

## Quality of Life and not Health Status Improves After Major Amputation in the Elderly Critical Limb Ischaemia Patient

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### WHAT DOES THIS STUDY/REVIEW ADD TO THE EXISTING LITERATURE AND HOW WILL IT INFLUENCE FUTURE CLINICAL PRACTICE

In elderly patients with critical limb ischaemia (CLI), guidelines about the definition of quality of life and the instruments that measure quality of life are sparse. Often quality of life is confused with health status. This study provides evidence that there is a discrepancy between quality of life and health status in elderly CLI patients undergoing major amputation. This raises the question, which outcome measurement is the most relevant for elderly CLI patients. We advocate the use of distinctive and *subjective* QoL questionnaires, like the WHOQOL-BREF, in future research.

**Objectives:** A patient-oriented appraisal of treatment has become extremely important, particularly in elderly patients with critical limb ischaemia (CLI). Quality of life (QoL) is an important patient-reported outcome in vascular surgery. Frequently, the physical domain of QoL questionnaires represents an ‘objective’ evaluation of performing activities, which is expected to be impaired after major limb amputation. However, an *objective* appraisal of physical function is an assessment of health status (HS) and not of QoL. Little is known about the *subjective* appraisal of physical health (QoL). The goal of this study was to evaluate, prospectively, QoL in relation to HS in elderly CLI patients undergoing major limb amputation.

**Methods:** Patients suffering from CLI aged 70 years or older were included in a prospective observational cohort study with a follow-up period of 1 year. Patients were divided according to having had an amputation or not. The World Health Organization Quality Of Life-BREF (WHOQOL-BREF) was used to assess QoL. The 12-Item Short Form Health Survey (SF-12) was used to measure HS. These self-reported questionnaires were completed five times during follow-up.

**Results:** Two-hundred patients were included of whom 46 underwent a major limb amputation within one year. Amputees had a statistically significant improvement of their physical QoL after six months (14.0 vs. 9.0 (95% CI -7.84;-1.45),  $p = 0.005$ ) and after a one-year follow-up (14.0 vs. 9.0 (95% CI -9.58;-1.46),  $p = 0.008$ ). They did not however show any statistically significant difference in HS. For non-amputees, both physical QoL and HS improved. An instant statistically significant improvement of the physical QoL appeared 1 week after inclusion (12.0 vs. 10.9 (95% CI -1.57;-0.63),  $p < 0.001$ ). Similarly, statistically significant improvement in the physical HS first occurred at 1 week follow-up (29.0 vs. 28.9 (95% CI -5.78; -2.23),  $p = 0.003$ ).

**Conclusions:** There is a clear difference between patients’ functioning (HS) and the patients’ appraisal of functioning (QoL). In elderly CLI patients, this study clearly suggests a discrepancy between the physical QoL (WHOQOL-BREF) and HS (SF-12) measurements in vascular amputees. This raises the question, which outcome measurement is the most relevant for elderly CLI patients. Individual treatment goals should be kept in mind when assessing the HS or QoL outcome of patients undergoing hospital care. With respect to shared decision making, distinctive and *subjective* QoL questionnaires, like the WHOQOL-BREF, provide a very important outcome measurement and should be used in future research.

**Keywords:** Quality of life, Health status, Amputation, Peripheral arterial disease, Frail elderly

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## INTRODUCTION

Critical limb ischaemia (CLI) is characterised by impaired mobility, which can negatively affect quality of life (QoL).<sup>1</sup> CLI, the end stage of peripheral arterial disease, is also the most common cause of major limb amputation in elderly patients.<sup>2,3</sup> Because major limb amputation is usually associated with poor physical function, high mortality, and assumed high revalidation costs, it is an outcome that health care providers fear.<sup>3–6</sup> However, in the elderly CLI patients, revascularization is not always possible and major limb amputation is often necessary, due to infection or severe pain in selected patients.<sup>7</sup>

Due to a lack of randomized controlled trials, no recommendation for therapy can be made in CLI patients.<sup>7,8</sup> Consequently, a patient-oriented appraisal of treatment is becoming increasingly important.<sup>9–11</sup> The importance of the patient-reported outcome measure, QoL, is broadly recognized. Unfortunately, the term QoL is used inconsistently and confusingly, possibly explaining some contradictory results.<sup>11–14</sup> Many studies claim to evaluate QoL but their findings are based on health status (HS) instruments.<sup>9,15</sup> HS is solely a patient's assessment of objective functioning having to do with the patient's functional status, that is associated with a certain disease.<sup>16–20</sup> Perceived health does not convey a patient's subjective wellbeing and QoL.<sup>9,15</sup> Particularly for CLI patients this can lead, for instance, to incorrect conclusions concerning what should be an adequate treatment.<sup>9,21</sup>

