Author's response to reviews

**Title:** Outcome and clinical changes in patients 3, 6, 12 months after a severe and major hand injury - can sense of coherence be an indicator for rehabilitation focus?

**Authors:**

Ragnhild Cederlund (ragnhild.cederlund@med.lu.se)
Eva Ramel (eva.ramel@med.lu.se)
Hans-Eric Rosberg (hanse.rosberg@med.lu.se)
Lars B Dahlin (lars.dahlin@med.lu.se)

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**Author's response to reviews:** see over
Dear Editor,

Thank you very much for the comments from the reviewers. We appreciate all the comments and have made both major and minor revisions. We would like to reply as follows 2010-10-22

Reviewer Eva Langeland

Major compulsory revisions

1. BACKGROUND. Using the SOC as an indicator is perhaps justified, but there is still the problem of interpreting the individual position on the healthy/unwell continuum. It is not clear where SOC no longer protects the movement towards the healthy end (Ref. Erikson, Lindström, 2005, Langeland, 2007)

Comments: We agree with the reviewer that we may not have been clear in this respect. However, as the results indicate there is a correlation between SOC and different health aspect. Thus, this may be a first step which can advice us how to continue with further studies in this field.

We have consulted our statistical advicer and performed correlations (Spearman) between significant variables in table 4 and 5 for persons with high/low SOC at 6 and 12 months. At six months, out of 18 tested variables, there were 13 significant correlations with correlation coefficients between -0.30 to 0.67, indicating a relationship between SOC and several health aspects. At 12 months, out of 18 tested variables, there were also 13 significant correlations with correlation coefficients between -0.35 to 0.64, indicating a relationship between SOC and several health aspects. We have included some
sentences in Results.

2. “Few studies..” – These studies needs to be referred to

Comments: Three relevant references are added on page 3.


3. PARTICIPANTS: Why these two samples? The recruitment procedure need to be further explained.

Comments: Patients were consecutively included in the study for 2 years. Our purpose was to include the injured patients with major injuries, which is a novel approach with respect to previous literature. After the first year we also included patients with slightly less complex injuries (i.e. severe due to a slow inclusion rate). Our ambition was to reach approximately 50 patients since approximately 30 patients with a major hand injury are referred to our department each year. However, at the time of final inclusion at 2 years 45 patients were included. Since these injuries are rare and our purpose was to collect a patient material with extensive injuries it was not possible to perform any regular power analysis. We have added text at page 4.

4. What about drop-outs?

Comments: There were only a single dropout: one patient’s questionnaire was missed at 3 months (thus, n=44). Tables 2-4 are changed accordingly. In the text a sentence in included, page 4.
5. You have to consider whether it is necessary to explain the treatment the patient’s received.

Comments: All patients were treated in the same rehabilitation department according to the latest evidence in the field of hand surgery and rehabilitation. The individual patients were treated according to their injury and the decision of the consultant. All patients were followed up between 3 - 12 months post trauma. Text is added on page 4.

6. ASSESSMENT INSTRUMENT. Why SOC was only measured once?

Comments: When the study was planned in the autumn of 2004 we also wanted to study possible differences between groups. We divided the group in subgroups (severity of injury, peripheral nerve injury, SOC). For SOC, we planned, according to Antonowskys views, that SOC is unchangeable when a person has reached adult age. In addition, we had an ethical approval to perform the study as originally planned. However, recent research has indicated that “SOC may change and it may not be as stable as Antonovsky initially assumed”... “SOC tends to increase with age” (Eriksson & Lindström, 2005) and is possible to improve (Langeland et al., 2007). However in the same review article (ibid) it says “Examining longitudinal studies the findings show a comparatively high predictability”. As pre-injury measure was not relevant as the patients had had a traumatic injury, we choose to assess SOC at 6 months. The reason was because after 3 months all patients were allowed to use their hands with no restrictions and after 6 months 19 out of 40 patients with a job before injury were back to their previous work to some extent. A whole paragraph is added on limitations of the study at page 12.

7. SENSE OF COHERENCE: Why was SOC dichotomized and why was median value used as criteria?

Comments: Other studies have chosen this way to split the group in subgroups. To our knowledge there are no other cut offs recommended for use. We also studied the two groups with a box plot to see if the two groups were overlapping, but in fact they were quite distinct differences, see figure below (not included in manuscript). Therefore, we are confined that our method is valid. We were interested in finding out if SOC could be an indicator of rehabilitation focus rather than severity of injury. Therefore we divided the sample in high/low SOC. Our aim was not to use SOC as a screening
instrument with a risk of stigmatizing patients (Eriksson & Lindström, 2005) but to help therapists focus on patient’s recourses rather than problems. Text is added on page 7 and 12.

