# Hull early walking aid for rehabilitation of transtibial amputees - randomized controlled trial (HEART)

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***Purpose:*** **To compare articulated and nonarticulated early walking aids (EWAs) for clinical and quality-of-life outcomes in transtibial amputees.**

***Methods:*** **Patients undergoing lower limb amputation in a tertiary-care vascular surgical unit were screened over a 4-year period. Recruited patients were randomized to receive articulated amputee mobility aid (AMA) or nonarticulated pneumatic postamputation mobility aid (PPAMA) during early rehabilitation. Primary (10-meter walking velocity) and secondary clinical (number and duration of physiotherapy treatments during EWA/prosthesis use) and quality-of-life (SF-36) outcome measures were recorded at five standardized assessment visits. Inter-group and intra-group analyses were performed.**

***Results:*** **Two hundred seventy-two patients were screened and 29 transtibial amputees (median age, 56 years) were recruited (14/treatment arm). No significant difference was seen in demographics and comorbidities at baseline. Inter-group analysis: Median 10-meter walking velocity was significantly (Mann-Whitney, $P = .020$) faster in the PPAMA group (0.245 m/s, interquartile range [IQR] 0.218-0.402 m/s) compared with the AMA group (0.165 m/s; IQR, 0.118-0.265 m/s) at visit 1. However, there was no difference between the groups at any other visit. Similarly, the number of treatments using EWA was significantly ($P = .045$) lower in the PPAMA group (5.0; IQR, 3.5-8.0) compared with the AMA group (6.0; IQR, 6.0-10.5). No difference was observed between the groups in duration of physiotherapy or SF-36 domain and summary scores. Intra-group analysis: Both treatment groups showed significant improvement in 10-meter walking velocity (Friedman test; AMA $P = .001$; PPAMA $P = .007$); however, other clinical outcomes did not show any statistically significant improvement. Only physical function domain of SF-36 demonstrated significant improvement (Friedman test; AMA $P = .037$; PPAMA $P = .029$).**

***Conclusions:*** **There is no difference in clinical and QOL outcomes between articulated and nonarticulated EWAs in rehabilitation of transtibial amputees. (J Vasc Surg 2010;52:1564-71.)**

Lower limb amputation (LLA) is associated with significant quality-of-life (QOL) and economic burden for the patient, society, and health care providers in developed countries.[1,2] The incidence of LLA is highly variable ranging from 22 to 1141 amputations per year per100,000 population over the age of 45 years,[3,4] with diabetes mellitus and peripheral vascular disease (PVD) being the most important etiological factors.[5] Transtibial amputation (TTA), or below-knee amputation (BKA), is the most commonly performed major amputation,[3,4,6] preferred because of the associated improved mobility and reduced energy expenditure in comparison to transfemoral amputation.[7,8] Amputee rehabilitation is initiated early to ensure a safe and rapid return to normal life.[9]

Early walking aids (EWAs) are routinely used by physiotherapists throughout the world and are an important part of amputee rehabilitation to aid early mobilization and gait re-education.[9,10] EWAs can be applied in the early postoperative period to accelerate healing of stump,[11,12] reduce complications,[13] and facilitate early fitting of definitive prosthesis.[14,15] There are several different EWAs currently used in patients with TTA ranging from simple pylon structures with adjustable sockets, pneumatic splints, and rigid frames to more complex articulated devices.[16-18] In the United Kingdom, the two most popular walking aids include the pneumatic postamputation mobility aid (PPAMA)[19] and the amputee mobility aid (AMA).[16] The articulation in AMA allows movement at the knee joint during walking unlike the rigid construct of PPAMA. PPAMA remains the most commonly used EWA worldwide due to easy availability, low cost, and simplicity of

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**Table I.** Inclusion and exclusion criteria

| *Inclusion criteria* | *Exclusion criteria* |
|---|---|
| • Unilateral transtibial amputation<br>• Expected to receive a functional prosthesis<br>• At least 18 years of age<br>• Able to tolerate and use EWA<br>• Able to walk a distance of 4 meters<br>• Willing to attend hospital-based rehabilitation program following prosthesis fitting<br>• Meet the manufacturer's recommendation for using the EWAs | • Major amputation of contralateral limb<br>• Not expected to receive a functional prosthesis (severe debilitating medical illness eg, severe dementia, fixed flexion deformity, severe Parkinson's disease, heart failure, etc)<br>• Unable to walk prior to amputation due to medical condition eg, spinal injury, stroke, rheumatoid arthritis<br>• Unable to follow instructions and/or participate in a rehabilitation program (not resident in the hospital catchments area)<br>• Unable to consent to take part in the study<br>• Do not meet the manufacturer's recommendations for using the EWAs |