Accordingly HS questionnaires, like the 12-Item Short Form Health Survey (SF-12), measure a patient's daily activities and provide an arguably objective assessment. HS questionnaires, take a *functional* approach by assessing physical, psychological and social functioning (e.g. whether a patient is able to adequately engage in specific activities, such as climbing stairs or using a vacuum cleaner). In contrast with HS, the WHOQOL (World Health Organization Quality Of Life) definition of QoL assesses a complete *subjective appraisal or evaluation* of physical, psychological, and social functioning and therefore takes into account a *subjective* evaluation of health.<sup>9,22</sup> The WHOQOL-BREF questionnaire asks patients if they are satisfied with their ability to perform their daily living activities. So in our opinion, the importance of HS measures in CLI patients is doubtful when approximately half of the vascular amputees are not able to walk one year after amputation.<sup>11</sup>

At the moment, prospective data related to suitable patient-oriented outcomes is missing in elderly vascular amputees.<sup>7,11</sup> In clinical practice a subjective appraisal of wellbeing would be more valuable to patients and health care providers. As mentioned above, the WHOQOL-BREF gives more insight into the patient's opinion about QoL. The goal of this study was to evaluate QoL (WHOQOL-BREF) in relation to HS (SF-12) in elderly CLI patients who underwent major limb amputation in comparison to elder CLI patients who did not.

## METHODS

Between January 2012 and February 2016, elderly patients with CLI in two peripheral hospitals (Amphia hospital and Bravis hospital, The Netherlands) were included in a prospective observational cohort study, as published previously.<sup>23</sup> Inclusion criteria were a diagnosis with CLI and an age of 70 years or older. CLI was defined as chronic ischemic rest pain with or without the presence of ulcers or gangrene. The diagnosis was confirmed by the ankle-brachial index or toe systolic pressure measurement when appropriate. Patients with malignancy, lack of Dutch language skills, or cognitive impairment were excluded from the study. A formal written waiver for ethical approval was not required according to the criteria of the Central Committee on Research Involving Human Subjects. This was confirmed by the institutional review board (AMOA). All patients included signed an informed consent.

A panel of experts at a weekly multidisciplinary vascular conference determined patients' inclusion. After inclusion, patients received a treatment that consisted of either surgical or endovascular revascularisation, conservative therapy or primary amputation.<sup>23</sup> Patients were selected for a treatment while taking into account comorbidities and TransAtlantic Inter-Society Consensus (TASC) lesion classification. Methods of patient inclusion and treatment selection have previously been described by Steunenbergh et al.<sup>23</sup> Major limb amputation was defined as an amputation proximal to the ankle joint. All additional treatment received during follow-up was duly recorded.

QoL and HS were prospectively measured using the WHOQOL-BREF and the SF-12, respectively. These self-report questionnaires were completed at the moment of inclusion, five to seven days after inclusion (mostly conducted during hospitalisation), and at six weeks, six months and 12 months.

The validated WHOQOL-BREF questionnaire is the shortened version of the WHOQOL-100. Studies using the WHOQOL-BREF have shown good validity in the elderly.<sup>24</sup> This patient-completed measurement of health-related QoL contains 26 items with a 5-point Likert type response scale. The following broad domains are measured: physical health, psychological health, social relationships, and environment.<sup>11,25</sup> In this study, the physical and psychological domains are used, which together consist of 13 items. The validated SF-12 was used to determine HS.<sup>26,27</sup> It is the short version of the 36-Item Short Form Health Survey and provides information about physical and mental functioning.<sup>11</sup> Patients who did not answer all questions of a domain did not reach an overall score for that particular questionnaire.

In this study, patients were classified into two groups at one-year follow-up: patients who had undergone major limb amputation and patients who had not, during the first year after inclusion. Results of the questionnaires were recoded to ensure that for each patient the first completed questionnaire, after major limb amputation, was considered

	<b>Non-amputees (n = 154)</b>	<b>Amputees (n = 46)</b>
Sex (male)	82 (53)	30 (65)
Age; median (IQR)	79.5 (9)	82 (10)
Rutherford-class 4	58 (38)	6 (13)*
Rutherford-class 5/6	96 (62)	40 (87)*
<b>Comorbidities</b>		
Cardiac comorbidity	101 (66)	38 (83)*
Neurologic comorbidity	49 (32)	16 (35)
Pulmonary comorbidity	80 (52)	33 (72)*
<b>Vascular risk factors</b>		
Renal impairment	86 (56)	28 (61)
Diabetes mellitus	69 (45)	27 (59)
Hypertension	106 (69)	28 (61)
Current smoking	37 (24)	9 (20)
<b>Type of amputation</b>		
Above knee amputation		14 (30)
Below knee amputation		32 (70)

Data are presented as n and (%), unless otherwise specified. IQR = interquartile range.

