured. The purpose of these analyses was to check the correlation between this new specific HRQoL questionnaire for sarcopenia and generic validated HRQoL questionnaires that are not specific to sarcopenia, namely the SF-36 questionnaire and the EQ-5D questionnaire. As the authors expected, the results showed that the total score of the SarQoL® was positively correlated with some domains of the SF-36 questionnaire (physical functioning [r = .49, p < .001], vitality [r = .72, p < .001], and general health [r = .67, p < .001]) and with the utility score of the EQ-5D questionnaire (r = .47, p = .002), the questions on the EQ-5D questionnaire related to usual activities (r = −.57, p < .001) and the Mobility Test questionnaire (r = .77, p < .001). These results confirmed the convergent validity.

The authors confirmed that the SarQoL® is valid, consistent, and reliable and can therefore be proposed for clinical and research purposes. However, they specified that this questionnaire still needs to be validated regarding its sensitivity to change. All the above-mentioned analyses were performed through a cross-sectional study. A longitudinal study is necessary to see the evolution of the SarQoL® results in relation to the evolution of muscle function.

3.4. Translation of the SarQoL®

The SarQoL® has been available in the literature since October 2015. To extend the availability and utilization of this questionnaire, a first translation in English has been performed [45] (the full version of the SarQoL® questionnaire is available in Supplementary data 1). For this translation, the authors developed a standardized protocol and followed five different phases. First, a translation of the SarQoL® from French to English was performed by two independent bilingual translators who were English native speakers. Secondly, the translations were synthesized to produce a ‘version 1’ of the translated SarQoL®. In the third phase, this version 1 was back-translated from English to French by two independent bilingual translators whose first language was French and who were blinded to the original French version. In the fourth phase, an expert committee review compared the back translations with the original questionnaire and agreed to a ‘version 2’ of the translated questionnaire. Finally, this version 2 was pretested to ensure good comprehension of each question of the questionnaire, and ‘version 3’, the final version of the English SarQoL®, was produced. The study sample was composed of 297 subjects (137 women (46.1%) and 160 men (53.9%) with a mean age of 79.5 ± 2.62 years) from the Hertfordshire Cohort Study (HCS) who agreed to participate in the UK component of the European Project on Osteoarthritis (EPOSA).

The 22 questions of the SarQoL® were translated without any major difficulties. The same validations that were performed for the French version were performed for the English version. The results were similar: the English SarQoL® showed good discriminative power, excellent test-retest reliability, excellent internal consistency and adequate construct validity. The English version of the SarQoL® is valid for England and has also been culturally validated for America.

At present, the SarQoL® has been translated in 11 other languages, including Dutch, German, Spanish, Italian, Greek, Hungarian, Romanian, Ukrainian, Polish, Persian, and Czech. Only the French, English, Polish and Romanian versions have already been validated. All these versions are available on the SarQoL® website (www.sarqol.org). The translation of the SarQoL® into another 20 different languages is also in progress (Table 2). Researchers interested in the translation and validation of the SarQoL® in their own language (not contained in Table 2) can contact the designers of the SarQoL® (Dr. Charlotte Beaudart, c.beaudart@ulg.ac.be and Pr. Olivier Bruyère, olivier.bruyere@ulg.ac.be). A standardized protocol of translation and validation has been developed to harmonize all the translation processes.

4. Conclusion

In the current context of population aging and improved life expectancy, a great challenge is to limit the burden of disease on individual and public health. Sarcopenia represents an important economic and social burden, and improvements in QoL for people with sarcopenia should be a priority for future interventions designed to prevent or treat sarcopenia. The recent development of the SarQoL®, a HRQoL questionnaire specific to sarcopenia, should help to validate these therapeutic interventions. The SarQoL® has been shown to be understandable, valid, consistent, and reliable and can therefore be recommended for clinical and research purposes. The questionnaire is now available in 11 different languages with an additional 20 translations in progress. The SarQoL®’s sensitivity to change needs to be assessed in future longitudinal studies and in interventional clinical studies.

