

## Accepted Manuscript

Title: Functional and psychological outcomes of delayed lower limb amputation following failed lower limb reconstruction

Author: Lana van der Merwe Franz Birkholtz Kevin  
Tetsworth Erik Hohmann



PII: S0020-1383(16)30199-1  
DOI: <http://dx.doi.org/doi:10.1016/j.injury.2016.05.027>  
Reference: JINJ 6740

To appear in: *Injury, Int. J. Care Injured*

Received date: 17-3-2016  
Revised date: 1-5-2016  
Accepted date: 16-5-2016

Please cite this article as: van der Merwe Lana, Birkholtz Franz, Tetsworth Kevin, Hohmann Erik. Functional and psychological outcomes of delayed lower limb amputation following failed lower limb reconstruction. *Injury* <http://dx.doi.org/10.1016/j.injury.2016.05.027>

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**Functional and psychological outcomes of delayed lower limb amputation following failed lower limb reconstruction**

**Lana van der Merwe**

**MBCChB (Pret), FCS Orth (SA)**

Department of Orthopaedics, University of Pretoria, Pretoria, South Africa

Walk-a-Mile Centre for Advanced Orthopaedics, Unitas Hospital & Mediclinic Midstream, Pretoria, South Africa

**Franz Birkholtz**

**MBCChB (Pret), FCS Orth (SA), MMed Orth (Pret)**

Department of Orthopaedics, University of Pretoria, Pretoria, South Africa

Walk-a-Mile Centre for Advanced Orthopaedics, Unitas Hospital & Mediclinic Midstream, Pretoria, South Africa

Department Orthopaedics, University of Pretoria, Pretoria, South Africa

**Kevin Tetsworth**

**MD, FRACS**

Department of Orthopaedic Surgery, Royal Brisbane Hospital, Brisbane, Australia

Queensland University of Technology, Brisbane, Australia

University of Queensland School of Medicine, Brisbane, Australia

Orthopaedic Research Centre of Australia

**Erik Hohmann**

**FRCS, FRCS (Tr&Orth), MD, PhD**

Medical School, University of Queensland, Australia

Orthopaedic Research Centre of Australia

Walk-a-Mile Centre for Advanced Orthopaedics, Unitas Hospital & Mediclinic Midstream, Pretoria, South Africa

**Corresponding Author:**

Erik Hohmann

Fax: +27 12 644 2642

Email: [ehohmann@optusnet.com.au](mailto:ehohmann@optusnet.com.au)

PostNet Suite #867, Private Bag X1007, Lyttleton 0140, South Africa

## **Abstract**

### **Purpose:**

The purpose of this study was to evaluate the functional and psychological outcomes of patients who underwent delayed lower limb amputation following failed limb salvage surgery.

### **Methods:**

This retrospective, descriptive study evaluated functional outcomes using the Sickness Impact Profile (SIP) and Short Form-36 (SF-36) in 12 patients. Inclusion criteria included patients who underwent limb reconstruction and delayed amputation between between July 2006 and December 2014, with an age range between 18-80 years of age, the ability to ambulate independently, a time interval between the last salvage procedure and amputation greater than six months, and a minimum follow-up of 24 months. Patients were contacted via telephone by the principal investigator and both the Sickness Impact Profile (SIP) and Short Form-36 (SF-36) were completed. Descriptive analysis (means and standard deviation) was used to determine outcomes for both SIP and SF-36 health profiles.

### **Results:**

Ten patients who had amputations following failed reconstruction (2006-2014) with a mean age of  $53 \pm 10$  years were interviewed. Six patients had a  $SIP < 5$ , three patients scored between five and 10 points and one scored  $>10$  points. The main deficit on the SF-36 was in the physical component. The SF-36 scores demonstrated a mean score of  $40.8 \pm 11.5$  for the physical component, and  $57.4 \pm 7.9$  for the mental component. Three patients returned to work after amputation and continued performing their pre-injury duties as farmers.

Three other patients returned to work, but were allocated to administrative duties. Two patients were pensioners at the time of their injuries, and the only female patient was a housewife. One patient went into early retirement.

**Conclusion:**

The results of this study strongly suggest that delayed amputation following failed limb salvage surgery can still result in good and satisfactory outcomes in the majority of patients and achieves results similar to early amputation and limb reconstruction techniques.

