

Application of the German standardized translation of the *Michigan Hand Outcomes Questionnaire (MHQ)* for patient-reported outcome assessment following selective fasciectomy in Dupuytren's disease

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Abstract

Background: Patient-reported outcome measures are of increasing interest to assess the functional result of selective fasciectomy in Dupuytren's disease. We hypothesized that a validated German translation of the Michigan Hand Questionnaire (MHQ) correlates to the Disability of Arm Shoulder Hand (DASH) score in terms of functional outcome.

Methods: First, a validated back-and-forth translation of the MHQ was performed by two experts from English to German, consensus conference, than a backward translation by two independent experts back to English with another consensus conference. This final validated German version of the MHQ was then distributed with the DASH score by mail to the patients. Outcome measures: DASH, DASH work, DASH sport, MHQ, patient satisfaction on six-graded Likert scale (1=best, 6=worst). 113 patients underwent selective fasciectomy due to Dupuytren's disease Iselin 2° to 4° in a single university hospital. Mean age was 54±12 years, follow-up 27±12 months.

Results: Mean DASH score was 17±20 (95% CI 13.3-20.7), subscores of DASH were DASH work with 16±23 (95% CI 11.7-20.3) and DASH sport was 22±26 (95% CI 17.2-26.8). Mean MHQ was 76±19 (95% CI 72.5-79.5). MHQ and DASH correlated with a $r^2=0.756$ ($y=-0.8192x+89.968$). A weaker correlation was found among MHQ with patients' satisfaction with the operated hand ($r^2=0.545$, $-9.6808x+102.43$) and MHQ and patients' satisfaction with the overall procedure ($r^2=0.5$, $-8.6111x+100.31$). Patient satisfaction with the operated hand was rated 2.7±1.5 (95%CI 2.4-3.0), satisfaction with the operative procedure was 2.9±1.6 (95% CI 2.6-3.2). 82% would undergo the procedure again. 13% were on TGF-beta inhibition using N-acetyl-cysteine. 15% were active smokers, 14% suffered a complication, 10% were diabetics.

Conclusion: The Michigan Hand Questionnaire (MHQ) in its validated German translation correlates well with the DASH score in a cohort of patients more than two years following selective fasciectomy. These patient-reported functional outcome scores might further delineate not only the operative result from a patient-perspective in Dupuytren's disease, but also serve as substantial clinical endpoints in further randomized-controlled clinical trials for disease modification in Dupuytren's disease..

Introduction

Dupuytren's disease is a progressive disease due to unknown causal agents or genetics. An epidemiological analysis of 566 cases in North Germany estimated that around 1.9 million Germans are suffering from Dupuytren's disease [1]. Dupuytren's disease contains nodules and cords in the fascia as the epicenter of disease progression. Nodules contain whorls of collagen bundles and are densely packed with contractile fibroblasts and myofibroblasts. These highly contractile cells are linked to the fascia matrix through transmembrane integrin receptors. The cytoplasmic tail domains of the alpha beta integrin receptors provide a structural link between extracellular matrix (ECM) and the actomyosin cytoskeleton. Depending on the degree of the flexion contracture in Dupuytren's disease, various therapeutic options are available to date. Surgery is often the mainstay in progressive Dupuytren's disease with either selective or total aponeurectomy. However, these operations are not free from complications and still bear the risk of recurrences.

Non-invasive options include percutaneous fasciotomy or collagenase injection. The latter has been tested in a randomized-controlled trial published in the New England Journal of Medicine with 308 patients enrolled (NCT00528606) [2]. Collagenase clostridium histolyticum significantly reduced contractures and improved the range of motion in joints affected by advanced Dupuytren's disease. In the long-term the cords at the level of the PIP joint appear to more recurrent than at the MP joint after collagenase injection with an eight year follow-up [3]. In early stage Dupuytren's contracture, radiotherapy has been suggested to limit disease progression. A cohort study of 135 patients with 208 hands involved received orthovoltage radiotherapy (120kV, 20mA) with a total dose of 30Gy separated by a six to eight week interval [4]. After a follow-up of 13 years nodules and cords remained stable in 59%, improved in 10% and progressed in 31%.