\*: Statistically significant difference compared to the other treatment group,  $p < .05$ .

the first measurement after baseline and so forth. Patients who did not get an amputation were considered the control group.

As reported previously,<sup>23</sup> a sample size calculation was performed for an ANOVA. Given a power of 0.80, an alpha of 0.05, and an effect size of 0.25, the total sample should be at least 159 persons. Statistical analyses were performed through a computerized software package, using IBM SPSS 23.0. Linear mixed models were used to assess the change of QoL and HS for both treatment groups at four specified times. Within mixed modeling, custom hypothesis tests were used to assess differences between baseline and follow-up measurements within each treatment group. An advantage of mixed modeling is that it analyzes all available data for each participant when some of the measurements are missing. Additionally, mixed models can take into account the fact that the time intervals separating the measurements differed across participants. Computing Pearson correlations assessed the association between QoL and HS. Common variance of the two questionnaires was determined using the scores of these correlations. Significance was evaluated at  $p < 0.05$ .

## RESULTS

During the study period (January 2012 through February 2016), 387 elderly patients were diagnosed with CLI. One hundred and eighty-seven CLI patients were excluded from our study because of cognitive impairment or refusal to participate, resulting in 200 included CLI patients. Of those patients, five were treated with a primary major limb amputation. One hundred and ninety-five CLI patients did

not undergo major limb amputation as a primary treatment, but instead were treated with endovascular revascularisation ( $n = 82$ ), surgical revascularisation ( $n = 67$ ), or received conservative therapy ( $n = 46$ ).

### Baseline characteristics

At one-year follow-up, all patients were reclassified as non-amputees and amputees. An additional 41 patients had received major limb amputation during the follow-up period. Hence, a total of 46 patients were amputees and 154 patients had not undergone major limb amputation. The patients' characteristics are presented in Table 1. In the amputee group, there were more patients with Rutherford 5 or 6, e.g. minor tissue loss or gangrene. Additionally, there were no statistically significant differences between the characteristics of patients that had a major amputation after a revascularization attempt or conservative therapy and the ones that had a primary major amputation done.

### Non-amputees

In Table 2, patients were grouped according to whoever received amputation as primary treatment and those who did not. Of those patients, 195 were treated without a primary major limb amputation. There was an instant statistically significant improvement in the physical QoL domain scores after five to seven days (12.0 vs. 10.9 (95% CI -1.57; -0.63),  $p < 0.001$ ). This statistically significant

**Table 2. WHOQOL-BREF vs. SF12 according to received amputation as intention to treat**

	<b>n</b>	<b>Non-amputees</b>	<b>n</b>	<b>Amputees</b>
<b>WHOQOL-BREF physical</b>				
Baseline	192	10.9 (2.8)	5	9.0 (2.8)
5-7 days	169	12.0 (2.8)*	3	8.3 (2.3)
6 weeks	160	12.7 (3.2)*	5	9.8 (2.5)
6 months	131	13.9 (2.7)*	4	14.0 (2.0)*
12 months	115	14.2 (2.7)*	2	14.0 (0.4)*
<b>SF-physical</b>				
Baseline	190	28.9 (8.7)	5	23.9 (7.0)
5-7 days	166	29.0 (8.7)*	3	23.5 (12.0)
6 weeks	160	31.9 (9.8)*	5	25.1 (8.7)
6 months	131	35.7 (9.6)*	4	33.2 (7.2)
12 months	115	35.7 (10.2)*	2	33.2 (3.9)
<b>WHOQOL-BREF Psychological</b>				
Baseline	195	14.1 (2.5)	5	14.4 (3.5)
5-7 days	169	14.6 (2.0)	3	12.0 (4.0)
6 weeks	160	14.6 (2.3)*	5	12.7 (4.1)
6 months	131	14.9 (1.9)*	4	14.8 (2.9)
12 months	115	14.9 (2.1)*	2	15.3 (2.8)
<b>SF-mental</b>				
Baseline	190	37.4 (11.1)	5	36.7 (13.5)
5-7 days	166	40.4 (8.4)*	3	33.8 (9.2)
6 weeks	160	40.8 (8.4)*	5	34.8 (8.8)
6 months	131	42.2 (7.7)*	4	38.7 (8.4)
12 months	115	42.7 (8.6)*	2	35.2 (5.0)

Data is presented as mean and standard deviation. n = number of patients; WHOQOL-BREF = World Health Organization Quality of Life-BREF; SF12 = 12-Item Short Form Health Survey.