**Key words:** Lower limb trauma; delayed amputation; limb reconstruction; limb salvage surgery

## Introduction

Lower limb injuries continue to place a significant burden on the orthopaedic trauma patient. Previous research has consistently demonstrated that major trauma results in significant functional limitations and has a negative impact on mental health [18,22,26]. The management of high energy trauma remains challenging, often involving multiple procedures that may take years to complete reconstruction and rehabilitation [33].

Treatment options include limb salvage, early, and delayed amputation [5,7]. The decision whether to reconstruct or salvage remains controversial [34]. Swiontowski, et al. suggested that muscle injury, absence of sensation, and vascular injuries influence that decision; patient factors did not play a significant role, with the exception of alcohol consumption and socioeconomic status [34]. Advances in orthopaedic, vascular, and plastic surgery have made it possible to treat severely injured lower limbs with salvage procedures [5,21]. However, limb salvage may not be in the patient's best interest as it is commonly associated with higher rates of rehospitalization, more surgical procedures, and a higher rate of complications when compared to primary amputation [7]. A recent meta-analysis by Busse, et al. did not observe significant differences for long-term functional outcome, return to work, and pain between patients undergoing limb-salvage or early primary amputation [7]. Regardless of the selected treatment modality, poor functional outcomes are consistently reported [2,7,24].

The timing of amputation appears to influence both subjective and objective outcomes. Several authors report early amputation results in better functional outcomes, lower rates of post-traumatic stress disorder, and a higher likelihood to engage in sporting activities [11,27,31]. In contrast, patients who underwent delayed amputation had significantly higher rates of out-patients visits, wound complications, and infections [27]. In addition, this cohort had higher rates of post-traumatic stress disorder and substance abuse; interestingly, these rates were similar to patients who underwent limb salvage surgery [27]. In those patients with persistent symptoms, delayed amputation subjectively improved function and resulted in a high degree of patient satisfaction [17].

The purpose of this study was to evaluate the functional and psychological outcomes of patients who underwent delayed lower limb amputation following failed limb salvage surgery. We hypothesized that patients undergoing delayed amputation would have satisfactory functional and psychological outcomes.

## Methods

The database from the XX was searched for all patients who were treated with delayed lower limb amputations following limb salvage surgery for major lower limb trauma. The following inclusion criteria were applied: limb reconstruction and delayed amputation between between July 2006 and December 2014; 18-80 years of age; ability to ambulate independently; time interval between the last salvage procedure and amputation more than six months; and a minimum follow-up of 24 months. Patients were excluded if they sustained multi-trauma, contra-lateral lower limb injury, traumatic brain injury or systemic pathology unrelated to their trauma. Ethical approval was obtained from the University's Faculty of Health Sciences Research Ethics Committee (Ref.: 546/2015).

### *Outcome measures*

The Sickness Impact Profile (SIP) and Short Form-36 (SF-36) were utilized to establish both perceived functional outcomes as well as emotional and mental health. The SIP is a validated functional measurement tool [10]. The SIP scores range from 0 to 100 points, with higher values indicating greater disability. The general population scores range between 2 and 3 points. A SIP of  $\leq 5$  post-injury suggests an acceptable recovery, and a SIP  $>10$  points indicates substantial residual disability [9,13]. The SIP is a multidimensional



measure of self-reported health status that can be self or interviewer administrated. It consists of 136 statements about limitations in twelve categories of function: (1) walking, (2) mobility, (3) body care and movement, (4) social interaction, (5) alertness, (6) emotional behaviour, (7) communication, (8) sleep and rest, (9) eating, (10) work, (11) home management, and (12) recreation and pastimes. Respondents are asked to endorse only the statements that describe their health most accurately on that given day. Scores are calculated for the overall instrument, for all twelve categories, and for the two major dimensions: physical health (summarized by the first three categories), and psychosocial health (a summary of the second four categories) [3].

One of the major benefits of the use of a generic health questionnaire is that the patient's psychological status can be assessed [14,16]. The SF-36 is a multi-purpose, short-form health survey consisting of 36 questions in eight sections; (1) vitality, (2) physical functioning, (3) bodily pain, (4) general health perception, (5) physical role functioning, (6) emotional role functioning, (7) social role functioning and (8) mental health. The score is transformed into a 0 to 100 scale for each section; with a score of zero equivalent to maximum disability and a score of 100 denoting no disability [35,36].

