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Transtibial Socket Design, Interface, and Suspension: A Clinical Practice Guideline

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ABSTRACT

Materials: NA

Methods: The guideline is based upon the best available evidence as it relates to socket design, interface, and suspension of definitive transtibial prostheses. Where possible, recommendations are drawn from systematic review and meta-analysis. Where this standard is unavailable, alternate academic literature has been used to support individual recommendations.

Results:

Recommendation 1: The static and dynamic pressure distribution of the residual limb within the socket are essential considerations in patient comfort, function and well-being.

Recommendation 2: Total Surface Bearing sockets are indicated to decrease fitting times and enable higher activity levels.

Recommendation 3: Compared to traditional foam-based interfaces, viscoelastic interface liners are indicated to decrease dependence on walking aides, improve suspension, improve load distribution, decrease pain and increase comfort.

Recommendation 4: Among modern suspension options, vacuum assisted suspension (VAS) sockets permits the least amount of pistoning within the socket, followed by suction suspension and then pin lock suspension. The traditional suspension options of supracondylar, cuff and sleeve suspension provide comparatively compromised suspension.

Recommendation 5: VAS sockets are indicated to decrease daily limb volume changes of the limb in the socket while facilitating more favorable pressure distribution during gait.

Recommendation 6: VAS sockets require both awareness and compliance on the part of the end user and are not universally indicated.

Conclusions: These clinical practice guidelines summarize the available evidence related to the socket design, interface, and suspension of definitive transtibial prostheses. The noted clinical practice guidelines are meant to serve on as “guides.” They may not apply to all patients and clinical situations. (*J Prosthet Orthot.* 2018;00:00–00)

KEY INDEXING TERMS: clinical practice guideline, transtibial, socket, interface, suspension, suction, vacuum, total surface bearing, patellar tendon bearing, liner

Of the 1.6 million persons living in the United States with limb loss, approximately 1.3 million (86%) have an amputation of the lower limb.^{1,2} Of these, estimates suggest that 28% or 378,000 individuals have transtibial amputation.³

The socket has long been described by lower-limb prosthesis users as the most important consideration in their satisfaction

with a lower-limb prosthesis.^{1,4,5} Its purpose is to transfer loads under both static and dynamic conditions with minimal movement between the limb and the prosthesis. Pressure distribution within the socket is an essential component to the comfort and function of the individual using a transtibial prosthesis. Ill-fitting sockets can lead to dermatologic concerns, injury to the limb, and decreased prosthetic utilization. The functional comfort of a transtibial prosthesis is dependent upon a number of interrelated factors including socket type and fit, interface materials, and suspension approaches.

For many decades, the standard of care for transtibial sockets was the joint-and-corset model in which the load-bearing forces were split between the socket and a thigh corset. Confining weight-bearing forces to the transtibial socket was not commonly performed until the introduction and popular acceptance of the patellar tendon bearing (PTB) socket in the 1950s.⁶ This approach is characterized by localized loading in load-tolerant areas and localized reliefs in areas that are generally intolerant to localized pressure. In the 1990s, the total surface bearing (TSB) socket was introduced in which the entire surface of the transtibial limb is used for load bearing.^{7,8} The efficacy of the latter appears to be enhanced by the integration of viscoelastic interface liners fabricated from a range of elastic materials including silicone,

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urethane, and other gel-like substances.^{9,10} Modern prosthetic sockets are generally a combination of PTB and TSB principles.¹¹

For many years, the interface options worn between the limb and the socket were confined to fabric fitting socks and various foam materials. More recently, the viscoelastic materials mentioned previously have been exploited for their cushioning and ability to integrate suspension. As the interface materials in modern transtibial prosthetic solutions are often integral with suspension of the device, it is difficult to examine these two variables discretely.

With the introduction of the PTB socket design, a number of anatomically based suspension mechanisms were used, including supracondylar socket contours and cuff-strap suspension. The introduction of the TSB socket was largely concurrent with the development of silicone suction suspension and the Icelandic roll-on silicone socket (ICEROSS).^{9,10} Modern suspension systems connect the residual limb to the socket using a locking silicone liner with a distal pin lock mechanism, through the creation of a suction environment by internal or external sealing

sleeves or rings and through active vacuum where the negative pressure within the suction socket is actively elevated and maintained by an external vacuum component.¹²

After transtibial amputation, successful prosthetic rehabilitation requires the development of a comprehensive socket strategy inclusive of a socket design, interface materials, and suspension strategy. The most common variants in these design elements are described in Table 1.

Clinical practice guidelines (CPGs) are increasingly common in health care, with the Federal Agency for Healthcare Research and Quality (AHRQ) now housing over 1700 practice guidelines in its National Guideline Clearinghouse.¹³ Yet, the field of orthotics and prosthetics is underrepresented in this area, with only a single CPG listed in the AHRQ database. Encouragingly, the field has begun to develop and publish practice guidelines across a range of care episodes including the management of plagiocephaly,¹⁴ postoperative care following transtibial amputation,¹⁵ prosthetic foot selection for individuals with lower-limb amputation,¹⁶ prescribing guidelines for microprocessor-controlled

Table 1. Summary of predominant socket design, interface, and suspension variants observed in transtibial prostheses

