European Journal of Physical and Rehabilitation Medicine
EDIZIONI MINERVA MEDICA

Evaluation of the new, patient-adjustable socket system Varos in the early phase of prosthetic rehabilitation: a pilot study

Arastoo NIA, Tomas KUBINEC, Gerhard TöTSCHINGER, Stephan DOMAYER

European Journal of Physical and Rehabilitation Medicine 2022 Feb 11
DOI: 10.23736/S1973-9087.22.07020-4

Article type: Original Article

Article first published online: February 11, 2022
Manuscript accepted: February 3, 2022
Manuscript revised: January 27, 2022
Manuscript received: April 17, 2021

Evaluation of the new, patient-adjustable socket system Varos in the early phase of prosthetic rehabilitation: a pilot study

Arastoo NIA[1] , Gerhard TOETSCHINGER[2], Tomas KUBINEC[2], Stephan DOMAYER[2*]

[1] Department of Orthopaedic and Traumatology, Medical University of Vienna, General Hospital of Vienna, Vienna, Austria;

[2] Orthopaedic Rehabilitation Center Zicksee, St. Andrä am Zicksee, Austria

*Corresponding author:

Priv. Doz. Dr. Stephan Domayer, PhD MBA

Orthopaedic Rehabilitation Center Zicksee, St. Andrä am Zicksee, Austria

Email: stephan.domayer@skazicksee.at

Tel: 02176/2325-12

ABSTRACT

BACKGROUND:

Current prosthetic sockets often provide limited anatomical fit, especially in patients with residual limb volume changes and fluctuations.

AIM:

To address these issues, Ottobock has developed the Varos Socket, a modular socket that can be adjusted by the user. Aim of this study was to evaluate the potential benefits and acceptance of a newly designed patient-adjustable socket in transfemoral amputees in early phase of prosthetic rehabilitation.

DESIGN:

A prospective A-B-A pilot study was conducted

SETTING:

Orthopedic Rehabilitation Clinic

POPULATION:

10 Patients with unilateral transfemoral amputation and recent amputation

METHODS:

All Patients underwent a standard rehabilitation program with physical therapy. The outcome measures included the Comprehensive Lower-limb Amputee Socket Survey (CLASS), Score Comfort Scale (SCS), a Socket Fit Scale, frequency of falls and stumbles, perceived pain and satisfaction.

RESULTS:

The total CLASS score and three sub-scores (i.e. stability, suspension, comfort) were significantly higher with Varos socket. Significantly improved comfort and quality of socket fit were observed as

measured by the Socket-Comfort-Scale and Socket-Fit-Scale and a trend towards reduced residual limb pain. 87.5% of the patients reported higher satisfaction than with the standard socket.

CONCLUSIONS:

The results suggest that the Varos socket improved comfort, stability, suspension, appearance, pain and satisfaction in transfemoral amputees during the early rehabilitation program. A larger study and a longer observation period are warranted to confirm the results of this study.

REHABILITATION IMPACT:

Quick and easy socket fitting as well as instant adjustability by the patient bear substantial potential to improve and accelerate the rehabilitation process in the early phase after amputation.

KEY WORDS:

Lower limb prosthetics, early ambulation, Socket satisfaction,

Introduction

The prosthetic socket is generally considered to be the most important component of a lower limb prosthesis and the most important factor for successful mobilisation of the patient, beginning as soon as the early rehabilitation phase. As a human-prosthetic interface, the socket should be designed properly to achieve adequate biomechanical load transmission, stability and efficient control for mobility to the greatest possible extent[1]. Beyond that functionality, comfort and adaptability to various residual limb conditions is intrinsically tied to optimal socket fit[2,3]. Continual technological progress in lower limb prosthetics has been made in recent years, including improvements in socket and component designs. The current generation of sockets is fabricated to provide "total contact", distributing mechanical forces evenly through the residual limb as much as possible. In contrast, earlier socket designs provided focal areas of weight-bearing and unloading. In addition, more sophisticated polymers and carbon fibres are used to manufacture sockets that are lighter and more durable and allow for combining rigidity and flexibility to optimise performance[4].