All patients were contacted via telephone by the principal investigator and both the Sickness Impact Profile (SIP) and Short Form-36 (SF-36) were completed. Study participants were allocated a study number to preserve anonymity. Descriptive analysis (means and standard deviation) was used to determine outcomes for both the SIP and SF-36 health profiles.

## Results

Thirteen patients (13 male and one female) were eligible for inclusion. One patient could not be contacted, and two patients were excluded because the amputation was performed within one month of the last salvage procedure. The ten remaining patients with a mean age of  $53 \pm 10$  years were contacted by the principal investigator between November and December 2015. The demographic details of all patients are summarized in table 1.

The mechanism of injury in two patients was due to a fall, five sustained motorcycle accidents, and three patients were involved in motor vehicle accidents. The mean number of surgical salvage procedures was  $7.1 \pm 2.8$ . The number of salvage procedures per patient involved in motorbike accidents was twice as high, with a mean of  $8.6 \pm 2.9$  compared to  $4.3 \pm 0.6$  for those patients involved in a motor vehicle accident. In addition, all patients involved in a motorbike accident required flap coverage compared to one patient in the motor vehicle group, reflecting the greater severity of motorbike injuries.

Three patients returned to work after amputation and continued performing their pre-injury duties as farmers. Three other patients returned to work, but were allocated to administrative duties. Two patients were pensioners at the time of their injuries, and the only female patient was a housewife. One patient went into early retirement. One patient returned to competitive athletics, and three patients participate in hiking and cycling sports.

Table 2 demonstrates the SIP and SF36 scores. Six patients had a total SIP score of <5; in fact these six patients had a score between 0.33 and 2.6, equivalent to the general population score. Three patients had a score between 5 and 10 indicating acceptable recovery with some residual disability, and one patient (no. 5) had a SIP score of 17. The physical and psychosocial dimension scores exhibited a very similar distribution.

The SF-36 scores demonstrated a mean score of  $40.8 \pm 11.5$  for the physical component, and  $57.4 \pm 7.9$  for the mental component. These results suggest that despite 90% normal and acceptable functional recovery, all included patients had residual general health and psychological issues. The SF-36 sub-scores were high for bodily pain ( $77.4 \pm 24.5$ ), general health ( $76.4 \pm 22.0$ ), vitality ( $86.5 \pm 10$ ), emotional role function ( $73.3 \pm 30.6$ ), and social function ( $81.2 \pm 27.2$ ). The SF-36 sub-scores were low for physical function ( $59.5 \pm 23.7$ ) and physical role function ( $59.5 \pm 38.1$ ), indicating there is a subjectively perceived functional disability. Patient no 5 was an obvious outlier in this cohort. He was referred with a septic non-union following a grade III pilon fracture; following amputation he had difficulties using the prescribed prosthetic limb, continued to use crutches, and appears to have a post-traumatic stress disorder.

## Discussion

The most important finding of this study was that delayed amputation resulted in good and satisfactory functional outcomes in the majority of patients (90%) in this small series of patients who sustained high energy lower-limb trauma and failed limb salvage surgery. However, there still was a perceived subjective functional disability in 50% of these patients, as demonstrated by lower SF-36 physical and physical role function sub-scores. As outlined earlier, patient no 5 was an obvious outlier not following the pattern observed in the remainder of this cohort. Despite his poor results, he was not excluded. Posttraumatic stress disorder, depression, and psychological disorders are common complications of these devastating injuries [26]. O'Toole, et al. were able to demonstrate in a large patient cohort that both the absence of depression and physical function are predictors of outcome [29].

Helgeson, et al. investigated the effect of delayed amputation in a group of 22 soldiers, the majority having sustained blast injuries [17]. The primary indications for amputation were neurologic dysfunction, pain, and recurrent infections. Their patient cohort was younger, the mean time to amputation was 10.2 months, and the follow-up was significantly shorter. These authors did not use

validated outcome measures, but documented that all patients reported subjectively improved function. Honkamp, et al. retrospectively reviewed 18 patients who underwent trans-tibial amputation for intractable pain, and reported significant improvements in pain, walking distance, return to work, and reduced use of narcotics [20].