### Table 2. Translation of the SarQoL® into foreign languages.

<table>
<thead>
<tr>
<th>Available translated versions</th>
<th>Translation in progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>French® (valid for French-speaking European countries)</td>
<td>Thai</td>
</tr>
<tr>
<td>English (valid for the UK and America)*</td>
<td>Portuguese (European)</td>
</tr>
<tr>
<td>Dutch</td>
<td>Arabic</td>
</tr>
<tr>
<td>Ukrainian</td>
<td>Lithuanian</td>
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<tr>
<td>Hungarian</td>
<td>Malaysian</td>
</tr>
<tr>
<td>Romanian®</td>
<td>Filipino</td>
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<tr>
<td>Greek</td>
<td>Russian</td>
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<tr>
<td>Polish®</td>
<td>Serbian</td>
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<tr>
<td>Italian</td>
<td>Slovak</td>
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<tr>
<td>German</td>
<td>Turkish</td>
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<tr>
<td>Portuguese (Brazil)</td>
<td>Vietnamese</td>
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<tr>
<td>Czech</td>
<td>Japanese</td>
</tr>
<tr>
<td>Spanish</td>
<td>Indonesian</td>
</tr>
<tr>
<td>Farsi/Persian</td>
<td>Bulgarian</td>
</tr>
<tr>
<td>Chinese (Cantonese)</td>
<td>Swedish</td>
</tr>
<tr>
<td>Swedish</td>
<td>Latvian</td>
</tr>
<tr>
<td>Croatian</td>
<td>Hindi</td>
</tr>
<tr>
<td>Slovenian</td>
<td>Farsi/Persian</td>
</tr>
</tbody>
</table>

*Psychometric properties have been checked for these versions.
5. Expert commentary

The measurement of HRQoL has become increasingly important in research and clinical practice over the past three decades. Indeed, HRQoL assessments are considered important for allowing health care providers and regulatory agencies to understand the needs and preoccupations of the population. HRQoL is increasingly used in observational studies and in interventional clinical studies, in which QoL can be considered a primary or secondary end point. Moreover, many current medical interventions are designed to improve QoL rather than to prolong life. The inclusion of QoL measures in studies is no longer restricted to highly developed Western countries but has expanded to countries throughout the world [46,47].

The SarQoL®, recently developed and validated with the purpose to assess HRQoL in sarcopenia, has been shown across different publications to be valid, consistent and reliable. It can be used to assess the QoL of elderly subjects suffering from muscle impairments such as sarcopenia. The SarQoL® can be used by doctors to assess the QoL of their patients in their daily practice, by researchers to assess the QoL of populations with sarcopenia or to determine the impact of non-pharmaceutical therapeutic strategies on sarcopenia, and by industries to evaluate the impact of their interventions (pharmaceutical interventions, dietary interventions, etc.) on the HRQoL of subjects with sarcopenia.

It should be pointed, however, that many different definitions of sarcopenia are available in literature. It has been shown that prevalence of sarcopenia across different definitions and diagnostic criteria can vary widely [48-51]. Therefore, to check whether the SarQoL® can discriminate between sarcopenic subjects and non-sarcopenic subjects in terms of their QoL, unpublished analyses have been performed; no less than six different definitions of sarcopenia have therefore been applied by the authors of the SarQoL® to compare the QoL of sarcopenic subjects with that of non-sarcopenic subjects. Among the six definitions used, two were based on low lean mass alone (Baumgartner [37], Delmonico [52]) and four required both low muscle mass and decreased performance on a functional test (Cruz-Jentoft [3], Studenski [5], Fielding [4], Morley [6]). This unpublished data (which was presented as an oral communication in EUGMS Congress 2016) showed that the SarQoL® is able to discriminate sarcopenic from non-sarcopenic subjects in terms of their QoL regardless of the definition used for the diagnosis as long as the definition includes an assessment of both muscle mass and muscle function. Of course, the prevalence of sarcopenia varied widely across definitions (the highest prevalence was found with Delmonico’s definition: 32.8%, and the lowest prevalence was found with Morley’s definition: 4.39%). Using the SarQoL®, a lower QoL was found for sarcopenic subjects compared to non-sarcopenic ones when using the definition of the definitions of Cruz-Jentoft (56.3 ± 13.4 vs. 68.0 ± 15.2, p < .001), of Studenski (51.1 ± 14.5 vs. 68.2 ± 14.6, p < .001), of Fielding (53.8 ± 12.0 vs. 68.3 ± 15.1, p < .001), as well as with the definition proposed by Morley (53.3 ± 12.5 vs. 67.1 ± 15.3, p < .001). No QoL difference between sarcopenic and non-sarcopenic subjects was found when using the definition of Baumgartner or Delmonico, which were only based on the notion of decreased muscle mass. In this dataset, poorer QoL seems to be more related to muscle function than to muscle mass.