\*Significant difference in the treatment group between this measurement and baseline,  $p < .05$ .

**Table 3.** WHOQOL-BREF vs. SF12 according to received major limb amputation during one year follow-up

	n	Non-amputees		n	Amputees
<i>WHOQOL-BREF physical</i>					
Baseline	151	10.7 (2.8)	Baseline	46	11.3 (2.7)
5-7 days	133	12.1 (2.8)*	Measurement 1	27	12.1 (3.1)
6 weeks	125	13.1 (3.2)*	Measurement 2	23	13.0 (3.1)*
6 months	106	14.0 (2.7)*	Measurement 3	14	14.7 (1.6)*
12 months	97	14.2 (2.8)*	Measurement 4	4	14.4 (1.1)*
<i>SF-physical</i>					
Baseline	150	28.3 (8.5)	Baseline	45	30.2 (9.5)
5-7 days	131	29.4 (8.7)	Measurement 1	26	31.1 (8.6)
6 weeks	125	32.8 (10.0)*	Measurement 2	23	31.8 (8.0)
6 months	106	36.3 (10.1)*	Measurement 3	14	35.2 (5.7)
12 months	97	35.9 (10.7)*	Measurement 4	4	33.7 (3.4)
<i>WHOQOL-BREF Psychological</i>					
Baseline	154	14.1 (2.5)	Baseline	46	14.0 (2.4)
5-7 days	133	14.7 (2.2)*	Measurement 1	27	13.5 (2.5)
6 weeks	125	14.8 (2.2)*	Measurement 2	23	13.8 (2.7)
6 months	106	14.9 (1.9)*	Measurement 3	14	15.2 (2.1)
12 months	97	14.9 (2.2)*	Measurement 4	4	14.8 (1.8)
<i>SF-mental</i>					
Baseline	150	37.1 (11.1)	Baseline	45	38.5 (11.6)
5-7 days	131	40.7 (8.7)*	Measurement 1	26	39.6 (7.9)
6 weeks	125	41.2 (8.3)*	Measurement 2	23	39.6 (8.2)
6 months	106	42.3 (7.7)*	Measurement 3	14	43.0 (10.1)
12 months	97	42.3 (8.8)*	Measurement 4	4	38.3 (6.3)

Data is presented as mean and standard deviation. n = number of patients; WHOQOL-BREF = World Health Organization Quality Of Life-BREF; SF12 = 12-Item Short Form Health Survey.

\*Significant difference in the treatment group between this measurement and baseline,  $p < .05$ .

improvement persisted during the one-year follow-up (14.2 vs. 10.9 (95% CI -3.70; -2.50),  $p < 0.001$ ). As presented in Table 3, these results remained the same for patients who did not undergo major limb amputation within the first year. Non-amputees showed an immediate increase of the physical QoL domain scores occurred after five to seven days (12.1 vs. 10.7 (95% CI -1.95; -0.90),  $p < 0.001$ ) and persisted after one-year follow-up (14.2 vs. 10.7 (95% CI -3.98; -2.65),  $p < 0.001$ ). However, statistically significant improvement in the physical HS domain only occurred after one week of follow up for primarily non-amputee CLI patients (29.0 vs. 28.9 (95% CI -0.80; -0.17),  $p = 0.003$ ) and after six weeks for patients who did not undergo secondary amputation (32.8 vs. 28.3 (95% CI -5.78; -2.23),  $p < 0.001$ ), as presented respectively in Tables 2 and 3. These results remained statistically significant over time for both groups.

As presented in Table 2, statistically significant changes were present in both the psychological QoL domain (14.6 vs. 14.1 (95% CI -4.14; -0.89),  $p = 0.003$ ) as well as the psychological HS domain (40.4 vs. 37.4 (95% CI -4.37; -1.16),  $p = 0.001$ ) in the primarily non-amputee group. These results did not differ for patients who remained non-amputees during follow-up (Table 3). Also, all measurements remained statistically significant over time.