8. DISCUSSION, SOC: The study has no baseline SOC. SOC was measured after 6 months and is used retrospectively. Discuss whether it is possible that SOC may have changed from baseline to follow-up due to such treatment, characteristics with the injury, pain, function. Research show that SOC may be changed due to major life events. In addition you have to discuss that research show that SOC generally vary +/- between different measures.

Comments, in text: It may be possible that SOC may change after a major hand injury, but we didn’t have that knowledge when we planned the study. When the study started in February 2005 we planned according to Antonowsky’s views that SOC is unchangeable when a person has reached adult age, see also comments above. We will now include SOC at the 5 year follow-up that is initiated to start this autumn. We have made comments in the manuscript (see above).
9. Is it possible to claim that SOC had an impact when it was just measured once; after 6 months? See also third sentence in the second paragraph. Consider to test SOC (continuous variable) as a predictor for change in the different variables from 6-12 months (Multivariate regression analysis). Then you investigate the impact of SOC on the different variables

Comments: We have performed additional analyses using Linear regression analyses but they did not really add any new information above the correlation analyses. All variables with significant differences in table 4 and 5 were tested with respect to SOC, age, Hiss (severity of injury) and the results indicated that Soc is the dominant factor. Age had a less significant effect on a few variables mainly physical functioning, general health and bodily pain. Therefore, we do not think that inclusion of separate paragraph about regression analyses may add further information, but will only increase the length of the manuscript. However, one may also consider other confounders such as ethnicity, education etc, but we have no data available. We do not want to include too many factors in regression analyses due to our limited number of patients.

10. The limitations of the study need to be clearly stated. Consider and discuss limitations related to the sample, the sample size, generalization, the fact that SOC was measured once and the problematic by dichotomize SOC related to possible changes.

Text about Limitations of the study is added on page 12 as suggested.

Minor essential revisions
11. The title reflects a main finding in the study but the purpose of the title is broader, consider to use a subtitle and a question mark after the main title

Comments: A new title has been added:
Outcome and clinical changes in patients 3, 6, 12 months after a severe and major hand injury – can sense of coherence be an indicator for rehabilitation focus?
12. Assessment instrument. In paragraph seven starting with the MOS...explain what MOS means

Comments and added in the text: Medical Outcome Study (MOS)

13. Data analysis. The last sentence referring to Cohen needs an exact reference.

Comments: According to Cohen’s criterion, an effect size of ≤ 0.20 is considered small, 0.50 medium, and 0.80 large [31]. (Cohen J: Statistical power analysis for the behaviour sciences. New York: Academic Press; 1977 p.40).

14. The tables. Make the tables self-explanatory such as showing high score = low score etc. Consider using footnotes.

Comments: Footnotes has been added to Tables 2-5.
Reviewer Felix Angst

Major compulsory revisions

15. The conclusion (determine the predictive power of SOC) do not match to the aims of the study (explore outcome).

Comments: The aim is now enlarged into two aims according to the study design, see page 3.

Text: Our objective was to explore outcome and clinical changes in hand function, satisfaction in daily occupations, sleep disturbances, health and quality of life in consecutive patients after a severe major hand injury. Our objective was also to investigate possible differences between groups according to severity of injury, presence of peripheral nerve injury and their sense of coherence.

16. A. There is no pre-injury data. B. The post-injury SOC may be influenced by the event of the injury itself and/or by post-injury therapy

Comments:
A. we had no pre-injury data because these patients were referred acutely.
B. See answer 6 to reviewer Langeland above. Comments are included in manuscript.

17. The sample size is very small n=45. By dichotomizing the data in to 2 groups by the median SOC dives groups with n=22 and n=23 which results in low valid data – indication of (wide) 95% CI (depending on n) would illustrate

Comments: See reply to reviewer Langeland.

Text in abstract, page 2, data analysis, page 6. Non-parametric tests were used since the study was small, most variables not normally distributed and almost all results were measured with ordinal scales.
18. Between that two n=22 and n=23 groups 54 (!) statistical tests have been performed (data in tables 4 and 5) with n=45 patients which is a high disproportion by statistical resons. At least, Bonferroni correction for multiple testing has to be applied and discussed.

Comments: We agree that 54 variables are many (i.e. not different from other studies published in the field). We used 18 variables at every follow-up (3x18=54). Bonferroni is one way to examine the risk for mass significance. However, there is a risk that you take away too many variables, i.e. it is too blunt. Another possibility is to use a lower p-value 0.01 instead of 0.05. According to our statistician we have so many significant differences between high/low SOC, 32 out of 54 variables, that the risk of too many false positive explained by pure chance is low.