Medical antifibrotic agents inhibiting TGF-beta such as N-acetyl-L-cystein (NAC) and Angiotensin-converting enzyme (ACE) inhibitors have been suggested [5] to be able to limit the progressive disease; however, no prospective clinical data are available currently in this regard. ACE inhibitors appear to limit fibrosis such as in muscle regeneration following injury [6] or limits capsular contracture around silicone implants in plastic surgery [7].

As highlighted in a recent article, patient satisfaction outcomes in plastic and hand surgery are rare and often unvalidated⁸ with a need for further refinement in the future.

In hand surgery, the *Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure* has been used in a number of clinical trials⁹. The DASH questionnaire has a good validity with the quality of life subscale of SF-36¹⁰.

Notably, the validation of the aforementioned DASH score included patients suffering from Dupuytren's disease. Longitudinal construct validity has been assessed in patients including those with Dupuytren's disease and the responsiveness is moderate (effect size 0,5). The DASH questionnaire has a good validity with the subscale of SF-36 [11]. The test-retest reliability of the DASH questionnaire has been found to be excellent (ICC = 0.96) [12]. The DASH score has been used in nine clinical trials to date (table 1).

Authors	N	Intervention	Mean DASH	Range
Degreeef et al. 2009	80	Baseline	15	0-69
Atroshi et al. 2006 [13]			24	
Skoff, 2004 [14]			37	
Zyluk and Jagielski, 2007 [15]	54	Selective aponeurectomy	54 vs. 32 (12 months)	
Ganeval et al. 2010 [16]	20	Fasciotomy	Postop Quick-DASH 20	0-73
Johnston et al., 2008 [17]	19	Brunner incisions, selective aponeurectomy	24±20 (3months) vs. 15±12 (14months) vs. 8±8	
Herweijer et al. 2007 [18]	46	Selective aponeurectomy	12±13 vs. 7±9 (10 months)	
Högemann et al. 2009 [19]	61	Total aponeurectomy	7	0-33
Jerosch-Herold et al. 2010	145	preoperatively	16	0-62

Table 1. Reported DASH scores at baseline and after surgical or non-surgical interventions in Dupuytren's disease.

However, side differences of the hand are often not adequately displayed since the “better” hand often over scores the “impaired” hand in the DASH assessment. As such, DASH values for Dupuytren’s disease are reported to be considerably good in contrast to limited range of motion (ROM) without any correlation of both²⁰. In addition, the room for improvement with considerable good baseline DASH scores is limited. As such, the study of Herweijer of 46 patients undergoing selective aponeurotomy reported a baseline DASH of 12±13 and 7±9 ten months postoperatively. Thus, only a moderate change is reflected by the improved DASH score, while the improvement for the Dupuytren’s patient might be considerable higher than reflected by DASH.

Therefore, we sought to evaluate another clinical questionnaire for outcome analysis of surgery for Dupuytren’s disease.

Another validated patient-related outcome score is the *Michigan Hand Outcome Questionnaire* (MHQ). The MHQ [21] is a side-specific questionnaire with 25 unilateral and 12 bilateral questions, including hand function, work performance, and cosmetic appearance. It generates a score from 0 (poor) to 100 (no disability at all). The MHQ is responsive to clinical change [22] and has been applied in two smaller clinical trials yet (table 2).

Authors	N	Intervention	Mean MHQ
Johnston et al., 2008 ²³	19	Brunner incisions, selective aponeurotomy	58±16 vs. 75±16 (3months) vs. 87±12 (14months)
Herweijer et al. 2007	46	Selective aponeurotomy	75±13 vs. 84±15

Table 2. Reported Michigan Hand Questionnaire (MHQ) scores at baseline and after surgical or non-surgical interventions in Dupuytren’s disease.