### Amputees

Patients who underwent a primary major limb amputation showed statistically significant improvements in their

physical QoL domain scores after six months (14.0 vs. 9.0 (95% CI -7.84; -1.45),  $p = 0.005$ ) and after one year (14.0 vs. 9.0 (95% CI -9.58; -1.46),  $p = 0.008$ ) follow-up (Table 2). No other domains showed a statistically significant change over time. Table 3 presents the results of the physical and psychological QoL and HS domains after reclassifying the groups at one-year follow-up. Amputees showed statistically significant improvement of the physical QoL domain after a median follow-up time of 182 days (measurement 2; 13.0 vs. 11.3 (95% CI -7.84; -1.45),  $p = 0.005$ ) and these results stayed statistically significant in the following measurements. Again, no other domains showed any statistically significant changes for these amputees.

Overall, our results indicated a discrepancy for the physical QoL and HS domains of the WHOQOL-BREF and SF-12 questionnaires. The Pearson correlation was used to measure the strength and direction of association that exists between the WHOQOL-BREF and SF-12 questionnaires. There was a strong positive relationship between the physical and psychological domains of both questionnaires for non-amputees as well as amputees. These results were statistically significant after one year in the non-amputee group, respectively  $r(95) = .78$ ,  $p < 0.001$  and  $r(95) = .73$ ,  $p < 0.001$ . After six months, there was a strong statistically significant positive relationship between the physical and psychological domains of both questionnaires in the amputee group,  $r(12) = .60$ ,  $p = 0.023$  and  $r(12) = .81$ ,  $p < 0.001$ . However these results did not stay statistically

significant after one year,  $r(2) = -.42$ ,  $p = 0.58$  and  $r(2) = .13$ ,  $p = 0.868$ . However, the sample size was so low that no conclusions can be drawn.

## DISCUSSION

The goal of this prospective observational cohort study was to evaluate QoL in relation to HS in 200 CLI patients aged 70 years and older undergoing major limb amputation. QoL is an important outcome in vascular surgery. The data shows that non-amputees had statistically significant improvement of both physical domains of QoL and HS. Amputees only had statistically significant improvement of the physical domain of the QoL and did not show any statistically significant difference in HS. Although, health care providers presume that disability in physical functioning, such as walking and climbing chairs, equals impaired QoL, we found something different. Instead, QoL (measured by WHOQOL-BREF) improved whereas HS did not. In our opinion, the explanation for this difference should be found in the questionnaire design.

HS is an assessment that measures objective functioning (e.g. whether a patient is able to adequately engage in specific activities). HS is an objective indicator of functional outcome, but does not measure a patient's subjective wellbeing.<sup>16–20</sup> The WHOQOL-BREF questionnaire provides the opportunity to assess the patient's evaluation of physical, psychological, and social functioning.<sup>9,22</sup> In contrast to HS questionnaires, the WHOQOL-BREF questionnaire does not express the level of functioning, but evaluates the patient's perception thereof. Rather than asking a patient whether he is able to perform daily activities, the WHOQOL-BREF questionnaire asks patients if they are satisfied with their ability to perform certain daily living activities.

The systematic review of Hawkins et al. showed that the SF-12 questionnaire was extensively validated to measure HS, including in vascular amputees. But then again HS is a generic measurement tool that does not adequately identify the physical, psychological, and social functioning of CLI patients.<sup>1,28,29</sup> The SF-12 questionnaire is based on health professionals' definitions of QoL.<sup>13</sup> Therefore, HS assesses disabilities in life whereas QoL assesses if patients are subjectively restricted in daily life. In CLI patients and especially in vascular amputees living without pain is prioritised over mobility. This results in a different perspective on QoL, which is difficult to measure.<sup>1</sup> Breek et al. stated an important difference between HS and QoL in patients with intermittent claudication (IC).<sup>9</sup> Our results endorse these findings in patients with CLI. Because of high amputation rates (35%–67%)<sup>3,8,30</sup> in CLI, a valid QoL outcome and HS is important in vascular amputees. In our study, vascular amputees (with a one-year mortality of 35%) showed statistically significant improvement in the physical QoL domain at one-year follow-up (survey response 67%,  $n = 20$ ).