Despite these achievements, socket fit, management of volume changes, performance, and comfort continue to present major challenges as many patients experience chronic problems with skin damage, infection, pain and frequently changing residual limb conditions, requiring further research and advancements in technology[2,5]. During the post-operative recovery period (the first 12–18 months after amputation), the residual limb experiences a substantial change in shape and volume due to oedema and muscle atrophy[6]. Daily fluctuations in residual limb volume, however, continue even years following the amputation[7,8]. In everyday clinical practice, the socket design is usually chosen by the prosthetist based on the patient's residual limb condition; ability to use technical features, such as donning tools, liners, valves and pumps; lifestyle; and activity level. This selection process is based on the prosthetist's personal experience rather than objective criteria[9]. Even with advances in computer-aided design and manufacturing (CAD/CAM), technical skills and craftsmanship are required of the prosthetist in order to fabricate and modify sockets until they fit adequately and comfortably[10]. Frequent adjustments of the socket volume during post-amputation are necessary, especially in individuals with peripheral vascular disease, whose impaired circulation due to swelling can delay

healing and rehabilitation[11,12]. The adjustment process can be extremely time-consuming for both prosthetist and patient, and may require numerous appointments as well as substantial resources, such as labour time for manufacturing and modifications. Additionally, patients may need to deal with interruptions to their rehabilitation process while the prosthetist is manually adjusting the socket and must invest significant time and effort in regaining lost walking proficiency in the early phase of rehabilitation[2].

The current, common methods of managing volume changes with conventional sockets include layering and removing pads, inflatable air bladders or fluid-filled bladders that can help to overcome stump volume changes. However, a sustainable standard could not be identified[3,5]. In recent years, manually adjustable pads have become increasingly used, reducing or enhancing the socket volume at specific locations of the socket. Several designs for adjustable sockets have also been introduced in recent years[13]. Some of those, however, only permit an adjustment by the prosthetist, which could be a limitation in the case of short-term or daily volume fluctuations adaption needs. Limited published research suggests that adjustable socket designs improve comfort, safety and functional mobility as compared to standard sockets in patients with residual limb volume changes[5,14].

Recently, a new, industrially pre-fabricated socket called Varos (PFSV) was introduced on the market. Varos was developed as a long-term socket that can be used starting in the early rehabilitation phase. Thus far, no clinical studies have been conducted with the PFSV. Therefore, the objective of this pilot study was to obtain the first clinical insights into the potential benefits and acceptance of the new, patient-adjustable socket technology in an in-patient rehabilitation setting.

Methods

Study device

Varos (Ottobock, Max-Näder-Straße 15, 37115 Duderstadt, Germany) is a pre-fabricated socket delivered in a kit with a liner for patients with transfemoral amputation and Medicare Functional Classification Levels (MFCL) 1-4 with and without residual limb volume changes and

fluctuations (Figure1)[15]. According to the manufacturer, it allows the patient to adjust the socket instantaneously as needed to accommodate changes in the anatomical situation of the residual limb without professional support, simply by pressing two buttons. This capability may reduce or prevent discomfort or even pain from swelling or shrinking of the residual limb or impairments in perfusion. The PFSV System was built to optimise the fitting process, particularly in the early phase of prosthetic rehabilitation.

Study design

A prospective cross-over interventional single-centre pilot study was conducted at an Austrian rehabilitation centre specialising in elderly patients with multiple comorbidities. The study was approved by the Ethics Committee of Burgenland (EC No.: 67/2016) and conducted in accordance with the standards set by the Declaration of Helsinki. All patients gave informed consent in written form prior to any procedures. The present report was drafted in line with the STROBE statement.