The *Michigan Hand Outcomes Questionnaire (MHQ)* has been implemented in 1998 by Kevin C. Chung in order to provide a patient-related outcome measure in hand surgery²⁴. One feature of the MHQ are side-specific questions (“*your left hand, your right hand, both hands*”), which is of special consideration especially in Dupuytren’s disease, where often times one hand is involved more severe. To date, only two smaller clinical trials have been

reported MHQ outcome scores in English. Currently, no validated German translation of the MHQ is available.

Since language adaptation is key to use the MHQ in a different lingual environment, we sought to translate the MHQ to German as an additional patient-related outcome measure. To date, validated translations of the MHQ have been posted in Dutch, Spanish, Chinese and Japanese. Following a validated step-wise language adaptation of the Michigan Hand Questionnaire from English into German, we applied the validated German MHQ translation to our surgical patients treated with selective fasciectomy at a single university hospital.

Methods

Validated language adaptation of the MHQ

The MHQ was translated using a team of translators fluent in both English and the desired language German. The validated standardized translation process consisted of the following components:

- **Forward translation:** Two translators independently translate the MHQ from English to German. The translators then meet to evaluate both translations and arrive at a consensus version.
- **Backward translation:** Two other translators independently translate the new version of the MHQ from German into English. The backward translation version is compared with the original English version. All 4 translators then meet to discuss and resolve any discrepancies.

This part is accepted for publication in *Plastic Reconstructive Surgery*²⁵.

Prospective clinical assessment of the German MHQ in selective fasciectomy

In addition, we prospectively applied the validated German MHQ in addition to the conventional DASH score among our surgical patients undergoing selective fasciectomy in Dupuytren's disease trials. The German MHQ was sought as an additional valuable patient-reported outcome measure in this regard.

A total number of 113 patients was referred to our department for selective aponeurectomy based on Dupuytren's disease Tubiana stage 2° to 4° either for primary or recurrent origin. Mean age was 54±12 years, follow-up 27±12 months. 13% were postoperatively on TGF-beta inhibition using N-acetyl-cysteine. 15% were active smokers, 14% suffered a complication, 10% were diabetics.

Results

German standardized translation of the Michigan Hand Questionnaire

The Michigan Hand Questionnaire was translated by two independent colleagues from English into German. Following a consensus conference, the consented German version was re-translated backward into English by two different independent colleagues. Another consensus conference led to a consented English version. This version was compared to the original English MHQ version. Finally, the German version was approved in a consensus conference. The German validated MHQ translation is attached as an attachment file 1.

Attachment 1. German standardized translation of the Michigan Hand Questionnaire (MHQ).

Surgical results following selective aponeurectomy

Follow-up of the 113 included patients was 100 % complete with a mean follow-up of 27 months. Surgical complication arose in 14% with prolonged wound healing. Antifibrotic medication involved N-acetyl-cysteine in 13%.

Postoperative German Michigan Hand Questionnaire and DASH score

Mean DASH score was 17 ± 20 (95% CI 13.3-20.7), subscores of DASH were DASH work with 16 ± 23 (95% CI 11.7-20.3) and DASH sport was 22 ± 26 (95% CI 17.2-26.8). Mean MHQ score was 76 ± 19 (95% CI 72.5-79.5).

Correlation of MHQ and DASH score

MHQ and DASH correlated with a $r^2=0.756$ ($y=-0.8192x+89.968$) (figure 1). A weaker correlation was found among MHQ with patients' satisfaction with the operated hand

($r^2=0.545$, $-9.6808x+102.43$) (figure 2) and MHQ and patients' satisfaction with the overall procedure ($r^2=0.5$, $-8.6111x+100.31$) (figure 3).

Patient satisfaction with the operated hand was rated 2.7 ± 1.5 (95%CI 2.4-3.0), satisfaction with the operative procedure was 2.9 ± 1.6 (95% CI 2.6-3.2). 82% would undergo the procedure again.