Frans et al. analysed the QoL in 150 CLI patients using the VascuQol questionnaire, of which 14 patients underwent major limb amputation.<sup>18</sup> After one-year follow up the overall QoL improved. The disease-specific VascuQol questionnaire is considered an accurate instrument to measure QoL in IC patients.<sup>29</sup> Nonetheless, the physical domain of the VascuQol questionnaire represents an 'objective' evaluation of performing activities instead of the patient's perception of his overall functioning.<sup>31,32</sup> Therefore the VascuQol questionnaire should be classified as a HS and not as a QoL measurement. Additionally, the differentiating power in CLI patients is poor and therefore it may not be generalizable to this specific patient group.<sup>1,31</sup>

Our study clearly suggests a discrepancy between the physical QoL (WHOQOL-BREF) and HS (SF-12) measurements. Currently, there is no consensus about which instruments are appropriate to measure QoL in elderly CLI patients.<sup>9,33</sup> We advocate the use of the validated WHOQOL-BREF questionnaire because it is a more precise method to describe QoL in CLI patients and it reveals whether a patient is satisfied with his/her overall functioning.<sup>22</sup> With respect to shared decision making, distinctive and *subjective* QoL questionnaires provide a very important outcome measurement and should be used in future research.

Clearly, this study has several limitations. HS and QoL are measured with the use of self-report questionnaires. Inaccurate reporting of patients can compromise self-reported information. In order to limit this risk, we excluded cognitively impaired patients. These patients combined with the patients who refused to participate resulted in the exclusion of 50% of the elderly CLI patients. This could cause a selection bias. Nonresponse bias was also present. Eighty-two included patients did not complete the questionnaires at the one-year follow-up because of decease ( $n = 59$ , 30%) and loss to follow-up ( $n = 13$ , 7%). The reason for loss to follow-up was mostly due to cognitive impairment. All patients lost to follow-up did not receive major limb amputation during the first year. Finally, this study represents the entire clinical course of CLI patients. Comorbid conditions and treatment received during follow-up could have had an influence on HS and QoL. Future studies could examine the repercussion of comorbidities and repetitive treatment on HS and QoL. Furthermore, a patient's view on QoL can also change over time. These changes can be a response to treatment, but can also be a result of adaptation to a chronic illness. Therefore, changes in QoL over time need not necessarily reflect on changes in disease related QoL.

There is a clear difference between patients' functioning and the patients' appraisal of functioning. In this study, elderly CLI patients who underwent major limb amputation showed an increase of QoL, but showed no changes in HS. This raises the question of what do we want to achieve for the elderly CLI patient population. Individual treatment

goals should be kept in mind when assessing the HS or QoL outcome of patients undergoing hospital care. With respect to shared decision making, distinctive and *subjective* QoL questionnaires, like the WHOQOL-BREF, provide a very important outcome measurement and should be used in future research.

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## APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2018.10.024>.