The study planned to enrol 10 patients in order to determine their experience with the newly developed socket. The following inclusion criteria were used when selecting the patients: unilateral transfemoral amputation, recent amputation (< 6 months), > 18 years of age, functional level MFCL 1-4, body weight up to 100 kg (without prosthesis). Furthermore, the residual limb was required to have a normal weight bearing capacity, a conical or cylindrical shape and be subject to at least minimal daily volume fluctuations. The residual limb's length was required to be between 200-320 mm, proximal circumference between 460-580 mm, distal circumference between 350-440 mm and residual limb hip flexion contracture less than 10°. Eligible patients were required to have a general health status sufficient to allow for the use of a prosthesis, were willing and able to independently provide informed consent and comply with study procedures, and positively completed a 'Study Socket test fitting'. The 'Socket test fitting' was a part of the clinical routine to determine the socket's suitability for the patient. This procedure was a short test fitting of a PFSV Test socket and its liner to ensure good fit without relevant discomfort.

Patients were excluded if any of the following applied: the residual limb skin revealed problems (i.e. open wounds, skin disease); sensitivity impairments at the residual limb or pronounced atrophic scars; the residual limb was very bulgy; patient suffered from conditions that would prevent participation and pose increased risk (e.g., unstable cardiovascular conditions that preclude physical activities such as walking); patient was prone to fall more than once a week for reasons that could not be corrected by the new prosthesis; patient was in an emergency, life-threatening situation; patient was unwilling/unable to follow instructions or unavailable to follow the entire study protocol; patient was pregnant.

The study used an A-B-A design in which each patient went through a sequence of socket interventions: standard socket – PFSV – standard socket. Throughout the study, the patients underwent a standard rehabilitation program at the clinic that included specific physical therapy related to prosthesis use. During enrolment, demographic data as well as data on the current prosthesis (with a standard socket and liner) was collected. The prosthetist ensured that the current prosthesis, which was finalised at the rehabilitation clinic, was aligned correctly such that the patient could proceed into the '1st A phase', which involved 1 week of standard socket use during rehabilitation in the clinic. At the end of that week, a set of outcome measures was assessed. Following the testing, the patient's standard socket was replaced with PFSV, while all the other prosthetic components remained unchanged ('B phase'). After a week of PFSV use during rehabilitation in the clinic, the patient was asked to complete a set of outcome measures. Afterwards, the patient was re-fitted with the same standard socket used previously ('2nd A phase'). After another week, the patient underwent a final assessment of the set of outcome measures.

Outcome measures

Patient-reported outcome measures were used to assess and compare socket fit, pain, comfort and patient satisfaction with the PFSV and standard socket during all three assessments. A validated, translated Comprehensive Lower-Limb Amputee Socket Survey (CLASS) was used as the primary endpoint. CLASS is a Likert-scale questionnaire comprising items grouped in four main categories of

prosthetic socket fit (stability, suspension, comfort and appearance) with excellent test-retest reliability and internal consistency[16]. The survey was not revalidated since this was left out due to the pilot character of the study.

Socket fit was assessed additionally by a Socket Fit Scale, which is a previously published 5-point Likert scale[17]. The Socket Fit Scale requires the patient to rank socket edge, socket bottom, adhesion, donning and doffing by choosing the most appropriate rating (‘very good’, ‘good’, ‘neutral’, ‘bad’, ‘very bad’). Subjective experience of socket comfort was assessed by means of the Socket Comfort Scale (SCS)[18]. Patients were asked to rate the comfort of their socket on a 0 - 10 scale, where 0 and 10 represent the most uncomfortable and the most comfortable socket imaginable, respectively.

During each assessment, patients were asked to rate perceived pain intensity in the residual limb and back on a 10-point Likert scale (0 – no pain, 10 – worst imaginable pain).

Satisfaction was assessed during each assessment by asking, ‘How satisfied are you with the current socket?’, to which the possible answers were ‘very satisfied’, ‘satisfied’, ‘neutral’, ‘unsatisfied’ and ‘very unsatisfied’. Safety was assessed by asking the patients how often they stumbled, fell or were injured in the past week. Fear of falling was assessed by asking, ‘Please rate your fear of falling where 0 represents no fear and 10 extreme fear’.