Discussion

The major finding of this study is: The German validated translation of the Michigan Hand Questionnaire appears as a valuable and clinically meaningful outcome assessment instrument following selective fasciectomy for Dupuytren's disease.

The strength of this study are the validated stepwise translation of the Michigan Hand Questionnaire (MHQ) from English to German and back with serial consensus conferences to obtain the best lingual version of the MHQ. Second, this is by far the largest cohort studied postoperatively using either the DASH or the MHQ and thus, our correlation analysis based on 113 patients with completed DASH and MHQ scores 27months following selective fasciectomy is valid.

Patient-related outcome measures are of increasing importance especially in diseases such as Dupuytren's disease. The chronic nature and the independence of functional impairment on the one hand (reflected by MHQ or DASH scores) and the range of motion (ROM) on the other hand, which has been highlighted by Jerosch-Herold recently [26]. They found only a weak correlation of functional impairment measured using the DASH score and the severity of flexion contracture, if at all ($r=0.264$).

Given the need for high level evidence clinical trials, the assessment of clinical primary endpoints used in Dupuytren's clinical trials so far should be highlighted here. The highest impact factor publication thus far by Hurst et al. in the *New England Journal of Medicine* used range of motion (ROM) as a primary outcome in their randomized-controlled trial evaluating collagenase injections. A recent RCT protocol regarding the use of splinting applied the DASH score as a primary outcome score [27]. Beyond these aforementioned trials, no randomized-controlled clinical trials have been published thus far in terms of modification of Dupuytren's disease.

Following the citations in the introduction, the MHQ might be a valuable additional patient-related outcome measure since it depicts side-difference much more in detail ("your right hand, your left hand") than the DASH score, where the results are supposed to be reported for the better hand. Thus, often the DASH result in Dupuytren's disease is rather good (as highlighted in table 1) and the room for improvement, e.g. the responsiveness to change

such as following selective fasciectomy is small with potential implications on sample size calculation. The MHQ appears to be responsive to change and concomitantly, highly correlated to the DASH score.

Limitations

Certain limitations should be highlighted when interpreting the data obtained in this trial. Language-adaptation is key and thus, the MHQ results derived in this study do not necessarily reflect the situation in a different country with a different culture and with another language. All patient-related outcome measures such as the DASH score and the MHQ have pertinent biases in the patient-perspective in common. Only serial assessment will at best reflect the current impairment of a given patient by Dupuytren's disease. We were seeking to apply our validated German translation of the MHQ on a fairly large cohort (113 patients, 27 months postoperatively) in a vertical rather than a longitudinal assessment. However, we currently enrol every patient scheduled for selective fasciectomy to fill out both, DASH and MHQ preoperatively and postoperatively in the further course. Thus, we will be able in the future to demonstrate the responsiveness in every given patient operated on for Dupuytren's disease in much more detail rather than our vertical assessment 27 months postoperatively. However, in order to correlate DASH with MHQ, we found it appropriate since we did not seek to demonstrate superiority of a given operation prospectively in this validation study.

Conclusion

The Michigan Hand Questionnaire (MHQ) in its validated German translation correlates well with the DASH score in a cohort of patients more than two years following selective fasciectomy. These patient-reported functional outcome scores might further delineate not only the operative result from a patient-perspective in Dupuytren's disease, but also serve as substantial clinical endpoints in further randomized-controlled clinical trials for disease modification in Dupuytren's disease..

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Figures 1-3.

