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A modified passive-dynamic ankle–foot orthosis: can it prevent amputation and arthrodesis in patients with ankle–foot trauma?

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Abstract

Introduction High-energy lower extremity trauma (HELET) may cause severe damage within the foot–ankle complex. Occasionally, arthrodesis or amputation are the only remaining options to increase activity levels. The modified passive dynamic ankle–foot orthosis (PDAFO) may prove to be a nonsurgical alternative. This study evaluated the effect of a modified PDAFO with a 6-week training program on pain and performance in patients after HELET.

Materials and methods A retrospective cohort study was conducted on seventeen patients who considered an arthrodesis or an amputation after HELET. In an attempt to avoid surgery, the modified PDAFO with a 6-week training program was provided. Pain scores was measured with the Numeric Rating Scale and administered at the start of testing, immediately after the two performance tests and at the end of the day of testing. Performance was evaluated with the 6-min walk test (6MWT) and the Comprehensive high-level activity mobility predictor (CHAMP).

Results A significant pain reduction was achieved after the treatment procedure. At the start of the test days ($p = 0.002$), after the 6MWT ($p = 0.001$), after the CHAMP ($p < 0.001$) and at the end of the day ($p < 0.001$). In addition, a significant improvement on performance was observed in the 6MWT ($p < 0.001$) and the CHAMP ($p = 0.01$). None of the patients considered a surgical intervention anymore.

Conclusions Patients after HELET show a decrease in pain and an improvement in performance after a 6-week training program with modified PD-AFO. The results suggest that the modified PDAFO is an effective alternative for a surgical approach.

Keywords Limb salvage · Foot injury · Rehabilitation · Orthosis · Arthrodesis · Amputation

Introduction

Decision-making with respect to a surgical or non-operative approach after high-energy lower extremity trauma (HELET) remains a challenge. Within military healthcare, this debate intensified after Operation Iraqi Freedom and Operation Enduring Freedom with the increase in combat-related HELET cases [1, 2]. The main challenge is the high activity level of these patients preceding their trauma and their goal to return to duty. To optimize triage decisions, several scoring systems have been developed; however, none have proven to adequately predict physical outcomes [3]. Therefore, it would be beneficial to have a non-operative treatment approach for these HELET patients before surgical interventions are opted. Within this research, we aim to implement a high-activity brace as an alternative to a surgical intervention approach.

These HELET patients often experience persisting pain and a reduced activity level. Foot and ankle injuries, as part of HELET, have a serious impact on quality of life. Polytrauma patients with foot and ankle injuries show higher pain levels and lower performance levels than those without foot and ankle injuries [4]. Second, the risk of developing

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posttraumatic arthritis is increased in severely comminuted fractures. To relieve the pain associated with posttraumatic arthritis, either ankle/subtalar arthrodesis or amputation could be performed. However, these surgical interventions do not tend to improve functional outcomes for either civilians or service members [5–7].

Multiple studies showed amputees to report a better functional outcome than the limb salvage groups, with better observed pain scores for the amputated group [8–11]. In an attempt to reduce the high rates of delayed amputations in service members, different passive-dynamic ankle–foot orthosis concepts, such as the Interpid Dynamic Exoskeletal Orthosis (IDEO) [12–16].

An equivalent of the IDEO, a modified Passive-Dynamic Ankle–Foot Orthosis (PDAFO) characterized by an interchangeable strut, was developed. The aim of this study was to evaluate whether the modified PDAFO with a 6-week training program should be considered as an alternative to amputation and arthrodesis interventions after HELET.

Materials and methods

Population

A retrospective cohort study was conducted on patients who considered a surgical procedure, i.e., an arthrodesis or an amputation after HELET. However, in an attempt to avoid surgery, modified PDAFO with a 6-week training program was provided.