Statistical analyses

Quantitative variables were summarised using standard descriptive statistics. Means and medians were reported in this analysis, depending on the data’s normal distribution and thus the rules for statistical analysis. The results were compared with appropriate non-parametric tests (e.g., Friedman’s Test, Wilcoxon signed ranked test). Observed power was computed using $\alpha = 0.05$ unless stated otherwise.

Results

Ten subjects were enrolled in this pilot study. Two subjects dropped out after screening and the selection phase. The collected data of the remaining 8 subjects were analysed. Characteristics of those patients are listed in Tables 1 and 2.

In this pilot study, no falls or stumbles occurred. A reduction in the perceived fear of falling was observed with the PFSV. However, this difference was not statistically significant (non-parametric Friedman's Test (1.75, $p = 0.417$).

The total CLASS score improved with PFSV as compared to the assessments for the standard socket (Table 3, Figure 2). The non-parametric Friedman's Test indicated a significant effect for total score ($p = 0.006$), as well as sub-scores stability ($p = 0.012$), suspension ($p = 0.015$), comfort ($p = 0.015$, $n = 7$ since one patient ranked as 'not relevant'), and appearance ($p = 0.038$) when comparing all three phases. Following up with the Wilcoxon signed-ranked tests for each pair, significance of differences was found for almost all sub-scores between the PFSV and the second standard phase (stability: $p = 0.018$; suspension: $p = 0.024$; comfort: $p = 0.033$). The comparisons between the PFSV and the first standard socket phase, as well as between the first and the second standard socket phase, did not reach the level of significance. Appearance did not show significant differences between phases.

The Socket Fit Scale scores showed a tendency towards improvement with the PFSV socket (Table 3, Figure 3). The total score when averaging across 5 items (socket edge, socket bottom, adhesion, donning and doffing) resulted in 6 patients rating PFSV as 'very good' or 'good'. These values were only 25% and 12.5% for the first and second assessment with the standard socket, respectively. Statistically significant differences in Socket Fit Scale scores were found for all 5 items and the total score evaluated with multiple Friedman's Tests: socket edge ($p = 0.042$), socket bottom ($p = 0.018$), suspension ($p = 0.016$), donning ($p = 0.041$), doffing ($p = 0.047$) and total score ($p=0.018$). Following up with the Wilcoxon signed-ranked tests for each pair, significant differences were found for all items between the PFSV and the second standard phase (socket edge: $p = 0.046$; socket bottom: $p = 0.024$;

suspension: p = 0.018; donning: p = 0.046; doffing: p = 0.046; total score: p = 0.024). The comparisons between the PFSV and the first standard socket phase, as well as between the first and second standard socket phase, found no significant differences for any of the items.

The three fitting phases (first standard socket, PFSV, second standard socket) resulted in significant differences in the Socket Comfort Score (Table 3, Figure 4), with the PFSV resulting in the highest level of comfort. The non-parametric Friedman's Test showed a significant difference between the Socket Comfort Scores for the three phases (p = 0.004). Following up with the pairwise Wilcoxon signed-ranked tests, significance was found for the differences between the PFSV and the second standard phases (p = 0.009). The differences between the PFSV and the first standard phases, as well as between the first and second standard phase, did not reach the level of significance.

Mean values for back pain declined over time and were 2.25±2.55 (first standard socket), 1.88±2.64 (PFSV) and 1.63±2.26 (second standard socket). Mean scores for pain in the residual limb were lower with the PFSV (1.13±2.10) compared to with the first (1.75±2.55) and second (1.50±2.14) standard socket assessments. The differences were not significant when running non-parametric Friedman's Tests.