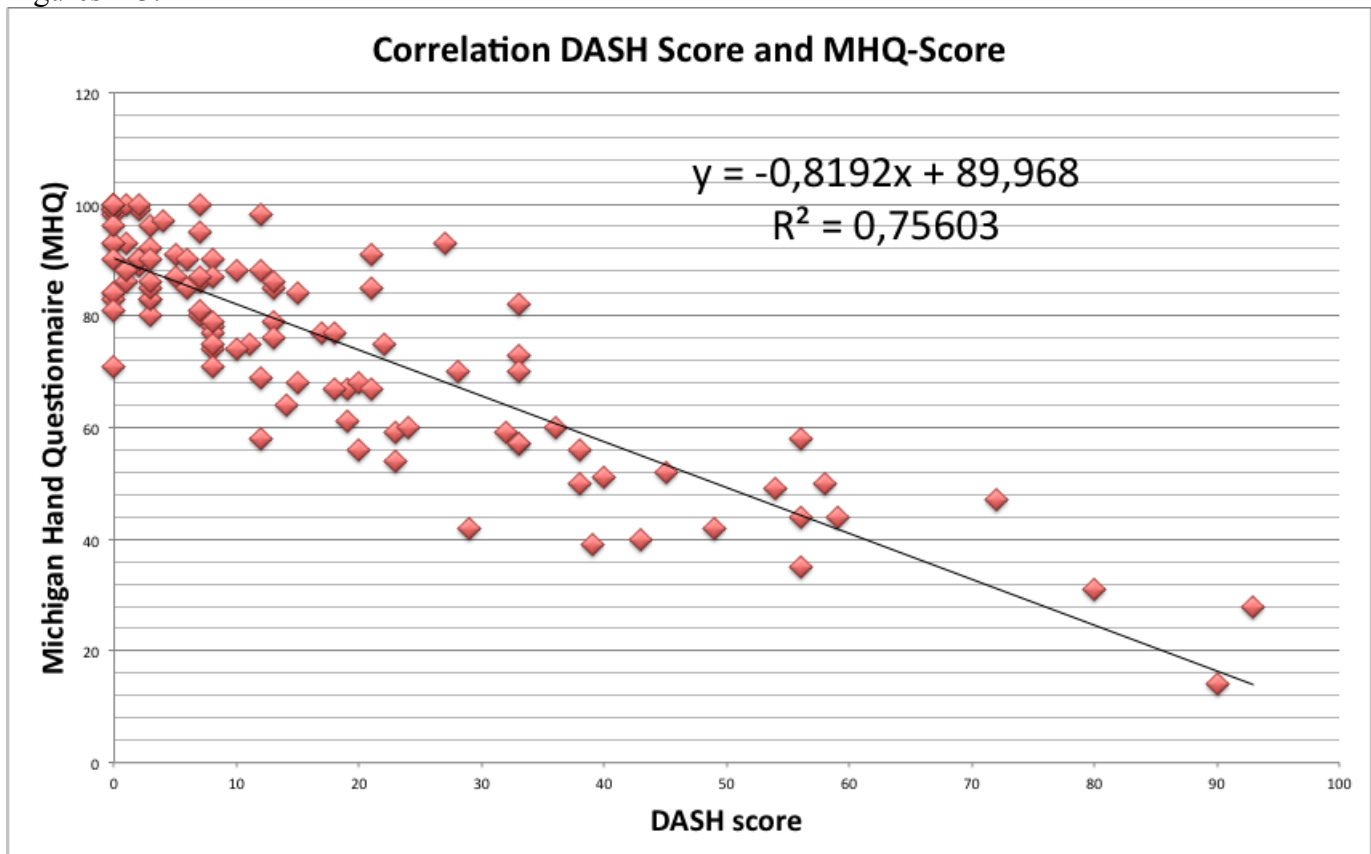


Figure 1. Correlation analysis of DASH score [0-100, x-axis] and Michigan Hand Questionnaire (MHQ) [0-100, y-axis] among 113 patients operated on with selective aponeurectomy 27 months postoperatively.

