

Electronic Supplementary File 2: Clinical outcomes of patients who elected for amputation post-PDAFO provision

BACKGROUND

Although lower-limb reconstruction and the provision of a PDAFO provide both the surgeon and patient with options, there remains an inability to predict which patients will succeed after surgery and MDT rehabilitation. Initial attempts to reconstruct a severely injured lower-limb may result in delayed amputation due to non-union, infection, limitations in function or chronic pain. In an effort to manage expectations of patients and clinicians, it is important to understand the injury characteristics and clinical outcomes of patients who were prescribed a PDAFO but subsequently elected for amputation.

Patient Demographic

Of the 65 UK military personnel who have been prescribed the PDAFO to date, 10 have subsequently elected for amputation. The authors believe 4 of these delayed amputations were unavoidable (3 due to osteomyelitis and 1 secondary trauma). Therefore, despite limb reconstruction and PDAFO provision alongside MDT rehabilitation, 6 patients decided amputation was the preferred option (due to a combination of persistent pain and unsatisfactory levels of function progress). The mean length of time from date of injury to PDAFO provision (n=8) was 22 ± 10 months (the other 2 patients had a degenerative conditions and were provided their PDAFO after 6.5 years and 4 years after initial injury). Prior to receiving their PDAFO, these 10 patients received a mean 5 ± 3 MDT rehabilitation

admissions over 13 ± 12 months. The demographic and injury characteristics of the 10 patients prior to the provision of the PDAFO are detailed in Table 1.

Table 1: Patient Demographic and Injury Characteristics

	Previous PDAFO users who later had a below knee amputation	*Below-knee trauma patients prior to PDAFO availability in UK military	
		Limb Salvage	Delayed Amputation
Number	10	13	15
	34 ± 8	30 ± 6	32 ± 7
Age (years)	(22-47)	(22-41)	(23-48)
Gender (% male)	100	92	100
Pre Injury Body	179 ± 10	179 ± 7	178 ± 9
Height (cm)	(170-193)	(167-192)	(163-197)
	91 ± 18	89 ± 10	95 ± 17
Body Mass (kg)	(71-125)	(68-101)	(77-124)
BMI (kg/m^2)	29 ± 4	28 ± 3	30 ± 5
	(24-35)	(23-33)	(25-38)
Blood Pressure (mmHg)			
Systolic	127 ± 12	132 ± 11	132 ± 8
	(109-148)	(108-146)	(115-146)
Diastolic	74 ± 8	74 ± 9	76 ± 10
	(65-82)	(68-80)	(70-82)
Mechanism of Injury			
IED	5	7	5
GSW	1	3	1
IDF Rocket	-	1	-
RTA	1	2	1
Crush	-	-	4
Sport	2	-	3
Non-Specific MSK Disorder	1	-	1
Injury Type #			
Fracture	7 (70%)	10 (77%)	11 (73%)
Nerve damage	1 (10%)	2 (15%)	3 (20%)
Extensive soft tissue or vascular trauma	2 (20%)	5 (38%)	3 (20%)
Degenerative	2 (10%)	-	1 (9%)
Foot/Ankle			
No. bone segments fractured (segments classified as Tibia/Fibula, hind, mid and fore-foot) †			
Tibia / Fibula	2 (20%)	9 (90%)	8 (73%)
Malleolus	2 (20%)	1 (10%)	6 (55%)
Hind Foot	6 (60%)	4 (40%)	8 (73%)
Mid Foot	4 (40%)	2 (20%)	1 (9)
Additional complications/diagnosis:			

Complex Regional Pain Syndrome (CRPS)	2 (20%)	2 (15%)	6 (40%)
Osteomyelitis	3 (30%)	-	2 (13%)
Compartment Syndrome	1 (10%)	3 (23%)	3 (20%)

The injury types do not add up to the number of patients because some patients had multiple injuries. † The numbers do not add up to the number of patients with fracture because some patients had injuries to multiple bone segments. The percentages of patients with fractured bone segments are a reflection of the total number of patients who experienced a fracture, not the total number of patients in each injury group. * Adapted from Ladlow et al 2016 [1]

METHODS

As the aim of this service evaluation is to assess the impact of PDAFO provision on lower-limb trauma patients; we have therefore excluded 4 patients with unavoidable amputations from follow-up analysis as the decision to amputate was not related to the orthosis. Two of the ten patients elected for amputation after leaving military service, therefore no follow-up clinical outcomes could be reported at DMRC, Headley Court. The remaining 4 patients who we will report on followed the UK military model of complex trauma rehabilitation, as previously described in Ladlow *et al.* (2016) [1].