Satisfaction was higher with the PFSV than with the standard socket. 7 patients reported being very satisfied with the PFSV, compared to only 2 patients during the first and no patients during the second standard socket assessments, respectively. No patient reported being 'not satisfied' or 'dissatisfied' with PFSV, while 2 patients reported so during the first and 4 reported so during the second standard socket assessment, respectively.

Discussion

The results of this pilot study suggest that the Varos socket may be appropriate for early fitting of transfemoral amputees, improving comfort, stability and satisfaction. Similar to the findings of Hanspal et al., in our study, general comfort in the Study Socket was reported as an average of 8[18].

These parameters are extremely important because early fitting can provide patients with the beneficial effects of mobilisation and a more independent life, generate a sense of achievement and reduce long-term rejection rates of prostheses due to low satisfaction levels that are mainly due to socket-related issues[3,19,20].

Resnik et al. found that receipt of training in using the initial prosthesis, amputation level and age were independently associated with device satisfaction and that older persons were more satisfied with their prostheses[21]. It must be noted that despite the mean age of 66.5 ± 8.2 years, there was no drop out due to psychological reasons, and in general patient participation was very good considering that they were required to change sockets multiple times during a short period.

Despite the small patient sample, several of the outcome measures used showed significant results suggesting advantages of the PFSV. Future studies should enrol a larger, more representative patient sample. It is interesting that in the case of CLASS, Socket Fit Scale, Socket Comfort Scale, residual limb pain and satisfaction, the values during the second standard socket assessment were worse than during the first standard socket assessment. Consequently, in many cases the significant results were found when comparing PFSV to the second standard socket assessment rather than the first assessment. The second standard socket assessment can be considered more informative than the first one because during the second assessment, the patient has already experienced both standard socket and PFSV and therefore has a better impression of the possible socket solutions. Similar observations were also made by Hafner et al. and Kaufman et al., in which patients transitioned from mechanical knees to microprocessor-controlled knees and back to mechanical knees; scores during the second mechanical knee assessment were considerably worse than during the first assessment[22,23].

The effects found in our study could be the result of a cumulative effect of the socket intervention as well as a positive effect of the rehabilitation program (including gait training) reported in previous

studies[24,25]. In future studies, a parallel group design in which patients are randomly assigned to either a group receiving PFSV or a standard socket should be used.

Standard sockets are extremely time-consuming for both prosthetist and patient, not only during initial fabrication but also during later adjustments that could result in delay or interruption of the rehabilitation process. Moreover, aside from the medical and anatomical aspects, psychosocial aspects also influence the treatment process[26]. Ability to reduce these difficulties with PFSV would be clinically relevant for the patients. This study also has several significant limitations. The most obvious limitation is the lack of a cohort of patients with a different socket. Another limitation is that the second fitting of the standard socket was performed without any modification to the socket itself, which could have influenced patients' perception due to possible volume and morphological fluctuations in the residual limb over time. In addition, the data are gathered from a single institution. As such, there is a selection bias. As our outcome measures were exclusively self-reported measurements, there is always the possibility of subjectivity making more objective assessments necessary in further studies such as functional tests and bone mineral density measurements. This was also a fairly small cohort of patients and thus may have been underpowered to demonstrate significant results. Another limitation is the missing revalidation of the translated version of CLASS, although in our case the other surveys confirmed the results. Revalidation will be necessary in future larger studies.

While the current study investigated use of the PFSV shortly following amputation and during early rehabilitation, the socket is also approved for long-term use. Long-term data will be collected in order to better understand the differences between the sockets and whether the PFSV and its adjustability could potentially reduce the need for new standard sockets in those patients with residual limbs prone to volume changes over time. In addition to patient-reported outcome measures, future studies should utilise validated performance-based outcome measures. Research is also needed to quantify volume fluctuations in the residual limb and to assess different socket designs with respect to their suitability for addressing this problem.