19. The methodology to determine the predictive power by dichotomizing the sample is arbitrary (determined by chance, whim, or impulse, and not by necessity, reason, or principle) and insensitive – some would even say inadequate....

Comments: To split a sample group in two according to high or low SOC there is no gold standard to do so, therefore the group was dichotomized into high (≥68) and low (<68) SOC according to their median value. The groups were checked by using a box plot diagram if reasonable doing so, see figure above in reply to reviewer Langeland. We can conclude that the two groups differ even if they are small.

20. There are no data about intervention/treatment which influence/confound the health parameters and the SOC.

Se comments at 5.

Minor essential revisions

21. Abstracts, Methods: Provide information about analysis (See also 1)
Comments: Some text is added to the abstract.

Text in abstract: For analysis non-parametric tests were used since almost all data were measured with ordinal scales, the study sample small, and most variables not normally distributed.

Methods: For analysis, non-parametric tests were used since almost all data were measured with ordinal scales, the study sample small, and most variables not normally distributed.

22. Data presentation, Tables: indicate 1 decimal place for scores (ev. 2 for all VAS) and 2 decimal places for effect sizes consistently and throughout the paper. For example 9.0 is not 9 because of the rules of mathematical precision.

Comments: All average measures are now presented with two meaningful digits and SD with three digits, see tables 2-5.

23. To describe the SOC, ref. 15 of the paper is not sufficient, (2) and (3) are also necessary. Add the major content of these references to the text.

Comments: We have included the reference by Eriksson & Lindström, 2005. However, the suggested reference by Antovovsky in Schwartz (1983) was not possible to find (Sweden or British Library). In many other articles the authors refer to the three references we have included in this manuscript by Antonovsky. The one by Antonovsky A: The structure and properties of the sense of coherence scale. Social Science Medicine 1993, 36(6):725-733 is often used when describing the instrument. There is also a description of the instrument in Antonovsky A: Unraveling the mystery of health. How people manage stress and stay well. San Francisco: Jossey-Bass; 1987, with a copy of the instrument in the last pages. We hope this is adequate.

24. Explain some of the instruments and scores more precisely: The HISS, DASH (has 30 items, page 7)

Comments: We have changed and added to the text according to reviewer’s suggestion.
HISS
New text, page 4. HISS is an objective anatomical assessment specifically designed for hand injuries. The HISS score is based on which tissues and which fingers that are affected by the injury.

DASH
New text, page 5: The disabilities of the arm, shoulder and hand (DASH) is a region-specific and standardized questionnaire. It is based on the WHO model of health, that assess impairments, activity limitations and participation restrictions for both work and leisure activities. Response options range from 0: no difficulty to 5: unable.

25. Scaling/transforming all instrument’s scores into 0=worst health to 100=best health – as in the SF-36 – would ease comparison of the data between the instruments.

Comments: We have changed accordingly to reviewer’s suggestion. See page 4-6.

26. Page 6. Explain the VAS grip strength (?)

Comments: In the field of hand surgery and hand therapy it is important to assess a patients objective hand function as well as their subjective perceived hand function; for example grip strength, dexterity, range of motion. There are many references using VAS in this way. The question is then asked “Describe your grip strength (dexterity, range of motion). The score is 0=best possible grip strength to 10=worst possible grip strength.

27. Give a reference for the Swedish population survey of the SF-36 (page 7)

Comments: We have added a reference by (Sullivan, 1995).


28. To compare the samples SF-36 data to the population norms: Use the Wilcoxon test and
give p-values and not Z-scores which requires Gauss’ distribution and are difficult to interprete for most readers (Table 3)

We have consulted our statistician. We decided to keep Z-scores in order to facilitate comparisons across studies but also did an additional analysis. The patients values were considered to have a 0 value and the Z-score was compared (Wilcoxon signed rank test). We found a large difference in role physical (Z-score -1.63) and role emotional (Z-score -1.16) in participants with a low SOC compared to the population norms. We have included this in Results at page 9.

We also compared (Man Whitney, table 5) the difference in Z-scores between patients with high and low SOC, where significant differences were seen (Table 5). In addition we found, with the same method as above, that the Z-scores of the patients with low SOC were significantly different from the population norms (Wilcoxon signed rank test).

29. Page 12/13. “Which coping strategy a person uses may not be relevant”. I don’t understand this sentence, especially not in this context. Coping was not measured.

Comments: This is a sentence in the book by Antonovsky. We have left the sentence out.

We hope that these changes are sufficient aned that you now can consider our manuscript suitable for publication in Journal.

Sincerely Yours

Ragnhild Cederlund