The inclusion criterion for the rehabilitation program with a modified PDAFO was mechanical pain, which increased due to passive movement of the ankle joint, and the patient was considering arthrodesis or amputation. Furthermore, a patient could experience one or more of the following: (1) the pain limited walking distance, (2) impaired ability to perform activities of daily living, and (3) other solutions, such as insoles and (semi-)orthopaedic shoes, were proven to be insufficient. The exclusion criteria were: (1) pain caused by axial loading, (2) complex regional pain syndrome and (3) pain sensations not reproducible by passive movement of the ankle joint.

Orthopedie Techniek Aardenburg at the Military Rehabilitation Center Aardenburg (MRC) in Doorn, the Netherlands, provided the modified PDAFO in the period from September 2018 to January 2020.

Intervention

The modified PDAFO uses the concept of a passive-dynamic ankle–foot orthosis, of which IDEO is an example. The modified PDAFO restricts pathologic ankle motion and prevents the pain to build-up within in the ankle. It consists of three main parts: the proximal carbon fibre tibial and calf cuff, a custom-shaped carbon fibre foot plate and a Posterior Dynamic Element (PDE™) Modular Composite Spring System (Fabtec systems, USA) connecting the proximal and distal parts. A foam wedge is placed underneath the heel to provide shock absorption during the loading response. In contrast to the IDEO, the strut is applied in different stiffness's depending on the weight and activity level of the participant and is interchangeable, see Fig. 1.

Following modified PDAFO provision, all patients were subjected to a 6-week training program. The focus of the rehabilitation was to familiarize the participant with modified PDAFO and to improve stability and muscle strength and to initiate agility training for the lower extremities [12]. The patients wore the modified PDAFO throughout the day.

Outcomes

Pain

The level of pain was evaluated with the Numerical Rating Scale (NRS). The NRS is a unidimensional measure of pain intensity that is widely used in diverse adult populations, including those with musculoskeletal diseases. This questionnaire requires patients to rate their pain from 0 (no pain) to 10 (pain as worse as it could be) [17]. Patients are requested to tick a score that best represents the intensity of the pain.

Fig. 1 Modified passive dynamic ankle foot orthosis. A proximal cuff connects the carbon fiber foot plate by a posterior posterior dynamic element

6-min walk test (6MWT)

The 6MWT is a submaximal exercise test measuring the total walking distance in metres over a span of 6 min [18]. Patients were instructed to walk at their self-selected walking speed for 6 min, and they could stop and rest when they felt unable to continue.

CHAMP

The Comprehensive High-Level Activity Mobility Predictor (CHAMP) is a validated test predicting high-level activity mobility. It is created for servicemen after traumatic lower limb loss. It consists of four tests, which are scored separately. The single limb stance (SLS) measures balance and postural stability of both legs separately, while the Edgren Side Step Test (ESST), T-shape agility-test (*T* test) and Illinois agility test (IAT) measure unidirectional, bidirectional and multidirectional coordination, power, speed and agility, respectively. The CHAMP score for each test ranges from 0 to 10 points. The total CHAMP score, that is, the sum of the scores of the four tests (range, 0–40 points), was calculated. A total score of 40 represents the highest level of performance, while a total score ≥ 33 represents the threshold level of performance, which is equivalent to the level of performance of active-duty service members [19, 20].

Testing protocol

Within the treatment protocol, two moments, before and after modified PDAFO provision with rehabilitation, are included to measure physical fitness by means of a 6MWT, the CHAMP and pain levels. The timing of pain level was at four instances: before testing, after the 6MWT, after the CHAMP and on the day of testing at 05.00 p.m. All physical tests were performed from 08.00 a.m. to 09.00 a.m.

Finally, at discharge, patients were asked about their satisfaction on a dichotomous scale: satisfied or not satisfied and if they still required a surgical intervention.