Finally, an additional patient group that might be of interest to study are elderly patients that often do not receive any prosthetic fitting. The literature suggests that only 1 in 5 elderly patients is fitted with a prosthesis after amputation[27]. There is some data indicating increased mortality in this multi-morbid cohort (e.g., in Austria, the overall mortality after major lower extremity amputation LEA was 13.5% after 1 month, 22.0% after 3 months, 34.4% after 1 year, and 66.7 % after 5 years in patients with diabetes mellitus[28]). However, this does not explain why so few patients receive a prosthesis in the first place. Thus, there appears to be a need to enable those patients currently not fitted to also use prosthetic solutions as soon as possible after wound healing to benefit from mobilisation, generate a sense of achievement, and reduce rejection of prostheses due to low satisfaction levels that are mainly due to socket-related issues[3,19]. Future studies with PFSV should investigate how new features (e.g. quick and easy fitting, patient adjustability and ability to don the prosthesis while seated) influence the prosthetic use and quality of fitting in elderly patients.

Clinical interpretation of the first cases

The results of this preliminary study demonstrate significantly increased stability, suspension, comfort, and socket fit as well as increased satisfaction and a reduction trend in socket-related pain in the residual limb with the PFSV system. All of these findings are important because successful early prosthetic fitting could positively influence long-term prosthetic usage, mobilisation, independence and quality of life.

Conclusion

The Varos socket improved comfort, stability, suspension and satisfaction with the socket in unilateral transfemoral amputees undergoing an early rehabilitation program. Larger clinical studies are needed to confirm these observations.

Literature

1. Mak AFT, Zhang M, Boone DA. *State-of-the-Art Research in Lower-Limb Prosthetic Biomechanics-Socket Interface: A Review*. Vol 38.

2. Esquenazi A, Meier RH. Rehabilitation in limb deficiency. 4. Limb amputation. *Arch Phys Med Rehabil*. 1996;77(3 SUPPL.).

3. Paternò L, Ibrahimi M, Gruppioni E, Menciassi A, Ricotti L. Sockets for limb prostheses: A review of existing technologies and open challenges. *IEEE Trans Biomed Eng*. 2018;65(9):1996-2010.

4. Pasquina PF, Perry BN, Miller ME, Ling GSF, Tsao JW. Recent advances in bioelectric prostheses. *Neurol Clin Pract*. 2015;5(2):164-170.

5. Sanders JE, Fatone S. Residual limb volume change: Systematic review of measurement and management. *J Rehabil Res Dev*. 2011;48(8):949-986.

6. Berke G. Post-operative management of the lower extrem-ity amputee: Standards of care. *J Prosthet Orthot*. 2004;(16(3S)):6–12.

7. Zachariah SG, Saxena R, Fergason JR, Sanders JE. Shape and volume change in the transtibial residuum over the short term: Preliminary investigation of six subjects. *J Rehabil Res Dev*. 2004;41(5):683-694.

8. Sanders JE, Harrison DS, Allyn KJ, Myers TR. Clinical utility of in-socket residual limb volume change measurement: Case study results. *Prosthet Orthot Int*. 2009;33(4):378-390.

9. Chen RK, Jin Y an, Wensman J, Shih A. Additive manufacturing of custom orthoses and prostheses-A review. *Addit Manuf*. 2016;12:77-89.

10. Sengeh DM, Herr H. A variable-impedance prosthetic socket for a transtibial amputee designed from magnetic resonance imaging data. *J Prosthetics Orthot*. 2013;25(3):129-137.

11. MacLean N, Fick GH. The effect of semirigid dressings on below-knee amputations. *Phys Ther*. 1994;74(7):668-673.

12. Wong CK, Edelstein JE. Unna and elastic postoperative dressings: Comparison of their effects on function of adults with amputation and vascular disease. *Arch Phys Med Rehabil*. 2000;81(9):1191-1198.

13. Isaacson BM, Lin SC, Rothberg DL. Improvement in functional outcomes with the infinite socket. *J Prosthetics Orthot*. 2018;30(4):181-186.

14. Kahle JT, Klenow TD, Highsmith MJ. Comparative Effectiveness of an Adjustable

Transfemoral Prosthetic Interface Accommodating Volume Fluctuation: Case Study . *Technol Innov*. 2016;18(2):175-183.