*EWA*, Early walking aids.
This table represents the inclusion and exclusion criteria for the trial.

use.[14,20-22] Previous studies have evaluated these aids individually;[16,18] however, this is the first study to directly compare these two EWAs in terms of clinical and QOL outcomes and rehabilitation duration. We hypothesized that the articulated AMA offers clinical and QOL advantage over the nonarticulated PPAMA.

## METHODS

The trial was approved by local research committee and conducted in a tertiary care university hospital. Patients admitted to the vascular surgical unit for unilateral transtibial amputation were screened for eligibility for inclusion in the study. The inclusion and exclusion criteria for the study are given in Table I. Eligible patients were contacted after the decision for amputation was made, evaluated by trained physiotherapists for assessment of rehabilitation potential, and were invited to take part in the study, if suitable. Emergency surgery patients were excluded due to unavailability of presurgical specialist physiotherapy assessment service outside normal working hours. Informed consent was obtained from the patients willing to participate in the study. Participants were randomized prior to surgery to receive one of the two EWAs using sealed envelopes. Transtibial amputations were performed by consultant vascular surgeons using standard predefined technique using long posterior flap and myoplasty ensuring a minimum stump length of 10 cm from the tibial tuberosity.

### Intervention

Early physiotherapy was encouraged and EWA use was commenced when the patients attended the physiotherapy unit and were able to tolerate EWA, after being discharged from the hospital following complete recovery from their surgery. Physiotherapy continued after the delivery of definitive prosthesis. The number of physiotherapy treatments administered was variable depending on individual patient needs. The patients used one of the two EWAs:

**Fig 1.** The Pneumatic Post Amputation Mobility Aid (PPAMA - left) and inflatable residuum bag (right). (Image reproduced with permission of Ortho Europe Ltd, Alton, UK. www.ortho-europe.co.uk.)

**Pneumatic post amputation mobility aid (PPAMA).** PPAMA, developed in 1978,[18,19] is the most commonly used EWA in the United Kingdom.[16] This nonarticulated EWA consists of a pneumatic bag, a supporting frame, and a rocker foot (Fig 1). As there is no articulation, the biological knee is kept in extension while walking.

**Amputee mobility aid (AMA).** AMA, developed in 1993, incorporates a simple hinge mechanism to replicate a more natural movement (active flexion and extension) of the knee[16] (Fig 2).

### Assessments

All assessments were performed in a specialist amputee rehabilitation physiotherapy unit staffed by physiotherapists with clinical expertise in this area. All patients were assessed to ensure optimal fit of either their EWA or prosthesis at each visit. As the number of physiotherapy sessions received by each patient was variable, five standard time points were identified for assessment of patients. These included time of initial fitting of EWA (visit 1), final rehabilitation session while using EWA (visit 2), time of first use of definitive prosthesis (visit 3), 2 weeks following fitting of definitive prosthesis (visit 4), and at discharge from active physiotherapy (visit 5) ensuring the safe use of prosthesis by the patient.

**Fig 2.** The articulated Amputee Mobility Aid (AMA). (Image reproduced with permission of Ortho Europe Ltd, Alton, UK. www.orto-europe.co.uk.)

### Outcome measures

All outcome measures were recorded at each of the five assessment visits.

**Primary.** Ten-meter walking velocity; at each visit, all patients were asked to perform a 10-meter walk from a standing start. Patients walked from the starting point for 5 meters using parallel bars for support, took a 180 degree turn, and walked back to the starting point. The time taken to complete this test was recorded using a digital stopwatch using standardized technique by a member of the research team, and 10-meter walking velocity was calculated.

**Secondary.** (1) Generic QOL analysis; using the Short Form 36 instrument, which comprises 36 items that are summarized to produce eight domain scores namely physical function (PF), role limitation physical problems (RP), bodily pain (BP), general health (GH), vitality (V), social function (SF), role limitation due to emotional problems (RE), and mental health (MH). Domain scores are grouped together to yield two summary scores namely physical component summary (PCS) and mental component summary (MCS). This instrument is valid, reliable, and responsive in this particular population.[23]

(2) Total number of physiotherapy treatments; including the number of physiotherapy sessions prior to and during EWA use and the number of sessions during prosthesis use.

