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**Title**

The Reliability and Validity of the Comprehensive Lower-limb Amputee Socket Survey: A measure of Stability, Suspension, Comfort and Appearance

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**Summary**

The CLASS is a self-report measure of socket stability, suspension, comfort and prosthetic appearance, with excellent test-retest reliability and internal consistency.

**Introduction**

The literatures frequently discuss prosthetic socket fit and comfort as an important measure for the determination of successful fitting. To date the only objective measure is the Socket Fit Comfort Score, which is a 10-point analog scale that asks amputees to rate the comfort of their socket. If a low score is received there is no indication to the cause of the socket dissatisfaction with the exception that it is “uncomfortable”.<sup>1</sup> There is a need for an outcome measure that can quantify the multiple constructs that influence user satisfaction of a prosthetic socket. This will provide prosthetists a method to evaluate and guide clinical decisions.

**Methods**

The aim of this study was to determine the reliability and validity. The CLASS is a Likert-scale questionnaire comprised of 24 items with four constructs 1) Stability, 2) Suspension, 3) Comfort and 4) Appearance. The CLASS takes less than five minutes to complete. To determine the test-retest reliability of the CLASS, the questionnaire was administered twice within a 48-hour period. It was completed by a convenience sample of 47 lower limb amputees (LLA); either unilateral transfemoral or transtibial. Intraclass Correlation Coefficient (ICC) values with 95% confidence interval (95% CI) were calculated for each item. Cronbach alpha was used to determine the internal consistency of each of the four constructs, and for item analysis. Mann-Whitney U test was used to determine known group validity.

## Results

Overall, the CLASS demonstrates excellent test-retest reliability ( $r=0.89$ , 95% CI: 0.74-0.92) and good internal consistency for each of the constructs. Following item-analysis, 5 questions were removed, improving the internal consistency as presented in Table-1. The Final CLASS was scored out of a possible 70 points. The average overall socket satisfaction of the CLASS administered to 47 LLA is 83.1% ( $\# = 58.17 \pm 9.11$ , 37-70). The average satisfaction score for each of the four constructs: Stability 86.7% ( $\# = 13.6 \pm 2.6$ ), Suspension 85% ( $\# = 13.6 \pm 2.6$ ), Comfort 81.8% ( $\# = 13.0 \pm 2.7$ ) and Appearance 77.3% ( $\# = 9.3 \pm 2.0$ ). No statistical significant difference was found in CLASS score based on amputation level ( $p=0.08$ ) or gender ( $p=.054$ ). However, there was a significant difference in the appearance construct based on gender (female= $8.6 \pm 2.1$ , male= $10.3 \pm 1.5$ ,  $p=.005$ ).

## Conclusion

The final version of the CLASS is a self-report measure of socket stability, suspension, comfort and prosthetic appearance, with excellent test-retest reliability and internal consistency. Validity tests showed that the overall CLASS is not gender-biased and can be used for individuals with LLA. Socket appearance has been found to be an important issue for women with LLA and the CLASS allows clinicians to assess both current perception and potentially change in perception due to a prosthetic intervention. In summary, the ability to determine where a socket issue occurs and how the prosthetist can remedy the problem is important for the quality of life and overall function of the LLA.

## References

1. Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. *Disabil Rehabil*,25:1278-820, 2003.

Image: CLASS Table 1\_2150.png

	<b>Original CLASS</b>		<b>Final CLASS</b>	
<b>Sub-category</b>	<b>Items</b>	<b><math>\alpha</math></b>	<b>Items</b>	<b><math>\alpha</math></b>
<b>Stability</b>	5	0.843	4	0.882
<b>Suspension</b>	5	0.897	4	0.926
<b>Comfort</b>	5	0.880	4	0.919
<b>Appearance</b>	5	0.792	3	0.850

  

<b>Sub-category</b>	<b>Lowest Mean Score (4 points)</b>		<b>Highest Mean Score (4 points)</b>	
<b>Stability</b>	Exercise	3.0	Sitting	3.6
<b>Suspension</b>	Exercise	2.9	Standing	3.5
<b>Comfort</b>	Exercise	2.8	Standing	3.3
<b>Appearance</b>	Tight pants	2.8	Sitting	3.3

**Table 1.** Cronbach  $\alpha$  values present the internal consistency of the CLASS constructs before and after item-analysis.