15. *Varos Instructions for Use. Ottobock*. Accessed April 9, 2021. https://shop.ottobock.us/media/pdf/IFU-647G1099-INT-03-1904-Varos.pdf
16. Gailey R, Kristal A, Lucarevic J, Harris S, Applegate B, Gaunaurd I. The development and internal consistency of the comprehensive lower limb amputee socket survey in active lower limb amputees. *Prosthet Orthot Int*. 2019;43(1):80-87.
17. Berry D, Olson MD, Larntz K. Perceived stability, function, and satisfaction among transfemoral amputees using microprocessor and nonmicroprocessor controlled prosthetic knees: A multicenter survey. *J Prosthetics Orthot*. 2009;21(1):32-42.
18. Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. *Disabil Rehabil*. 2003;25(22):1278-1280.
19. Spoden M, Nimptsch U, Mansky T. Amputation rates of the lower limb by amputation level - Observational study using German national hospital discharge data from 2005 to 2015. *BMC Health Serv Res*. 2019;19(1):8.
20. Lilja M, Johansson S, Öberg T. Relaxed versus activated stump muscles during casting for trans-tibial prostheses. *Prosthet Orthot Int*. 1999;23(1):13-20.
21. Resnik L, Borgia M, Heinemann AW, Clark MA. Prosthesis satisfaction in a national sample of Veterans with upper limb amputation. *Prosthet Orthot Int*. 2020;44(2):81-91.
22. Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee. *Arch Phys Med Rehabil*. 2007;88(2):207-217.
23. Kaufman KR, Bernhardt KA, Symms K. Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. *Clin Biomech*. 2018;58:116-122.
24. Gailey R, Gaunaurd I, Raya M, Kirk-Sanchez N, Prieto-Sanchez LM, Roach K. Effectiveness of an evidence-based amputee rehabilitation program: A pilot randomized controlled trial. *Phys Ther*. 2021;100(5):773-787.

25. AlSofyani MA, AlHarthi AS, Farahat FM, Abuznadah WT. Impact of rehabilitation programs on dependency and functional performance of patients with major lower limb amputations. *Saudi Med J*. 2016;37(10):1109-1113.

26. Carabello A, Schellnock J, Schleifenbaum S, et al. Investigation of Orthopedic Prosthesis Socket Management after Transfemoral Amputation by Expert Survey. *Prosthes 2021, Vol 3, Pages 137-156*. 2021;3(2):137-156.

27. Davie-Smith F, Paul L, Nicholls N, Stuart WP, Kennon B. The impact of gender, level of amputation and diabetes on prosthetic fit rates following major lower extremity amputation. *Prosthet Orthot Int*. 2017;41(1):19-25.

28. Aziz F, Reichardt B, Sourij C, et al. Epidemiology of major lower extremity amputations in individuals with diabetes in Austria, 2014–2017: A retrospective analysis of Health Insurance database. *Diabetes Res Clin Pract*. Published online September 28, 2020:108477.

Disclosures

Stephan Domayer discloses an advisory contract with Otto Bock. All other authors report no conflicts of interest. Varos Sockets and Liners were made available by Ottobock.

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Author Arastoo Nia and author Stephan Domayer have given substantial contributions to the conception, analysis, interpretation and design of the manuscript, author Gerhard Toetschinger and author Tomas Kubinec to acquisition of the data. All authors have participated to drafting the manuscript, author Stephan Domayer revised it critically. All authors read and approved the final version of the manuscript.

Acknowledgements: Not applicable

Table Legend

Table 1.Patient demographics.