(3) Physiotherapy duration in days while using EWA, definitive prosthesis, and overall duration.

### Statistical analysis

Data were recorded using Microsoft Excel 2003 (Microsoft Corporation, Redmond, Wash) and analyzed using SPSS 16.0 (SPSS Corporation, Chicago, Ill). All continuous variables were checked for normality using histograms and normality tests (Kolmogorov–Smirnoff test). Hypothesis testing was performed using nonparametric tests for inter-group (Mann-Whitney test) and intra-group (Friedman test) analyses of continuous variables. Categorical variables were analyzed using Fischer exact test. Adjustments were made to the *P* values for multiple testing using Bonferroni method.

### Sample size calculation

There were no previous studies reported in the literature comparing walking velocities in TTA patients using EWAs. We, therefore, performed sample size calculation using studies that reported 10-meter walking velocities in transtibial amputees using definitive prosthesis.[24,25] The first study reported the mean velocity of 0.28 m/s at week 1 improving to 0.51 m/s at week 4 with rehabilitation (82% improvement),[24] while the second study reported a mean velocity of 0.78 m/s.[25] We used the higher mean velocity available with pooled standard deviation from the two studies. Considering the evidence of 82% improvement in the first study, we calculated the sample size for mean velocity of 0.78 m/s with pooled SD of 0.33; the required sample size for 90% power and 5% significance was six patients in each group. We then looked at the difference in highest mean velocities as quoted in the two studies. This showed a 53% difference in the two values (0.51 m/s vs 0.78 m/s). We used this difference to guide our sample size calculations, thus, using the highest mean velocity (0.78 m/s) and a pooled standard deviation (0.33), we required 13 patients in each arm to detect a 50% difference in 10-meter walking velocity at discharge for 90% power and an alpha of 0.05.

## RESULTS

Two hundred seventy-two amputations were performed over a three and a half year period between September 2005 and April 2009. Only 10.7% (n = 29) of these patients were eligible for inclusion, consented to participate, and were randomized to one of the two treatment arms. Three patients were lost to follow-up giving us a total of 13 patients in each treatment arm as per requirement (CONSORT diagram, Fig 3).

### Inter-group analysis

There was no difference between the two groups for age, height, weight, indication for surgery, comorbidities, hospital stay, and time to commencement of ambulation postsurgery (Table II).

**Ten-meter walking velocity (Table III).** At visit 1, patients using the PPAMA had significantly faster 10-meter walking velocity than patients using the EWA. However, at

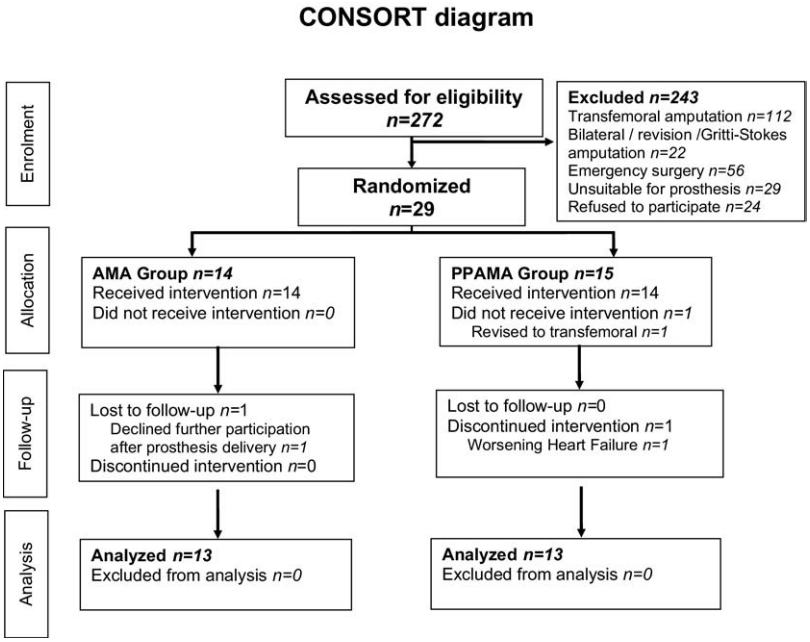


**Fig 3.** CONSORT diagram of trial participants.

all other visits, there was no significant difference in 10-meter walking velocity between the two groups.