Even if the SarQoL® is demonstrating an interesting discriminative power, regardless of the definition used for the diagnosis of sarcopenia, a weakness of this questionnaire is that one of the major psychometric properties has still not been checked: sensitivity to change. Indeed, the score of the SarQoL® is supposed to vary according to the evolution of muscle function. The SarcoPhAge study [27] showed that the scores of subjects with severe sarcopenia (n = 16) were even lower than those obtained by the sarcopenic subjects, which indicates that the SarQoL® can capture the severity of sarcopenia. However, it is still insufficient to indicate that the SarQoL® can vary according to the evolution of muscle function. The publications related to sarcopenia refer to cross-sectional study design. Sensitivity to change needs to be evaluated using prospective data.

At present, unpublished preliminary data regarding sensitivity to change have been obtained from the SarcoPhage study [27]. The SarQoL® and two generic HRQoL questionnaires (EQ-5D and EQVAS) were completed by 301 subjects from the SarcoPhAge study [27] at baseline and after 1 year of follow-up. The results showed that the QoL of the general population (75.0 ± 5.97 years, 59% women) decreased over time, regardless of the questionnaire that was used (p < .001 with the SarQoL®, p = .03 with the EQVAS, p < .001 with the EQ-5D). The skeletal muscle index (ALM/ h²) did not change significantly, but a decrease in muscle strength and gait speed was observed (p < .001 for both). A significant correlation was found between the 1-year decrease in gait speed and the 1-year decrease in QoL only when the SarQoL® was used (r = .21 (p < .001) for the whole cohort population and r = .41 (p = .013) for the sarcopenic population (n = 38). These associations were not observed for muscle mass (p = .65) or muscle strength (p = .06). In a multivariate regression, the association between decreased gait speed and decreased QoL, assessed with the SarQoL®, was significant independent of age, sex, number of comorbidities and number of drugs used (p < .001 for both the whole cohort and the sarcopenic subjects). These findings suggest that a decrease in physical performance (gait speed) is associated with a decrease in QoL, specifically in terms of muscle impairments, in the elderly, specifically those suffering from sarcopenia. The specific SarQoL® seems better adapted than generic tools to identify muscle function-related decreases in QoL.

6. Five-year view

More robust data regarding sensitivity to change should be available in the next few years. Indeed, currently, the SarQoL® is being used within the SarcoPhAge study [27]. Each year, people aged 65 years and older complete this questionnaire. Moreover,
aside from the studies involved in the translation and validation of the SarQoL®, this sarcopenia-specific QoL questionnaire is also being used in three different prospective studies: one in Lyon, France, one in Geneva, Switzerland, and one in Toulouse, France. This means that prospective data should be available soon to assess the evolution of the QoL for evaluating the evolution in muscle function among populations aged 65 years and older.

The SarQoL® should also be tested in interventional studies to assess its sensitivity to change. If interventions can increase muscle mass, muscle strength and muscle performance, it could be hypothesized that these same interventions will also increase HRQoL. The SarQoL® has still not been tested in such types of interventional studies, but future results regarding the evolution of HRQoL in sarcopenic subjects following a therapeutic intervention should be available in the next few years.

Finally, the development of a short-form of the SarQoL® is also scheduled. The purpose is to facilitate and increase the use of this questionnaire by clinical doctors in their daily practice.

Key issues

- Limit the burden of sarcopenia on individual and public health is a great issue;
- Improvement of QoL in sarcopenia should be a priority for future intervention designed to prevent or treat sarcopenia;
- The recent development of the SarQoL®, a HRQoL questionnaire specific to sarcopenia, should help to validate these therapeutic interventions.
- The SarQoL® has been shown to be understandable, valid, consistent, and reliable and can therefore be recommended for clinical and research purposes. The questionnaire is now available in 11 different languages with an additional 20 translations in progress. The SarQoL®’s sensitivity to change needs to be assessed in future longitudinal studies and in interventional clinical studies.

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Declaration of interest

C Beaudart, O Bruyère and JY Reginster are the shareholders of SarQoL® sprl. The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

References

Papers of special note have been highlighted as either of interest (+) or of considerable interest (+++) to readers.


**First operational definition of sarcopenia.**


**Development of the original SarQoL® questionnaire.**