Statistical analysis

The statistical analysis was performed using SPSS (Version 25.0. Armonk, NY: IBM Corp, USA). Group characteristics are depicted in mean values with a standard deviation. Due to a non-normal distribution of the data, the changes between pain scores and physical testing were tested with a Wilcoxon signed rank test. All results are reported with a median score with interquartile range. Before–after comparisons were performed for all four pain scores as well as the CHAMP and the 6MWT. In addition, a comparison was performed within the same trial, testing the pain in ascending order compared with the initial pain score. The significance level was set to an alpha of 0.05 for all statistical tests.

Ethics approval

This study was approved by the Dutch Defence Healthcare Organization of the Ministry of Defence (MOD) and the Medical Research Ethical Council (METC Brabant no NW2020-37). All participants signed an informed consent form before their data were included in the study.

Results

A total of 19 individuals were eligible for participation. Two dropouts were reported. One suffered from mental problems. The other patient had a BMI of 37.9 and suffered from induced pain by axial loading. The patient was excluded after being provided the modified PDAFO, and their axial pain was restrictive to proceeding. The remaining 17 patients fulfilled the complete protocol and were analysed (Tables 1, 2).

Group demographics

The group consisted of 2 bilaterally and 15 unilaterally impaired patients. The mean ($\pm$ SD) age was 38.2 ($\pm$ 9.0 years), with a BMI of 26.5 ($\pm$ 4.6 kg/m^2). The interval between injury and provision of the modified PDAFO was 7.2 ($\pm$ 4.9 years).

Pain level before intervention

At the start of the 6-week program, pain was measured at four moments during the physical testing without the modified PDAFO (Fig. 2). Before the start of the performance tests, the pain [median (interquartile range)] was reported at 2.0 (1.0–3.0). After the first-test (6MWT), a significant increase in pain was reported to be 3.0 (2.0–4.5, $p = 0.02$). This was followed by a significant increase in pain after completing the CHAMP to 5.0 (3.5–6.5, $p = 0.001$), which was not significantly reduced at the end of the day to 5.0 (3.0–6.5, $p = 0.35$).

Pain level after intervention

The tests were executed while wearing the modified PDAFO. The pain (median (IQR)) at the start of the tests was 0 (0–1), followed by a nonsignificant change of the 6MWT to 0 (0–2, $p = 0.18$). This was comparable to the nonsignificant change in pain after CHAMP to 0 (0–2.5, $p = 0.23$). At the end of

Table 1 Generic information on group demographics, level of injury and indication before rehabilitation intervention

Patient	Sex	Age (y)	BMI	Population	Injured side	Injury	Interval (y)	Surgical indication
1	Male	30	26.2	ES	L	Talus fracture	11	Arth
2	Male	40	29.1	S	B	Pilon fracture, arthritis	9	Arth
3	Male	37	29.1	S	L	Pilon fracture	3	Arth
4	Male	24	19.9	C	L	Peritalar fracture	2	Amp
5	Male	47	27.9	S	R	Navicular fracture arthritis	14	Arth
6	Female	39	23.1	C	R	Pilon fracture	15	Arth
7	Male	32	24.8	C	R	Talus fracture	4	Arth
8	Male	31	37.9	C	R	Weber C fracture arthritis	3	Arth
9	Male	34	19.7	C	R	Weber C fracture, peroneus tendon rupture, Gracilis flap	1	Arth
10	Male	57	24.8	C	R	Weber C fracture	17	Amp
11	Female	37	24.8	S	R	Talar dislocation fracture	5	Arth
12	Female	30	22.9	ES	L	Transchondral fracture talus. Arthritis tibiotalar joint and	5	Arth
13	Female	30	21.1	ES	L	Talus Dislocation fracture arthritis	4	Arth
14	Male	47	29.1	ES	R	Weber-C fracture and arthritis	4	Arth
15	Male	36	30.2	S	L	Talus fracture and arthritis	11	Arth
16	Male	45	30.9	S	B	TMT III and IV fracture	10	Arth
17	Male	53	28.7	S	R	Calcaneus fracture	5	Arth