RESULTS

Their time course of treatment, length of rehabilitation and follow-up dates are presented in Table 2. The clinical outcomes pre-PDAFO provision, last admission (whilst wearing their prosthesis) and at follow-up are demonstrated in Table 3

Table 2: Length of Rehabilitation and time of follow-up analysis

Length of Time	PDAFO provision to amputation	Date of amputation to final admission	Last admission to follow-up questionnaire	Date of amputation to follow-up questionnaire
Number of patients	4	4	4	4
Number of months	12 ± 7	10 ± 3	10 ± 3	21 ± 6
Number of 3 week admissions	4 ± 4	5 ± 2	-	-

Functional Outcomes

The patients who were previously prescribed the PDAFO but later elected for amputation demonstrated a significantly shorter 6MWD (370 ± 61 m, $p < 0.05$) prior to the provision of their PDAFO than those who continued with their PDAFO alongside MDT rehabilitation (440 ± 75 m). The prevalence of patients able to walk comparable speeds to the general population in the 6MWT prior to PDAFO provision were less in the elective amputee group compared to patients who continued with their PDAFO alongside MDT rehabilitation. Also levels of ambulatory function (prevalence able to walk independently) were considerably less in this elective amputee group..

Following MDT rehabilitation, all amputee patients demonstrated significant improvements ($P < 0.001$) in 6 MWD compared to their pre-PDAFO admission. Prior to their PDAFO provision none of these patients were able to walk distances comparable to age matched general population and only 25% could walk independently, at their last admission all four patients could walk independently and 75% could walk greater than general population norms (>459 m) in their prosthetics. At follow-up (21 months after amputation) the four amputees reported lower ambulatory function (prevalence able to walk and run independently) compared to PDAFO users.

Psychosocial Outcomes

Prior to the provision of their PDAFO, the elective amputee group scored significantly greater mean depression and anxiety scores ($p < 0.05$) compared to those patients who were able to continue using their PDAFO alongside MDT rehabilitation. A greater prevalence of 'moderate symptoms' in depression (75%), anxiety (75%) and requirement for mental health support (100%) were all notably higher than in the patients who continued using their PDAFO (13% reported 'moderate' depression and anxiety, and 25% requiring mental health support, respectively). At follow-up (21 months after amputation) the four amputees reported less favourable psychosocial outcomes (depression and anxiety) compared to medium-term outcomes reported in the PDAFO users.

Table 3: Functional and Psychosocial outcomes, prior to the passive dynamic ankle foot orthosis (PDAFO), last admission of rehabilitation wearing their prosthesis and at follow up.

	Delayed Below-Knee Amputation Post PDAFO		
	Admission Pre PDAFO Provision	Last Admission With Prosthetic	>12 months follow-up
Number	4	4	4
<i>Functional Outcomes</i>			
6-MWT *†§#	370 ± 61 (290-430)	500 ± 63 (445-590)	-
Achieved >459m (%)	0	75	-
Run Independently (%)	0	0	25
Walk Independently (%)	25	100	75
Walk with aid/adaptation (%)	100	100	100
	25	100	100
ADL Independently (%)			
ADL with aid/adaptation (%)	100	100	100
<i>Mental Health Outcomes</i>			
PHQ-9 (Depression)	17 ± 6 (9-22)	10 ± 2 (8-12)	12 ± 6 (3-18)
<5 No Symptoms (%)	0	0	25
>10 Moderate symptoms (%)	75	50	75
>15 Moderate to Severe Symptoms (%)	75	0	50
GAD-7 (Generalised Anxiety Disorder)	14 ± 4 (8-18)	10 ± 3 (5-12)	11 ± 7 (1-16)
<5 No Symptoms (%)	0	0	25
>10 Moderate Symptoms (%)	75	50	75
>15 Severe Symptoms	50	0	25
Requires Mental Health Support (%)	100	75	50
<i>Pain</i>			
Report No Pain (%)	0	50	50
Able to Control Pain (%)	100	100	100

DISCUSSION

It is important to note that the sample size for this elective amputees group was small making any conclusions generalizable to a wider population difficult and caution must be used if using this data to inform practice. However, an interesting finding from this group of elective amputees was that they demonstrated a significantly shorter 6MWD (370±61m, $p < 0.05$), reduced prevalence able to walk independently, greater depression/anxiety scores and a greater prevalence required mental health support prior to the provision of their PDAFO than those who continued with their PDAFO. Discussions surrounding these clinical measurement

might prove informative when making decision about the suitability of the brace for specific patients and whether the PDAFO will benefit the patient in the long term.

Our depression and anxiety findings supports previous research that found elective amputation often results in no change to a patient's mental well-being from pre-amputation to post-amputation [2]. In one US military rehabilitation centre, over 80% of patients treated with the IDEO avoided lower-limb amputation within the first year [3]. The unavoidable amputation rate of PDAFO users in the UK military after 21 months is 9% (6 out of 65 users).

References

1. Ladlow P, Phillip R, Coppack R, et al. Influence of Immediate and Delayed Lower-Limb Amputation Compared with Lower-Limb Salvage on Functional and Mental Health Outcomes Post-Rehabilitation in the U.K. Military. *J Bone Joint Surg Am* 2016;98(23):1996-2005.
2. Krueger CA, Rivera JC, Tennent DJ, et al. Late amputation may not reduce complications or improve mental health in combat related, lower extremity limb salvage patients. *Injury* 2015 Aug;46(8):1527-32.
3. Hill O, Bulathsinhala L, Eskridge SL, et al. Descriptive Characteristics and Amputation Rates With Use of Intrepid Dynamic Exoskeleton Orthosis. *Mil Med* 2016;181(S4):77-80.