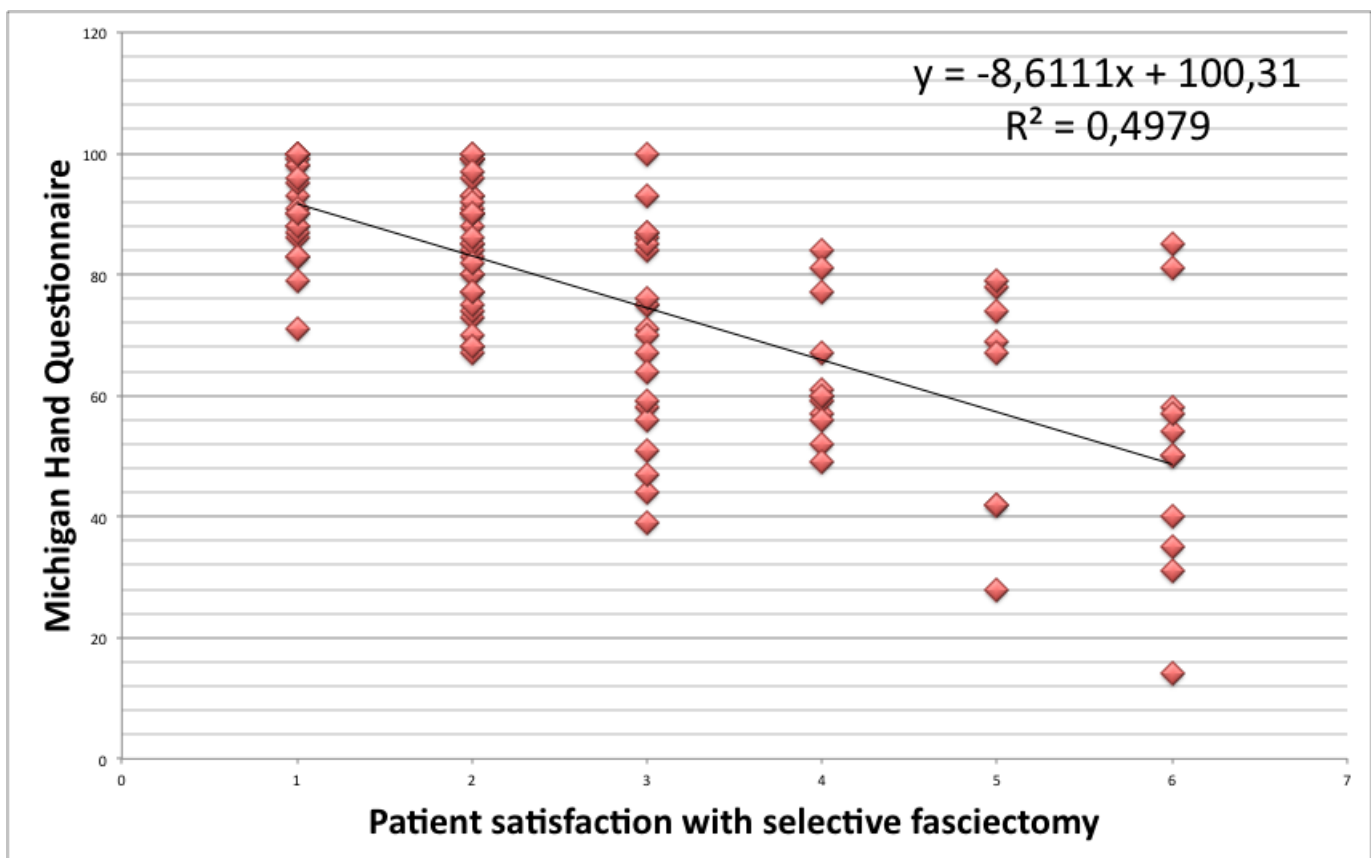


Figure 2. Correlation analysis of Patient satisfaction with selective fasciectomy [1=best, 6=worst, x-axis] and Michigan Hand Questionnaire (MHQ) [0-100, y-axis] among 113 patients operated on with selective aponeurectomy 27 months postoperatively.