**Number of physiotherapy treatments (Table IV).** There was no statistically significant difference in the number of physiotherapy treatments received by patients in either group prior to EWA use and during definitive prosthesis use. However, the median number of treatments received by patients using the PPAMA was significantly lower ($P < .05$) than those using the AMA during the EWA use.

**Duration of physiotherapy treatment (Table IV).** The median duration of physiotherapy treatment during EWA and prosthesis use was shorter for patients using PPAMA compared with those using the AMA. Conversely, the total duration of physiotherapy was shorter in the AMA group. However, these differences were not statistically significant.

**QOL outcomes (Figs 4 and 5).** There were no statistically significant differences between the two treatment arms in any of the SF-36 physical or mental health domain at any time point. Consequently, there was no difference seen in the physical and mental component summary scores.

### Intra-group analysis (Tables III and V; Figs 4 and 5)

Both groups demonstrated statistically significant improvements in the 10-meter walk velocity and in the SF-36 physical function domain over time (Friedman test, $P < .05$). No statistically significant difference was observed in any other SF-36 domain and summary scores in any treatment arm.

## DISCUSSION

Our study has clearly demonstrated that there is no difference between articulated and nonarticulated EWAs for clinical and QOL outcomes in transtibial amputees. This is the first reported study to analyze and compare these outcomes at length. Although a previous study compared interface pressures between the two EWAs and range of movement of the AMA mechanical knee and the amputee knee joint,[16] no effort was made to compare other clinical outcomes including duration of rehabilitation or walking times.

Ten-meter walking velocity is a well-established outcome measure[25,26] and has been used previously to demonstrate functional ability in transtibial amputees.[24,27] It is affected by age,[28] lower limb strength,[29] vascular status of the contralateral limb,[30] balance,[31] and energy expenditure.[32] In our study, although the 10-meter walking velocity improved significantly within each group and was clearly faster in the PPAMA group at visit 1, there was an interesting difference in trend. Patients with AMAs took longer to complete the walk at the first visit; however, they improved progressively in all later visits with a shorter walking time at each subsequent visit. The fastest velocity was recorded at the last visit in this group. Conversely, patients in the PPAMA group were quicker to start at visit 1 and improved in visit 2, however, they were considerably slower with the definitive prosthesis when using it for the first time (visit 3). This improved in subsequent visits but remained slower compared with the AMA group. The articulation in AMAs can possibly explain this phenomenon. Patients using AMAs initially take longer due to active control of knee

**Table II.** Inter-group analysis – Basic demographics, indications, comorbidities, and postoperative parameters

| *Variable* | *Treatment arm* | | P *value* |
|---|---|---|---|
| | *AMA (n = 13)* | *PPAMA (n = 13)* | |
| Age (y)[1] | 57.00 (41.50 to 67.00) | 55.00 (40.50 to 65.50) | .817[a] |
| Male:female | 12:01 | 10:03 | .593[b] |
| Right:left | 07:06 | 06:07 | 1.000[b] |
| Height (meters)[1] | 1.77 (1.71 to 1.83) | 1.75 (1.61 to 1.85) | .572[a] |
| Weight (kg)[1] | 77.0 (72.70 to 99.50) | 88.0 (70.60 to 94.40) | .918[a] |
| Indication for surgery[2] | | | |
| Ischemia | 3 (23.1) | 5 (38.4) | .709[c] |
| Neuropathic painful foot | 3 (23.1) | 4 (30.8) | |
| Infected diabetic foot | 5 (38.4) | 4 (30.8) | |
| Venous ulcers | 1 (7.7) | 0 (0.0) | |
| Neoplasia | 1 (7.7) | 0 (0.0) | |
| Comorbidities[2] | | | |
| Hypertension | 1 (7.70) | 5 (38.5) | .160[b] |
| Diabetes | 5 (38.5) | 4 (30.8) | 1.000[b] |
| Hypercholesterolemia | 0 (0.0) | 3 (23.1) | .220[b] |
| Ischemic heart disease | 2 (15.4) | 3 (23.1) | 1.000[b] |
| CVA | 2 (15.4) | 0 (0.0) | .480[b] |
| COPD/asthma | 2 (15.4) | 1 (7.7) | 1.000[b] |
| Postsurgery[1] | | | |
| Hospital stay (d) | 18.00 (8.50 to 32.00) | 12.00 (8.00 to 26.50) | .472[a] |
| Time to ambulation (d) | 15.50 (10.50 to 33.50) | 15.00 (10.50 to 33.00) | .978[a] |

*AMA,* Amputee mobility aid; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; *PPAMA,* pneumatic post amputation mobility aid.

