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

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Summary
Results from a pilot study using a new patient-adjustable socket system are presented. During in-patient rehab after TF amputation, patients wore a new adjustable socket for a week. Patients reported improved comfort and greater satisfaction with the new socket compared to the standard socket.

Introduction/ basics
As a critical component of a lower limb prosthesis, the prosthetic socket should be designed to achieve adequate biomechanical load transmission, stability and mobility control to the greatest extent possible (Mak, 2001). Beyond this functionality, comfort and adaptability to various residual limb conditions is intrinsically tied to optimal socket fit (Esquenazi, 1996, Paternó, 2018). Current prosthetic sockets often provide limited anatomical fit, especially in patients with residual limb volume changes and fluctuations (Esquenazi, 1996, Spoden, 2019). The objective of this pilot study was to evaluate the potential benefits and acceptance of a newly designed patient adjustable socket (PAS) in transfemoral (TF) amputees in the early phase of rehabilitation.

Material method; implementation/ process
A prospective A-B-A pilot study was conducted in which patients during in-patient rehab after TF amputation wore a standard socket for one week, the PAS for one week and then returned to the standard socket for one week. The study was approved by the Ethics Committee and all patients gave informed consent prior to any study procedures. The outcome measures included: Comprehensive-Lower-limb Amputee-Socket-Survey (CLASS), a study-specific Socket-Fit-Survey, Socket Comfort Score, frequency of falls/stumbles, perceived pain and

satisfaction. Patients underwent a standard rehabilitation program which included prosthetic alignment or physical therapy for prosthesis use. Results were compared with appropriate non-parametric tests (e.g. Friedman's Test, Wilcoxon signed ranked test) using alpha = 0.5.

Results

Ten subjects with unilateral transfemoral amputation enrolled in the study. Two dropped out, 1 after a fall from the wheelchair unrelated to the prosthesis and 1 who withdrew prior to first data collection. Data from the remaining 8 were analyzed, 5 males and 3 females. The mean age was 66.5±8.2 yrs, mean time since amputation 2.9±1.2 months. The amputation types were traumatic (1) and dysvascular (7). The mean residual limb length was 24.8±3.9 cm. The mobility grade levels were 0 (1), 1 (5), 1/2 (1) and 2 (1). Seven subjects wore a locked knee and 1, a polycentric.

The total CLASS score and three sub-scores (stability, suspension, comfort) were significantly higher with the PAS (p=0.006 for the total and p=0.01 for subscores). See Figure 1. Significantly improved comfort and quality of socket fit were observed as measured by the Socket-Comfort-Scale and Socket-Fit-Scale. The PAS socket showed a trend towards reduced residual limb pain. Satisfaction was higher with the PAS than with the standard socket with 87.5% of the patients reporting to have been very satisfied. See Table 1.

Discussion/ conclusion; conclusion for the practice

Discussion

Use of the PAS socket in this study in early fitting of TF amputees resulted in improvements in comfort, stability, suspension, pain and satisfaction without compromise in safety in terms of stumbles and falls. Early fitting can help patients become more mobile, independent and reduce rejection rates due to socket issues (Paterno 2018, Spoden 2019, Lilja 1999). The study was limited by small sample and short duration of use. In addition, the improvements were a result of both socket intervention and the on-going rehabilitation, although the benefits of the rehabilitation are assumed to increase with time.

Conclusion

The results suggest that the PAS 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.

Conclusion for the practice

The patient-adjustable socket could be a viable option for patients with volume fluctuations, especially during early rehabilitation.

References

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Paternó, IEEE Trans Biomed Eng, 65(9), 1996-2010, 2018

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Image: Figure 1_Total CLASS scores by socket condition_v3_269_269.jpg

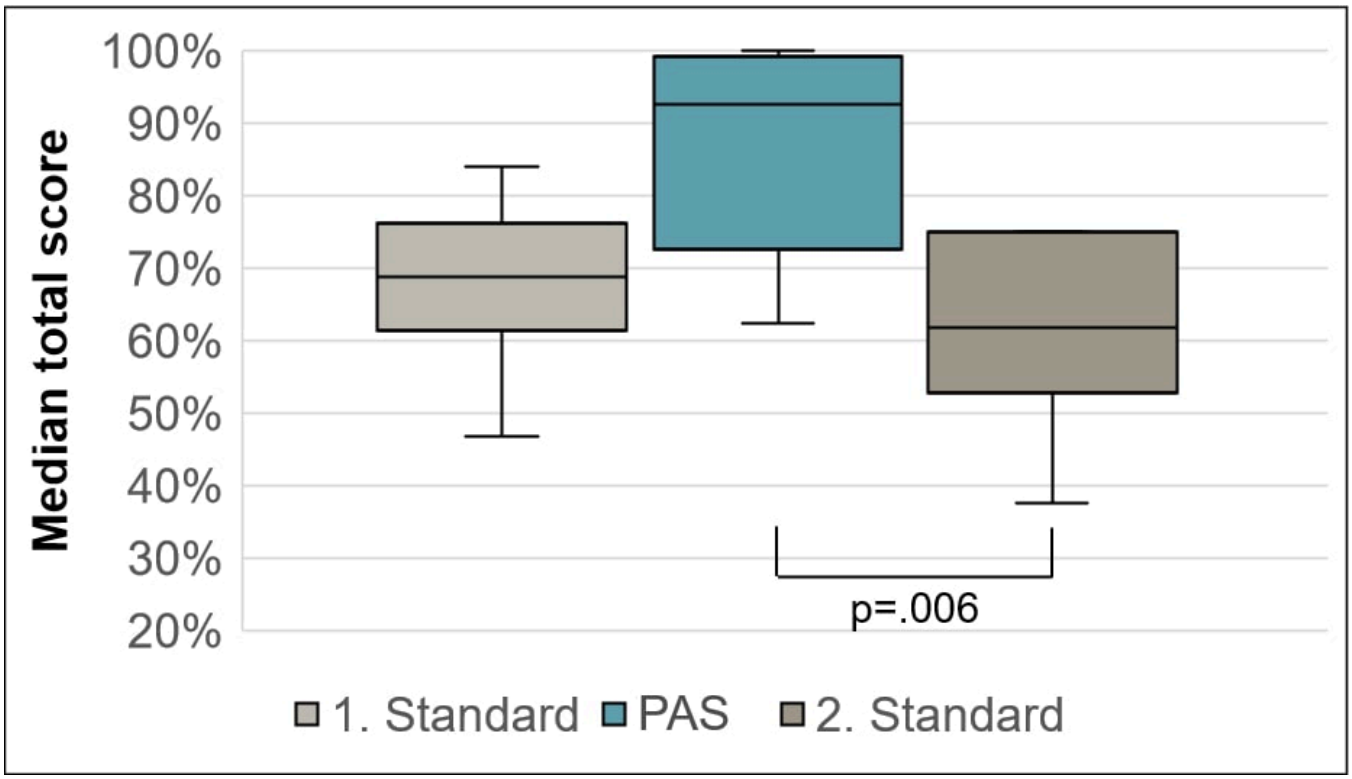

Image: Table 1. Patient satisfaction by socket condition_v2_270_270.jpg

	Standard	PAS	Standard
Very satisfied	2	7	0
Satisfied	1		2
Neutral	3	1	2
Unsatisfied	2		2
Very unsatisfied	0		2

Table 1. Patient satisfaction by socket condition