Amp amputation, *Arth* arthrodesis, *B* bi-lateral, *BMI* body mass index, *C* civilian, *ES* ex-service member, *interval* interval between injury and brace provision, *L* left, *R* right, *S* service member

Table 2 Individual results of the 6MWT, the CHAMP and pain at the end of the day before and after the rehabilitation intervention

At the start of the rehabilitation intervention							After the rehabilitation intervention					
Patient	NRS before	6MWT distance	NRS after	CHAMP	NRS after	NRS end of day	NRS before	6MWT distance	NRS after	CHAMP	NRS after	NRS end of day
1	0	**650**	0	**33.0**	3	1	0	**696**	0	**31.5**	0	0
2	3	**564**	3	**28.0**	3	3	0	**667**	0	**27.0**	2	0
3	2	**520**	3	**22.0**	6	5	1	**599**	3	**29.0**	4	2
4	2	**367**	6	**9.0**	5	8	2	**623**	2	**29.5**	3	2
5	2	**578**	3	**26.5**	5	5	0	**627**	0	**28.0**	0	0
6	1	**500**	2	**23.0**	4	*5*	0	**679**	0	**27.0**	2	1
7	1	**531**	2	**23.5**	3	4	0	**617**	0	**32.0**	0	0
8	0	**637**	0	**29.0**	7	4	0	**666**	0	**33.0**	0	0
9	5	**539**	7	**26.5**	8	8	3	**717**	3	**31.0**	3	3
10	6	**400**	8	**16.5**	9	9	0	**599**	8	**20.0**	4	0
11	3	**571**	3	**31.0**	5	4	0	**600**	0	**28.5**	0	3
12	2	**565**	2	**28.0**	4	2	0	**670**	0	**28.5**	0	1
13	2	**583**	3	**20.5**	5	5	2	**583**	2	**24.5**	2	2
14	3	**450**	4	**20.0**	5	6	0	**653**	0	**28.5**	1	2
15	0	**583**	2	**30.0**	2	2	0	**668**	0	**29.5**	0	0
16	3	**524**	5	**27.0**	7	7	1	**708**	1	**23.5**	2	2
17	2	**418**	4	**14.5**	5	3	0	**677**	0	**26.5**	0	0

The bold values represent physical tests. The values before and after these test represent the pain values on a scale from 0 to 10. 0 no pain and 10 the worst pain imaginable

NRS numeric rating score, *6MWT* 6-min walk test, *CHAMP* comprehensive high-level activity mobility predictor