There is considerable debate whether amputation achieves better results than limb-salvage surgery in the post-traumatic setting [12,32]. Over 20 years ago Giordadis, et al. suggested that patients with a salvaged limb took longer to full weight-bearing, were less willing to work, had higher hospital charges, were more likely to consider themselves severely disabled, and had more problems with occupational and recreational activities [12]. More recently Doukas, et al. (the METALS study) suggested that patients undergoing amputation had better functional outcomes than those undergoing limb salvage [11]. These findings are in contrast to Busse, et al, who performed a meta-analysis of observational studies comparing complex limb-salvage versus early amputation [7]. There was no difference between the two groups for functional outcomes at seven years, but the limb salvage group had a significantly longer rehabilitation time, more surgical procedures, and a higher rate of complications. Akula, et al., performed a meta-analysis investigating amputation versus limb salvage from the patient's perspective, and noted that reconstruction is psychologically more acceptable [1]. Similar to Busse, et al., they reported there, were no significant between group differences for functional outcomes [1,7].

The results of our study demonstrated that delayed amputation for failed limb salvage surgery achieved good and excellent outcomes, with a mean total SIP score of 4.8; 4.9 for the physical SIP, and 1.8 for the psychological SIP. These mean scores are substantially better than those reported by multiple authors for early amputation [5,8,24]. Akula, et al reported the mean physical scores for early amputation were 16.2, and 15.6 for the psychological SIP [1]. MacKenzie 2005 reported mean physical and psychosocial scores at 24 and 84 months; for below knee amputees the physical scores were 9.4 at 24 months, and 16.4 at 84 months. The psychosocial scores were 11.5 at 24 months, and 16.7 at 84 months [24]. Bosse, et al reported physical SIP scores of 10.1 and psychosocial SIP scores of 11.1 at 24 months for early amputations [5]. When comparing the results of this study to these earlier reports, the outcomes of delayed amputation for failed limb salvage surgery in this series are more comparable to early amputation. One possible explanation for these findings could involve chronic pain, a common sequelae of limb salvage and a major indication for conversion to amputation [6]. Both Clark, et al. and Holbrook, et al. reported that experiences involving war injuries in soldiers with poorly controlled pain resulted in chronic pain and posttraumatic stress disorder [8,19]. By removing the painful extremity patients may have reduced levels of chronic pain, resulting in both better functional and psychosocial scores following amputation. In contrast, chronic pre-amputation pain also creates a neurologic imprint which may account for phantom pain [6,28]. It is important to note that this practice deals with civilian injuries only, and utilizes a multi-disciplinary approach including experienced physiotherapists and occupational therapists, psychologists, orthotists and specialized nursing staff. This stable framework of experienced support staff guarantees continuity of care during the entire course of treatment and may contribute to better outcomes in this cohort of patients.

Return to work is one of the most powerful metrics against which to evaluate treatment outcomes [22]. Factors associated with return to work include age <55, Caucasian ethnicity, having a high school or college education, non-smoking, and average to high self-efficacy [22]. MacKenzie, et al. reported that 53% of patients who underwent early amputation returned to work, but 20-25% are limited in performance [22]. Of the ten patients in this study, eight (80%) were working at the time of injury. Of these eight patients, six (75%) returned to work but only three resumed duties at pre-injury level. The remaining three patients (37%) were accommodated at work in administrative or managerial positions. The rate of return to work is higher in our case series when compared to the LEAP data [22], and the higher SIP and SF-36 scores in our cohort may be the reason for this finding. Differences in the severity of injury between the LEAP cohort and this small cohort may also be responsible for the discrepancy in the rate of return to work. Intuitively, patients with more severe injuries would be expected to have a lower rate of return to work. However, Ly, et al could clearly demonstrate that lower extremity severity scoring systems are not predictive of functional recovery in patients with successful limb reconstruction [21]. The patients in this case series were referred for definitive treatment; the severity of the initial injury is therefore unknown, but it is unlikely the severity of that injury or the multiple procedures prior to referral have influenced outcomes.