## REFERENCES

- Suckow BD, Goodney PP, Nolan BW, Veeraswamy RK, Gallagher P, Cronenwett JL, et al. Domains that determine quality of life in vascular amputees. *Ann Vasc Surg* 2015;29:722–30.
- Van Eijk MS, van der Linde H, Buijck B, Geurts A, Zuidema S, Koopmans R. Predicting prosthetic use in elderly patients after major lower limb amputation. *Prosthet Orthot Int* 2012;36:45–52.
- Klaphake S, De Leur K, Mulder PG, Ho GH, de Groot HG, Veen EJ, et al. Mortality after major amputation in elderly patients with critical limb ischemia. *Clin Interv Aging* 2017;12:1985–92.
- Christiansen CL, Fields T, Lev G, Stephenson RO, Stevens-Lapsley JE. Functional outcomes after the prosthetic training phase of rehabilitation after dysvascular lower extremity amputation. *PM R* 2015;7:1118–26.
- Nehler MR, Coll JR, Hiatt WR, Regensteiner JG, Schnickel GT, Klenke WA, et al. Functional outcome in a contemporary series of major lower extremity amputations. *J Vasc Surg* 2003;38:7–14.
- Schoppen T, Boonstra A, Groothoff JW, de Vries J, Göeken LN, Eisma WH. Physical, mental, and social predictors of functional outcome in unilateral lower-limb amputees. *Arch Phys Med Rehabil* 2003;84:803–11.
- Bosma J, Vahl A, Wisselink W. Systematic review on health-related quality of life after revascularization and primary amputation in patients with critical limb ischemia. *Ann Vasc Surg* 2013;27:1105–14.
- Farber A, Eberhardt RT. The current state of critical limb ischemia: a systematic review. *JAMA Surg* 2016;151:1070–7.
- Breek JC, de Vries J, van Heck GL, van Berge Henegouwen DP, Hamming JF. Assessment of disease impact in patients with intermittent claudication: discrepancy between health status and quality of life. *J Vasc Surg* 2005;41:443–50.
- O'Boyle CA. Assessment of quality of life in surgery. *Br J Surg* 1992 May;79:395–8.
- Hawkins AT, Henry AJ, Crandell DM, Nguyen LL. A systematic review of functional and quality of life assessment after major lower extremity amputation. *Ann Vasc Surg* 2014;28:763–80.
- Steunenbergh SL, Raats JW, te Slaa A, de Vries J, van der Laan L. Quality of life in patients suffering from critical limb ischemia. *Ann Vasc Surg* 2016;36:310–9.
- Carr AJ, Higginson IJ. Are quality of life measures patient centred? *BMJ* 2001;322:1357–60.
- Granger CV, Hamilton BB, Keith RA, Zielezny M, Sherwin FS. Advances in functional assessment for medical rehabilitation. *Top Geriatr Rehabil* 1986;1:59–74.
- Bradley C. Importance of differentiating health status from quality of life. *Lancet* 2001;357:7–8.
- Muldoon MF, Barger SD, Flory JD, Manuck SB. What are quality of life measurements measuring? *BMJ* 1998;316:542–5.
- Vogel TR, Petroski GF, Kruse RL. Functional status of elderly adults before and after interventions for critical limb ischemia. *J Vasc Surg* 2014;59:350–8.
- Frans FA, Met R, Koelemay MJ, Bipat S, Dijkgraaf MG, Legemate DA, et al. Changes in functional status after treatment of critical limb ischemia. *J Vasc Surg* 2013;58:957–65.
- Cieri E, Lenti M, De Rango P, Isernia G, Marucchini A, Cao P. Functional ability in patients with critical limb ischaemia is unaffected by successful revascularisation. *Eur J Vasc Endovasc Surg* 2011;41:256–63.
- Lejay A, Delay C, Georg Y, Schwein A, Gaertner S, Thaveau F, et al. Endovascular surgery, open surgery, and primary amputation in nonagenarians presenting with critical limb ischemia. *Ann Vasc Surg* 2016;32:25–33.
- Suckow BD, Stone DH. Vascular surgery institutional-based quality and performance measures for the care of patients with critical limb ischemia. *Semin Vasc Surg* 2015;28:92–6.
- Nelson CB, Lotfy M, O'Connell KA, WHOQOL Group. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. *Qual Life Res* 2004;13:299–310.
- Steunenbergh SL, de Vries J, Raats JW, Thijssen WJ, Verbogt N, Lodder P, et al. Quality of life and mortality after endovascular, surgical or conservative treatment of elderly patients suffering from critical limb ischemia. *Ann Vasc Surg* 2018;51:95–105.
- Von Steinbüchel N, Lischetzke T, Gurny M, Eid M. Assessing quality of life in older people: psychometric properties of the WHOQOL-BREF. *Eur J Ageing* 2006;3:116–22.
- Trompenaars FJ, Masthoff ED, Van Heck GL, Hodiament PP, De Vries J. Content validity, construct validity, and reliability of the WHOQOL-Bref in a population of Dutch adult psychiatric outpatients. *Qual Life Res* 2005;14:151–60.
- Ware Jr J, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220–33.
- Penn-Barwell JG. Outcomes in lower limb amputation following trauma: a systematic review and meta-analysis. *Injury* 2011;42:1474–9.
- Chetter IC, Scott DJ, Kester RC. An introduction to quality of life analysis: the new outcome measure in vascular surgery. *Eur J Vasc Endovasc Surg* 1998;15:4–6.
- Knipfer E, Reeps C, Dolezal C, Zimmermann A, Pelisek J, Behrens J, et al. Assessment of generic and disease-specific health-related quality of life instruments in peripheral arterial disease. *Vasa* 2008;37:99–115.
- Reinecke H, Unrath M, Freisinger E, Bunzemeier H, Meyborg M, Lüders F, et al. Peripheral arterial disease and critical limb ischaemia: still poor outcomes and lack of guideline adherence. *Eur Heart J* 2015;36:932–8.
- de Vries M, Ouwendijk R, Kessels AG, de Haan MW, Flobbe K, Hunink MG, et al. Comparison of generic and disease-specific questionnaires for the assessment of quality of life in patients with peripheral arterial disease. *J Vasc Surg* 2005;41:261–8.
- Conijn AP, Santema TB, Bipat S, Koelemay MJ, de Haan RJ. Clinimetric evaluation of the vascular quality of life questionnaire in patients with lower limb ischaemia. *Eur J Vasc Endovasc Surg* 2017;53:412–8.

33 Aboyans V, Ricco JB, Bartelink MEL, Björck M, Brodmann M, Cohnert T, et al. Editor's choice - 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in

collaboration with the European society for vascular surgery (ESVS). *Eur J Vasc Endovasc Surg* 2018;55:305–68.