Patient characteristics PP (n=8)	**Values**
Gender (male/female)	5/3
Time since amputation (months)	2.9 ± 1.2 [mean ± SD]
Amputation type (traumatic / vascular)	1/7
Age (years)	66.5 ± 8.2 [mean ± SD]
BMI	27,5 ±3,2
Residual-limb length (cm)	24.8 ± 3.9 [mean ± SD]
Flexion contracture (degree)	5 ± 0 [mean ± SD]
MFCL at enrollment	MFCL-0: 1 MFCL-1: 5 Between MFCL-1 and 2: 1 MFCL-2: 1
MFCL at study end	MFCL-0: 0 MFCL-1: 1 Between MFCL-1 and 2: 2 MFCL-2: 5
Common comorbidities	cardiovascular disease: 4 metabolic disease: 4 renal disease: 4 chronic obstructive pulmonary disease: 1 osteomyelitis: 1 rheumatoid arthritis: 1
Prosthetic knee	
Locked knee	7
Polycentric knee	1
Daily prosthesis use (mean hours) at enrollment	3.1±1.3

Table 2. Patients' weight and residual-limb circumferences at different assessments.

	Enrollment	1st Standard socket data collection	Varos data collection	2nd Standard socket data collection
Weight (kg) [mean ± SD]	73.4 ± 13.4	73.8 ± 13.9	74.1 ± 13.7	74.4 ± 13
Proximal stump circumference (cm) [mean ± SD]	53.1 ± 4.8	53.5 ± 4.6	53.6 ± 4.5	53.8 ± 4.2
Distal stump circumference (cm) [mean ± SD]	42.5 ± 2.0	42.8 ± 1.6	42.4 ± 1.7	42.9 ± 1.8

Table 3. Scores for CLASS, Socket Fit Scale and Socket Comfort Scale.

	1. Standard		Varos		2. Standard	
	Median [IQR]	Mean (SD)	Median [IQR]	Mean (SD)	Median [IQR]	Mean (SD)
CLASS						
Stability	75% [0]	75% (9)	94% [25]	89% (12)	75% [22]	67% (11)
Suspension	75% [30]	72% (17)	100% [25]	90% (13)	66% [25]	63% (12)
Comfort	59% [25]	61% (13)	100% [31]	85% (19)	50% [39]	54% (19)
Appearance	75% [20]	65% (17)	75% [25]	81% (17)	75% [25]	63% (18)
Total score	69% [14]	68% (11)	93% [27]	87% (14)	62% [22]	62% (13)

Socket Fit Scale						
Socket edge	2.5 [1]	2.5 (0.9)	4.5 [1.8]	4.13 (1.1)	2.5 [1]	2.5 (0.9)
Socket bottom	3.5 [1]	3.5 (0.9)	4.5 [1.8]	4.13 (1.1)	2.5 [1]	2.5 (0.9)
Suspension	3 [1]	3.3 (0.7)	4.5 [1.8]	4.1 (1.1)	2 [1]	2.5 (0.7)
Donning	3 [1.8]	2.8 (1)	4.5 [2]	4 (1.1)	2 [1]	2.5 (0.7)
Doffing	3 [1.5]	2.9 (0.9)	4.5 [2]	4 (1.1)	2 [1]	2.5 (0.7)
Total score	3 [1.5]	3.1 (0.9)	4.5 [1.8]	4.1 (1.1)	2 [1.8]	2.3 (1)
Socket Comfort Scale	5 [2.5]	5.1 (1.5)	8 [4]	7.9 (1.8)	4 [3.5]	4.1 (1.8)

Figure Legend

Figure 1. Varos socket system consists of a liner and a socket. The silicone liner has a distal magnet (2) and a special fabric (1). Both connect with the socket to secure the suspension. The socket has two shells (3a, 3b) that are connected with a cable system (4). The cable system allows the patient to regulate the volume of the socket. The flexible shells will overlap and adopt to the individual shape of residual limb. The shells in connection with the cable system allow to open the socket, so that donning and doffing is possible even if seated.

Figure 2. Comprehensive lower-limb amputee socket survey (CLASS).

Figure 3. Socket Fit Scale. Median scores for different socket phases.

Figure 4. Socket comfort scale scores in three phases.