

Socket Comfort of Volume-Adjustable Interfaces Compared to the Standard of Care

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Clinical Question: Do adjustable-volume interfaces improve socket comfort compared to traditional sockets in persons with lower-extremity limb loss?

Background: The human-device interface, or socket, is considered the most important part of a prosthesis.¹⁻³ Lack of socket fit can lead to pain, discomfort, skin irritation and breakdown, subsequent prosthetic abandonment, and therefore activity reduction, reduced social participation, psychosocial problems, and deleterious health effects due to inactivity.^{1,3} Adjustability has been stated as a desire of patients and as a potential solution to socket fit issues for several years, but market penetration for adjustable sockets in clinical prosthetics has been limited. This may change with reimbursement reform. Further, the evidence regarding socket comfort of adjustable-volume (AV) interfaces has not been synthesized. The purpose of this CAT is to evaluate current literature comparing socket comfort of AV interfaces to the standard of care (SoC) of the profession, rigid-volume definitive sockets.

Search Strategy:

Databases Searched: PubMed, Google Scholar, Cochrane Library, O&P IQ

Search Terms: (prosthesis* OR artificial limb[MeSH] OR amput* OR amputation[MeSH] OR limb loss) AND (socket OR interface OR design) AND (adjust* OR prosthesis adjustment[MeSH] OR modular OR adapt*)

Inclusion Criteria: English or German, direct applicability to population with limb loss, prosthetic interface with some adjustable-volume (AV) and/or modular feature, reports socket comfort score (SCS) as outcome measure.

Exclusion Criteria: Technical notes and editorial opinions without SCS, review articles without critical appraisal, prototypes tested on able-bodied individuals. Published before January 2000.

Synthesis of Results: Four articles were identified comparing socket comfort of AV interfaces to the SoC with a variety of study designs. All studies compared an AV socket to legacy SoC sockets, meaning the sockets the subjects had been wearing prior to entering the studies. Isaacson et al. compared a large sample of subjects with lower extremity amputation who were dissatisfied with the SoC and were being fit with a LIM Infinite™ socket.⁴ The subjects experienced a mean SCS improvement of 3.12 which is slightly greater than published minimally detectable change (MDC) values from 2.31-2.73.⁵⁻⁷ Nia et al. compared a small sample of subjects with transfemoral amputation (TFA) being fit with an Ottobock Varos™ socket in the acute stage of rehabilitation using a pre-post-pre design which showed a mean SCS improvement of 2.8 and 3.8, respectively, compared to the SoC.⁸ The last two articles are case studies. The first, by Kahle et al., was prospective, comparing the LIM Infinite™ socket to the SoC at baseline, as well as simulated volume loss and volume gain conditions.⁹ The SCS was 37% better for LIM compared to SoC at baseline and 93% better in the volume loss condition. The subject could not don the SoC socket in the volume gain condition for comparison. The second case study, by Mitton et al., compared a LIM Infinite™ to the SoC at 35-weeks post-TFA following difficult SoC fitting.¹⁰ The SCS improved from 4 to 8 with the LIM compared to SoC for this subject.

Clinical Message: Literature regarding socket comfort with AV sockets compared to the SoC is limited, but positive. All articles reviewed showed a significant improvement in socket comfort, as measured with the SCS, in newly-fit AV interfaces compared to legacy sockets in subjects with multiple levels of lower extremity amputation in various stages of prosthetic rehabilitation. The described results would indicate AV sockets have utility for individuals in the acute phase of rehabilitation where volume fluctuation is most prevalent as well as for individuals with volume fluctuations in the typical course of care. Sockets with AV capabilities were also effective for individuals who were dissatisfied with SoC sockets. While these results are positive, AV interfaces should be compared to the SoC in prospective randomized clinical trials to determine the extent of their efficacy in adequately-powered samples of individuals with problematic volume fluctuations and/or painful traditional SoC interfaces, commonly encountered in clinical settings. Clinical practice guidelines (CPGs) could then be established to provide better care direction for practitioners and patients. Until then, AV sockets should be

considered viable alternatives for subjects with unmet medical needs relating to socket comfort and residual limb volume fluctuations with SoC traditional sockets.

Evidence Table

	Isaacson, 2018	Nia, 2022	Kahle, 2016	Mitton, 2017
Population	127 adults with lower extremity limb loss (18 transtibial, 109 transfemoral), ≥ 6 months of conventional socket wear and were dissatisfied.	10 adults with unilateral transfemoral amputation <6 months post-operative.	1 adult male with unilateral transfemoral amputation.	1 adult female with unilateral transfemoral amputation, 35 weeks post-operative
Study Design	Experimental comparison	Prospective A-B-A crossover pilot	Prospective experimental case study	Interventional case study.
Intervention	Infinite™ Socket [LIM Innovations, San Francisco, CA, USA]	Varos™ Socket [Ottobock SE & Co. KGaA, Duderstadt, GER]	Infinite™ Socket [LIM Innovations, San Francisco, CA, USA]	Infinite™ Socket [LIM Innovations, San Francisco, CA, USA]
Comparison	LIM Infinite Socket to legacy conventional socket	SoC conventional socket to Varos then back to SoC	LIM Infinite Socket to SoC conventional IRC socket	LIM Infinite Socket to SoC thermoplastic socket
Methodology	SCS and physical performance measures were completed in legacy conventional socket and new Infinite Socket.	SCS and other measures collected following each period: 1 week of SoC, 1 week of Varos, 1 week of SoC.	SCS and other measures collected at baseline, then at simulated volume loss and volume gain condition.	SCS administered 23 weeks post-op when SoC was abandoned and week 35 - day 1 following LIM fitting.
Outcome Measures	SCS	SCS	SCS	SCS
Key Findings	Improved comfort for AV socket. LIM: 7.64 ± 2.00 , SoC: 4.52 ± 2.22	Improved comfort for AV socket compared to pre and post condition. SoC1: 5.1 ± 1.5 , Varos: 7.9 ± 1.8 , SoC2: 4.1 ± 1.8	Improved comfort for AV socket. 37% improved at base condition, 93% in volume loss simulation. Subject could only complete volume gain simulation using LIM, not SoC.	Improved comfort for AV socket. SCS improved 4 to 8.
Study Limitations	Study was not IRB approved, accommodation in LIM socket was short but not quantified, subjects had previous poor experience with SoC.	Study performed at a single center for elderly ill patients, SoC socket not adjusted for second period.	Case study.	Case study.

Abbreviations: AV – adjustable-volume, SCS – Socket Comfort Score, SoC – standard of care

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