This table represents basic demographics, indications for surgery, comorbidities, and postsurgery parameters for the trial participants. All continuous variables are represented as median (interquartile range) and categorical variables are represented as N (%). Similarly, *P* values are generated using $\chi^2$ test for trend, Mann-Whitney, and Fischer exact tests.

[1]Median (IQR).

[2]N (%).

[a]Mann-Whitney test.

[b]Fischer exact test.

[c]$\chi^2$ test for trend.

**Table III.** Primary outcome –10-meter walking velocity

| *10-meter walk velocity (meters/s)* | *Treatment arm* | | P *value*[a] |
|---|---|---|---|
| | *AMA* | *PPAMA* | |
| Visit 1 | 0.165 (0.118-0.265) | 0.245 (0.218-0.402) | **.020** |
| Visit 2 | 0.411 (0.373-0.536) | 0.481 (0.307-0.761) | .412 |
| Visit 3 | 0.561 (0.447-0.667) | 0.426 (0.332-0.618) | .974 |
| Visit 4 | 0.822 (0.569-0.959) | 0.800 (0.495-1.104) | .305 |
| Visit 5 | 1.083 (0.642-1.134) | 0.790 (0.742-1.127) | .605 |

*AMA,* Amputee mobility aid; *PPAMA,* pneumatic post amputation mobility aid.

This table represents the 10-meter walking velocity for both groups at all time points. All values are presented as median (interquartile range). *P* values represent inter-group comparisons using Mann-Whitney test. All significant comparisons are represented in bold font.

[a]Mann-Whitney test.

movement on the amputated side required during gait re-education. However, once learned, they progressed swiftly without any problems. On the other hand, the rigid construct of PPAMA made it relatively easy to use on the first visit. However, active movement of the knee while walking was experienced when the patients used the definitive prosthesis for the first time. This resulted in slower walking times during this session, however, this improved in all subsequent sessions. Eventually, there was no significant statistical difference between the two groups when ambulating with the definitive prosthesis at discharge from active physiotherapy. Thus, gait re-education pattern was different for the groups without any significant effect on clinical outcome.

There is reported evidence in literature to support subtle differences between the two EWAs in knee angles and gait pattern during gait re-education as a result of physiotherapy and rehabilitation.[16] We have previously analyzed the kinematic gait adaptation during rehabilitation comparing the two EWAs and have reported some differences in cadence, early temporal-spatial adaptation, and gait pattern, which persisted during transfer to functional prosthesis; however, both groups demonstrated similar rates and levels of improvement in walking performance reaching an acceptable level of walking activity.[33] We have now demonstrated, with this current study, that articulation of an EWA does not reduce the duration of physiotherapy, or the number of physiotherapy treatments prior to EWA and during definitive prosthesis use. In fact, these parameters were shorter in the nonarticulated EWA group; however, failure to reach statistical significance is a likely consequence of a smaller sample size. Nonetheless, we can

**Table IV.** Secondary clinical outcome measures

| *Variable* | *Treatment arm* | | P *value*[a] |
|---|---|---|---|
| | *AMA* | *PPAMA* | |
| No. of treatments prior to EWA | 1.50 (1.00-5.25) | 2.00 (0.50-3.50) | .824 |
| Time using EWA (d) | 38.00 (18.00-56.25) | 21.00 (12.00-39.00) | .281 |
| No. of treatments during EWA use | 6.0 (6.00-10.50) | 5.00 (3.50-8.00) | **.045** |
| Time using prosthetic limb (d) | 52.50 (39.00-66.75) | 39.00 (27.50-63.50) | .590 |
| No. of treatments during prosthesis use | 7.50 (5.00-11.50) | 7.00 (5.00-13.00) | .956 |
| Total duration of physiotherapy (d) | 92.00 (74.50-213.00) | 112.00 (67.50 – 148.00) | .590 |

*AMA*, Amputee mobility aid; *PPAMA*, pneumatic post amputation mobility aid.
This table represents the secondary outcome measures for both groups. All values are presented as median (interquartile range). *P* values represent inter-group comparisons using Mann-Whitney test. All significant comparisons are represented in bold font.
[a]Mann-Whitney test.