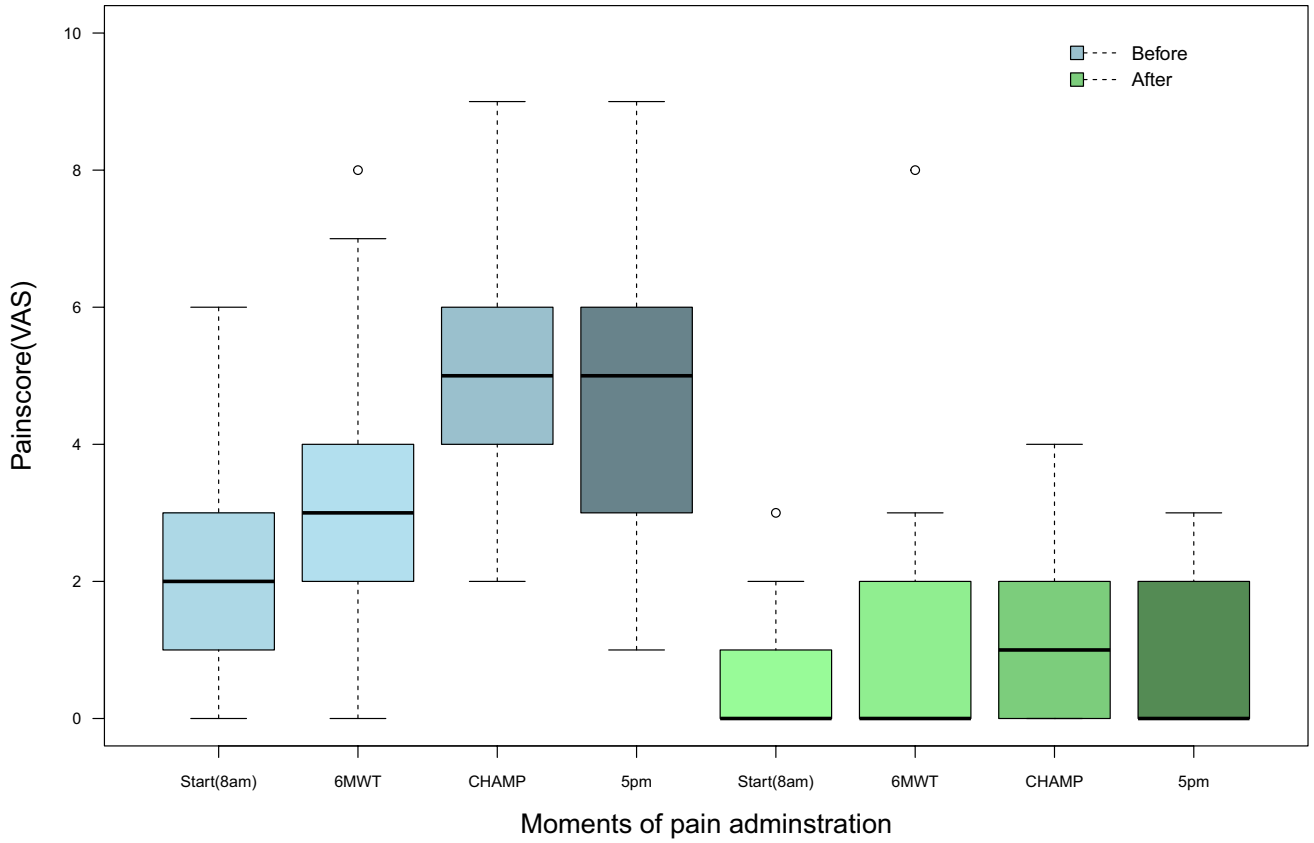

Fig. 2 Boxplots showing the pain score before (blue) and after (green) physical testing. There are four moments at which the pain score is administered: "Before the physical test at 8 am", "after the 6-min walking test", "after the CHAMP" and "at the end of the testing day". Pain during and after testing

the day, a nonsignificant decrease in pain to 1 (0–2, $p=0.50$) was observed.

Comparison of the pain scores at the start without brace versus discharge after 6 weeks of training with brace showed significant decreases in pain: at the start ($p=0.002$), after the 6MWT ($p=0.001$), after the CHAMP ($p<0.001$) and at the end of the day ($p<0.001$).

Physical performance tests

The results of the performance tests are depicted in Table 3, which shows significant improvements in the 6MWT ($p<0.001$) and the CHAMP score ($p=0.01$). Walking speed was increased by 23.6% from 5.4 km/h before training and without the modified PDAFO to 6.7 km/h after training with the modified PDAFO. These significant increases in performance were reported together with a significant reduction in pain during all physical tests (3.3).

Table 3 Results of the performance tests before and after PDAFO provision and rehabilitation

Performance test	Before rehabilitation Median (IQR)	After rehabilitation Median (IQR)	*p* value
6MWT (m)	539.0 (475.0–580.5)	666.0 (608.5–678.0)	<0.001
SLS (s)	54.0 (35.0–60.0)	36.0 (33.0–44.5)	0.083
ESST (m)	14.0 (11.0–17.5)	20.0 (18.5–22.5)	<0.001
T test (s)	22.1 (20.9–30.6)	15.9 (15.1–17.9)	<0.001
IAT (s)	30.3 (26.0–44.9)	22.9 (21.0–24.8)	<0.001
CHAMP (points)	26.5 (20.3–28.5)	28.5 (26.8–30.3)	0.01

6MWT 6-min walk test, *CHAMP* Comprehensive High-Level Activity Mobility Predictor, *ESST* Edgren side-step test, *IAT* Illinois agility test, *IQR* interquartile range, *SD* standard deviation, *SLS* single-limb stance, *m* meters, *s* seconds

All patients were satisfied with the results of the modified PDAFO and the training program, and none opted for a surgical intervention after completing the rehabilitation.