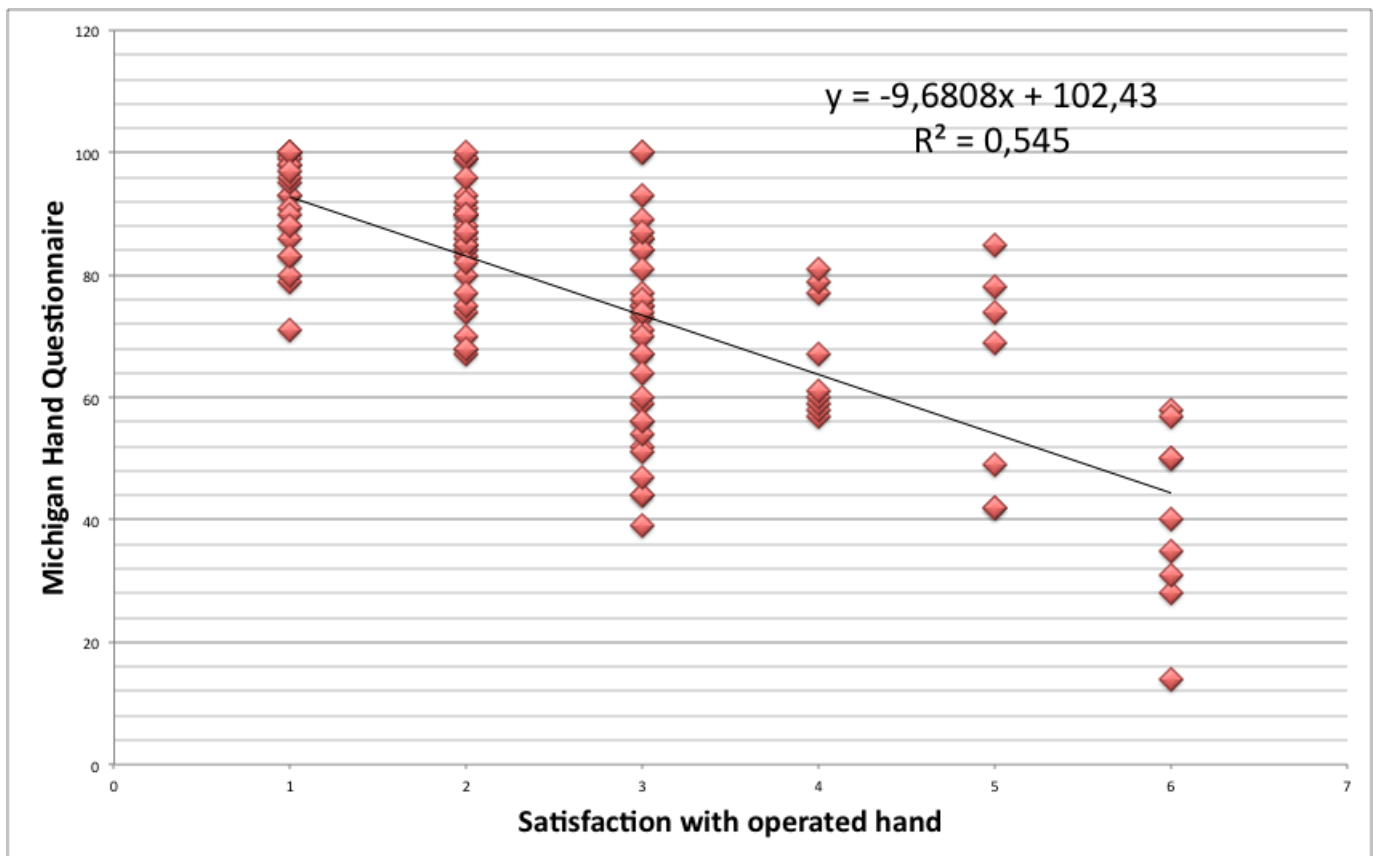


Figure 3. Correlation analysis of patient satisfaction with operated hand [Likert scale 1=best, 6=worst, x-axis] and Michigan Hand Questionnaire (MHQ) [0-100, y-axis] among 113 patients operated on with selective aponeurectomy 27 months postoperatively.