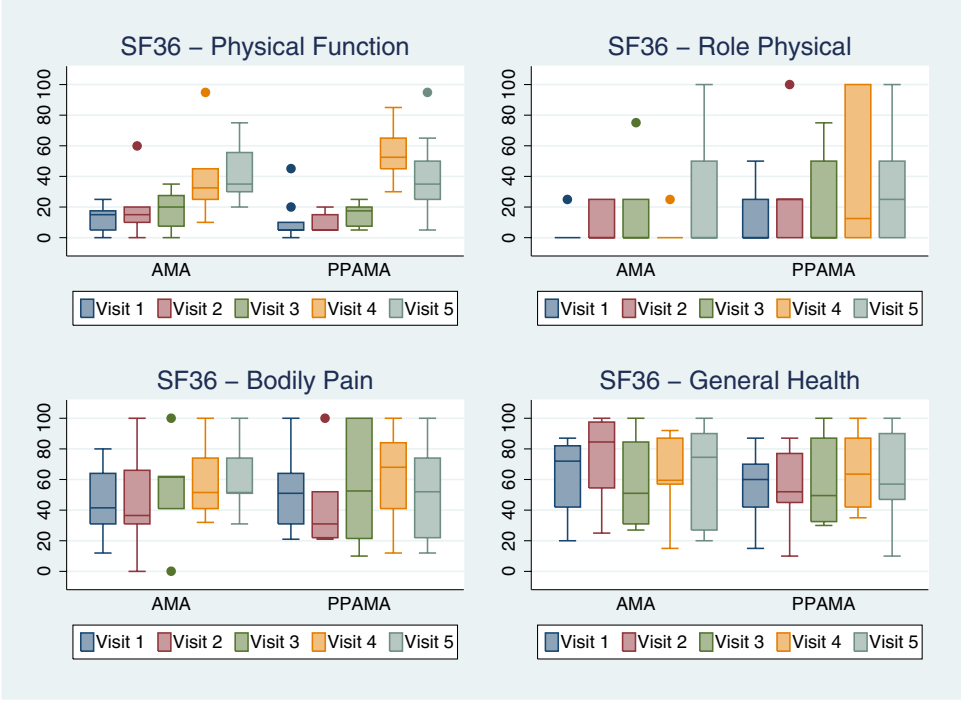


**Fig 4.** This figure represents the inter- and intra-group comparison of the physical health domains of the SF-36 represented by a box and whisker plot. The line in the middle of the box represents the median, the box represents the interquartile range (IQR), and the whiskers represent up to 1.5 times the IQR. Outliers beyond 1.5 times the IQR are represented by an asterisk.

conclude that the differences in gait re-education pattern between the two EWAs have no bearing on the clinical outcome.

QOL outcomes are as important as clinical endpoints and are now reported routinely in all clinical trials.[34] There is a relative dearth of studies reporting QOL outcomes in EWA trials and ours is the only one to date to investigate these outcomes. The significant improvement observed in physical function in both treatment arms is hardly surprising, as this is the most relevant domain of SF-36. However, the lack of any difference between the treatment arms in domain or summary scores should be interpreted with caution for a number of reasons. First, the sample size calculations were performed for clinical outcomes and, therefore, perhaps the study was inadequately powered to detect QOL differences. Second, we used a generic QOL instrument that is influenced by overall health and circumstances, when perhaps a disease-specific instrument may have been more appropriate and responsive to QOL changes in this situation. Nonetheless, these results provide basis for further investigations in future trials.

The economic implications of the findings of this trial are far reaching. EWAs are used extensively and routinely in all postamputation rehabilitation programs.[9,10] The artic-