One patient who had dropped out due to mental problems underwent a surgical intervention.

Discussion

The results of this study indicated a significant reduction in pain at the end of the day without a brace versus discharge after 6 weeks of training with a brace. In addition, significant improvements in the 6MWT and the CHAMP were observed. All patients refrained from having surgery. This suggests that a non-operative approach with modified PDAFO should be considered as an alternative to a surgical intervention after HELET.

Pain may reduce activity levels and/or induce mental health problems. However, while a reduction in pain in the ankle–foot complex is expected to be obtained, there is limited evidence suggesting that pain is reduced using PDAFO [13]. One study on service members using the IDEO combined with an 8-week training program reported a significant reduction in pain score [15]. A subgroup analysis of that study showed that one group ($N=12$) had either isolated ankle fusion or ankle fusion combined with ipsilateral subtalar fusion. The other group ($N=11$) had a subtalar fusion only. Only the latter demonstrated a significantly lower pain score [16].

Another important consideration within our study design was the addition of rehabilitation with PDAFO provision. This was based on the results of a study assessing perceived pain in patients with PDAFO. Scoring was performed in terms of 'no pain', patients were 'able to control the pain' or 'the pain was not under control'. One hundred percent of the patients who received inpatient multidisciplinary rehabilitation post-PDAFO provision reported that they were able to control their pain versus 78% of the group who did not receive inpatient multidisciplinary rehabilitation post-PDAFO provision [14]. This difference suggests the added value of rehabilitation combined with providing PDAFO within a non-operative approach. However, it does inform us on the immediate effect of a PDAFO with rehab intervention, but with no follow-up, it remains challenging to make a statement on long-term effects.

Our results show a significant improvement in performance level by means of the 6MWT and CHAMP. The 6MWT was comparable to one other study with patients using a PDAFO [14]. Even though a significant change in the 6MWT was reported at the start of our study, it is equally important to note the increase in reported pain after the test. After the study's intervention, a significant increase in walking speed with an even more important significant reduction in pain was reported.

Another study assessed high-level mobility with the CHAMP in patients with lower extremity fractures utilizing the IDEO [21]. Patients participated in a rehabilitation program called the Return to Run Clinical Pathway. There were significant improvements in the *T* test and the total CHAMP. No significant changes were noted in the SLS, ESST or IAT. Our population contained only HELET patients, while the study from Mazzone also contained patients with less severe injuries (e.g., stress fractures) [21]. They might have obtained higher scores on the tests without the brace, resulting in a smaller difference between pre- and post-brace scores.

Our study used the CHAMP as an overall score. Two studies only investigated IAT due to the high cut-off score. One of the studies did not report the outcome on this test [22]. Another study demonstrated improvement on the IAT with median scores of 29.0 s at the start and 22.5 s after a 4-week training program [23]. This is similar to our results with an IAT improvement with a median score from 30.3 to 22.9 s. Moreover, it is also important to note the reduction in the IQR in this before-and-after design.

Two studies used other performance measures: the four-square step test, the self-selected walking speed, the time stair ascent test and the shuttle run or 40-yard dash [15, 24]. All tests improved significantly. In one of these studies, the PDAFO even proved to be superior to a blue rocker and a posterior leaf spring brace [24]. Other long-term outcome results on performance are return to duty rates in two studies of 20% [25] and 51.3% [26] and return to running (80%) in another study [12].