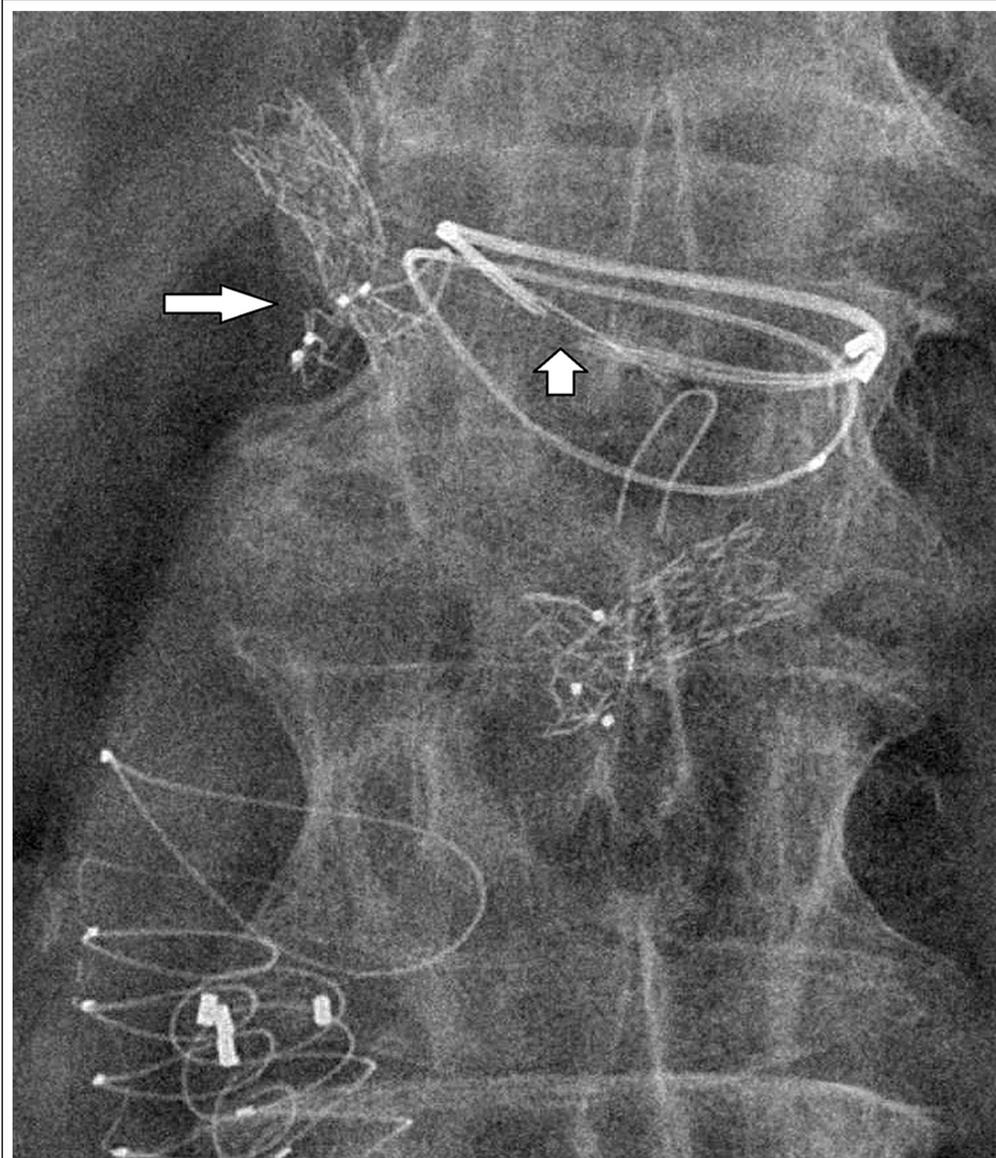
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## COUP D'OEIL

# Fractured Proximal Nitinol Ring in a Fenestrated Anaconda Device

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A 75 year old woman was treated for a 53 mm juxtarenal abdominal aortic aneurysm with an endograft with a fenestration for both renal arteries (Anaconda, Terumo Aortic, Inchinnan, Scotland, UK). At three years, a fracture of the proximal nitinol ring with downward migration was diagnosed (abdominal radiograph anteroposterior view; short arrow). Also the covered stent in the fenestration to the right renal artery appeared to be fractured (long arrow). The second nitinol ring was intact. At four years, no further migration has occurred. Duplex ultrasound shows a decrease of the aneurysm diameter down to 38 mm with right renal artery flow.

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