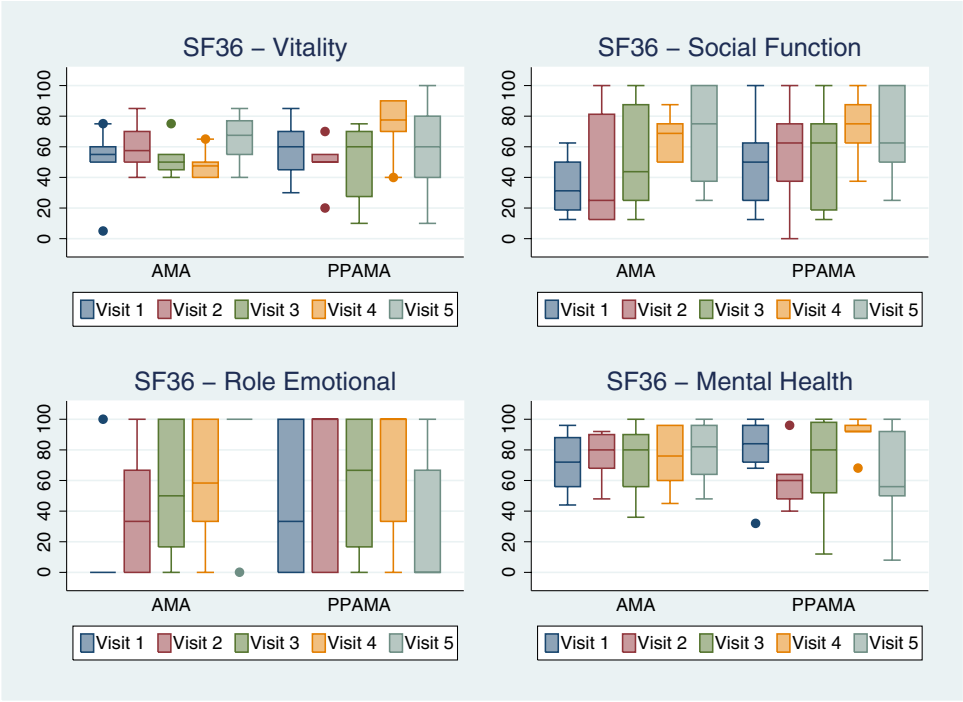


**Fig 5.** This figure represents inter- and intra-group comparison of the mental health domains of the SF-36 represented by a box and whisker plot. The line in the middle of the box represents the median, the box represents the interquartile range (IQR) and the whiskers represent up to 1.5 times the IQR. Outliers beyond 1.5 times the IQR are represented by an asterisk.

**Table V.** Intra-group analysis: Friedman test for continuous variables

| | *Significance (P value)* | |
|---|---|---|
| *Variable* | *AMA* | *PPAMA* |
| 10-meter walk time | **.001** | **.007** |
| Physical function | **.037** | **.029** |
| Role physical | .572 | .175 |
| Bodily pain | .695 | .919 |
| General health | .768 | .958 |
| Vitality | .162 | .117 |
| Social function | .131 | .232 |
| Role emotional | .277 | 1.000 |
| Mental health | .308 | .321 |
| Physical component summary | .284 | .086 |
| Mental component summary | .801 | .615 |

*AMA*, Amputee mobility aid; *PPAMA*, pneumatic post amputation mobility aid.
This table represents intra-group comparison for clinical and QOL (SF-36) outcome measures in both groups. *P* values are generated using Friedman test. All significant comparisons are represented in bold font.

ulated AMA is more expensive (£2495/$3900, made to order only) compared with the nonarticulated PPAMA (£881/$1378). Although we have not performed a formal calculation of utilities and costs in this study, we have demonstrated that there is no clinical or QOL advantage of using one over the other. Thus, routine use of more expensive AMA is likely to incur additional costs without significant clinical advantage. Therefore, AMA should only be reserved for situations where PPAMA is unsuitable or unavailable as per usual practice in most of the rehabilitation centers. A full economic evaluation needs to be formally undertaken to compare the cost-effectiveness of these EWAs in the future to aid decision makers in health care for policy making and application.

## CONCLUSIONS

EWAs are useful adjuncts in gait re-education and rehabilitation of transtibial amputees and help to improve the walking velocity and physical function. However, presence of articulation to aid early knee joint movement (AMA) does not offer any clinical or QOL advantage over nonarticulated PPAMA in these patients. Further studies are required to evaluate any disease-specific QOL differences and the full economic impact of using different EWAs.

## AUTHOR CONTRIBUTIONS

Conception and design: BB, LS, RP, AH, NV, IC
Analysis and interpretation: FM, KM, CB, JK, NV, IC
Data collection: FM, CB, BB, LS, RP, AH
Writing the article: FM, KM, JK, AH, NV, IC
Critical revision of the article: FM, KM, CB, JK, BB, LS, RP, AH, NV, IC

Final approval of the article: FM, KM, CB, JK, BB, LS, RP, AH, NV, IC
Statistical analysis: FM, KM, JK, NV, IC
Obtained funding: CB, BB, LS, RP, AH, NV, IC
Overall responsibility: IC

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