This study is limited by the small sample size, and has the typical limitations and biases inherent in a retrospective case series. However, the total number of late and delayed amputations is relatively small [17], and the reported failure rates for lower-limb reconstruction range from 9-18% [6]. In addition, only a small subset of patients require late amputations. The results of this study demonstrated a 90% success rate for delayed amputation despite variation in age, mechanism of injury, time from injury to

amputation, and the number of previous procedures. Self-reported outcome measures do not investigate objective variables such as gait patterns, muscle strength, and other biokinetic parameters. The outcome scores used in this study are validated and reliably measure function [3,30], disability, and mental health in a variety of diseases. These scores have been used by the LEAP investigators [5,7,22-26], facilitating comparison with our results. This small cohort involved variable demographics, and had a broad range of injuries encompassing multiple different skeletal and soft tissue procedures. While typical of these severe injuries, this potentially introduced an element of treatment bias. The SIP and SF-36 scores were obtained by remote interview and it has been suggested that patients report fewer symptoms by telephone, perhaps introducing reporting bias [4,15].

## **Conclusion**

The results of this study strongly suggest that delayed amputation following failed limb salvage surgery can result in good and satisfactory outcomes in the majority of patients, and can achieve outcomes comparable to early amputation or limb salvage.

## **Conflicts of interest**

none



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Tables

**Table 1:** Demographic data of all patients included

	age	gender	Mechanism of injury	Previous Procedures	Flap Coverage	Type of Amputation	Interval Injury - Amputation	Interval Amputation - Interview	Interval Injury - Interview
1	61	M	MBA	9	Y	TKA	10	68	78
2	52	F	FALL	6	N	BKA	24	25	49
3	45	M	MVA	5	Y	TKA	61	49	110
4	45	M	MBA	8	Y	BKA	11	23	44
5	48	M	MVA	4	N	BKA	20	40	60
6	75	M	MBA	13	Y	BKA	26	85	111
7	39	M	MBA	8	Y	BKA	33	58	91
8	55	M	FALL	9	N	BKA	15	38	53
9	55	M	MBA	5	Y	BKA	7	66	73
10	55	M	MVA	4	N	BKA	52	29	81
<b>Mean/SD</b>	<b>53±10</b>			<b>7.1±2.8</b>			<b>25.9±18.1</b>	<b>48.1±20.7</b>	<b>75±23.9</b>



**Table 2:** SIP and SF36 scores including its subscores

	SF-36 Score										SIP Score		
	Physical Function	Physical Role Function	Bodily Pain	General Health	Vitality	Mental Health	Emotional Role Function	Social Function	Physical Component (PCS)	Mental Component (MCS)	Total	Physical Dimension	Psychosocial Dimension
<b>1</b>	60.00	25.00	84.00	95.00	95.00	92.00	66.66	100.00	41.6	62.5	5.81	3.31	0.0
<b>2</b>	40.00	75.00	52.00	67.00	75.00	76.00	33.33	75.00	38.4	48.7	2.62	0.28	0.0
<b>3</b>	45.00	00.00	74.00	77.00	85.00	84.00	66.66	50.00	33.0	55.1	6.40	7.01	2.13
<b>4</b>	50.00	00.00	84.00	77.00	80.00	72.00	33.33	62.50	39.1	46.8	8.90	8.10	0.0
<b>5</b>	10.00	00.00	22.00	20.00	55.00	68.00	33.33	25.00	14.3	44.9	17.64	16.86	17.58
<b>6</b>	80.00	75.00	100.00	87.00	90.00	92.00	100.00	100.00	50.1	61.6	0.63	1.79	0.0
<b>7</b>	90.00	100.00	100.00	100.00	95.00	92.00	100.00	100.00	56.7	60.1	0.33	0.0	0.0
<b>8</b>	75.00	75.00	84.00	77.00	95.00	92.00	100.00	100.00	45.5	63.6	1.81	4.15	0.0
<b>9</b>	70.00	50.00	74.00	82.00	95.00	92.00	100.00	100.00	41.1	65.5	2.15	3.67	0.0
<b>10</b>	75.00	75.00	100.00	82.00	100.00	96.00	100.00	100.00	47.9	64.8	1.64	3.67	0.0
<b>Mean/SD</b>	<b>59.5±23.7</b>	<b>47.5±38.1</b>	<b>77.4±24.5</b>	<b>76.4±22.0</b>	<b>86.5±13.5</b>	<b>85.6±10.0</b>	<b>73.3±30.6</b>	<b>81.2±27.2</b>	<b>40.8±11.5</b>	<b>57.4±7.9</b>	<b>4.8±5.3</b>	<b>4.9±4.9</b>	<b>1.8±5.5</b>