Improvements in test scores were reported for all patients for all components of the CHAMP except for the SLS. This reduction in SLS score could probably be related to single-limb stance postural control. This is maintained by movements in the ankle joint (inversion/eversion, dorsiflexion/plantar flexion) and the ankle strategy. Since a modified PDAFO fixes the ankle, it will preclude an effective ankle strategy. Consequently, less stability and a lower score for the SLS are reported. It could be that a similar trend has been observed by other researchers, since Hsu et al. notified in their proposed study that they planned to use performance tests as the SLS [22]. However, in the definitive report of the results, they did not describe the outcome of the SLS. In addition, when comparing our results to the Trans Tibial Amputation group, it should be noted that a prosthetic foot has a larger mediolateral adaptability due to its carbon fibre structures. PDAFO was restricted due to the stiff construction around the foot–ankle complex.

Limitations

The outcomes suggest that pylon and ankle fractures or secondary complication, e.g., post-traumatic arthritis, a vascular necrosis, may be appropriate indication for the modified PDAFO. However, it is probably not limited to this group.

Future research is required to investigate if this intervention could provide a positive impact for other indications at the ankle/foot complex.

This sample size represents two populations: service members and civilians. The types of injury differed. No subgroup analysis could be performed due to the heterogeneity of the group. While including our participants it is suggested that a high BMI may be a factor that limits the use of the brace; however, not enough information is available to draw robust conclusions.

Furthermore, this case series study contains a small sample size, which increases the margin of error. However, although this is a small sample size it seems that it is large enough to detect clinically significant improvements in pain levels and performance on the 6MWT and the agility tests of the CHAMP. Although we found significance in pain reduction after the program it is questionable if the clinical impact of this finding met the Minimal Clinically Important Difference which is not available for this domain. Moreover, it is clear that all patients were satisfied with the results of the program.

This study evaluated short-term effects after a 6-week training interval. The time span is too short to predict long-term user friendliness and convenience in daily activities. This needs to be investigated and evaluated in future studies.

Recommendations

Future research attention should be directed towards exploring muscular compensation and changes in activity around the hip and knee joints of the ipsilateral leg and joints of the contralateral leg. The modified PDAFO locks the ankle joint; therefore, the power that would normally be handled by the ankle–foot complex is transferred through the modified PDAFO in such a way that it appears to be similar to walking with a transtibial prosthesis. Forces will be transferred upwards, and muscular compensation needs to occur.

Further research should focus on a more diverse implementation of the brace for highly active patients with disability of the ankle–foot complex. A focus could be on participation in daily life activities in terms of questionnaires and steps taken per day, as well as long-term effects.

Conclusion

HELET patients frequently experience persisting pain and a reduced activity level due to posttraumatic arthritis and arthrodesis or amputation is the usual option.

This research indicates that a modified PDAFO provision with a 6-week training program has a positive impact on pain and physical capabilities in patients with chronic pain at the ankle–foot level after HELET.

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Author's contributions N. Jonkergouw: study design, data acquisition/analysis and interpretation, drafting of manuscript, and final approval. LGM de Kruijff: study design, analysis and interpretation, drafting of manuscript, and final approval. REG Bongers: data acquisition/analysis and interpretation, critical revision, and final approval. MW Swaan: study design, data acquisition, critical revision, and final approval. HR Holtslag: data acquisition, critical revision, and final approval. A van der Meer: data acquisition, critical revision, and final approval. P van der Wurff: data acquisition/analysis and interpretation, critical revision, and final approval.

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Data availability The data sets used and/or analysed during the current study are available from the corresponding author upon reasonable request.

Code availability Not applicable.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study was approved by the Dutch Defence Healthcare. Organization of the Ministry of Defence (MOD) and the Medical Research Ethical Council (METC Brabant no NW2020-37).

Informed consent All participants signed an informed consent form before their data was included in the study.

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