Consideration	Variants	Description
Socket design	Patellar tendon bearing	Characterized by the localization of load-bearing pressures on designated “pressure tolerant” regions, and targeted offloading of regions generally intolerant to pressure.
	Total surface bearing	Characterized by globally reduced socket volumes and relatively equal load bearing pressures throughout the entirety of the socket. This allows increased surface area for weight bearing through reduced localized socket pressures.
Interface	Socks	Compressible textiles, occasionally infused with thermoplastic elastomer gels. Primarily used to accommodate changes in limb volume, but occasionally used as a primary interface between the limb and socket.
	Foam liners	Nonporous material of soft to moderate durometer, frequently heat contoured over a positive model of the limb to mimic the contours of the socket.
	Elastic liners	Interface liners composed of silicone, urethane, and other thermoset elastomeric materials. Used with and without external fabric covers and imbedded matrices of reinforcing mesh material. Fabricated in custom and noncustom variants.
Suspension	Anatomic	Proximal socket contours are shaped to secure purchase over the bony shape of the femoral condyles.
	Mechanical “locking” liner	A combination of an elastic liner fitted with a distal locking pin (or alternate locking element), which engages a locking mechanism fabricated into the socket. Suspension results from the suction suspension of the liner and transfers through the locking mechanism attached to the socket. A reinforcing mesh is frequently impregnated into the liners distally to limit longitudinal distension of the liner.
	Suction	The creation of an airtight socket environment precludes excessive distraction of the socket from the residual limb. Frequently obtained through the use of a proximal sealing sleeve worn against the thigh and outer surface of the socket, but alternately obtained with sealing gaskets worn over the external surface of the interface liner and sealing against the inner surface of the socket. Enhanced with the inclusion of a one-way expulsion valve that allows air to be pushed from the socket environment but prevents air from entering the socket environment. During periods of the gait cycle when the prosthesis would separate from the limb, the airtight socket environment results in an increase in negative pressure as the prosthesis further separates from the limb resulting in an increasing force keeping the prosthesis on the limb.
	Vacuum-assisted suction	Similar to suction suspension as described above with the addition of a vacuum element that actively draws air from the socket environment (in the space between the interface liner and the interior socket wall), resulting in elevated negative pressure without need for initial prosthesis distraction from the residual limb to obtain negative pressure.

prosthetic knees in South East England,¹⁷ and a two-part “Dutch evidence-based guidelines of amputation and prosthetics of the lower extremity.”^{18,19}

The scope and depth of CPGs is variable, with direct implications on their resultant clinical relevance and ultimate incorporation into practice. The current effort is modeled after the CPGs of the American College of Physicians,²⁰ with necessary adaptations to accommodate the emerging evidence base of orthotic and prosthetic care. The stated goals of this approach are to “provide clinicians with clinical-based guidelines based upon the best available evidence; to make recommendations on the basis of that evidence; to inform clinicians of when there is no evidence; and finally, to help clinicians deliver the best health care possible.”^{20(pp194)}

Clinical utility is of paramount importance in this effort, culminating in a small number of succinct, actionable evidence-based recommendations.²¹ Notably, within this framework, although the resultant CPGs represent a comprehensive overview of available literature, deficits in the available literature preclude CPGs within this framework from providing comprehensive clinical guidance.

The purpose of this guideline is to present the available evidence on definitive transtibial socket design options, interface considerations, and suspension variations. The target audience for this guideline includes prosthetists, surgeons, physicians, therapists, case managers, and policy makers. The target patient population comprises individuals with transtibial amputation due to traumatic, dysvascular, or alternate etiologies.

Table 2. Explicit Evidence Statements*

Highsmith et al. ³	<ul style="list-style-type: none"> Compared with traditional PTB-designed interfaces, the use of gel liners reportedly decreases walk aid dependence; improves prosthetic suspension when used with a shuttle lock mechanisms compared with supracondylar, cuff, or corset alternatives; improves load distribution; and decreases pain and increases comfort. Compared with TSB-designed interfaces with pin locking suspension mechanism, VAS interfaces reportedly reduce time to prosthetic fitting and improve mobility postoperative or postulceration, decrease step activity, decrease pistoning, decrease positive pressure in stance phase, and increase negative pressure in swing phase when walking.
Highsmith et al. ²²	<ul style="list-style-type: none"> Provision of PTB sockets for patients with transtibial amputation costs 40% less than total contact socket alternatives; however, PTB sockets require up to three times longer to achieve a proper fit with no clinical performance differences between the alternatives.
Gholizadeh et al. ²³	<ul style="list-style-type: none"> VAS sockets should be slightly undersized. VAS systems could decrease daily limb volume changes, pistoning, and peak positive pressure during stance. This should maintain a better socket fit; increase negative pressure during swing; and improve mobility, comfort, stability, proprioception, functional outcome, overall satisfaction, prosthetic function, and quality of life. VAS systems could also reduce skin irritation, cure residual limb wounds faster, and decrease pain. Some participants were more satisfied with their pin/lock systems than VAS systems. Some VAS users had significantly fewer steps compared with using their pin/lock system Attention and skills are needed for donning the liner, socket, and sleeve. This may be difficult for older individuals with amputations. More maintenance was required for VAS systems.
Richardson and Dillon ²⁴	<ul style="list-style-type: none"> There is insufficient research to differentiate between the user experience of different transtibial liners and suspension methods.
Kahle et al. ²⁸	<ul style="list-style-type: none"> There were two studies representing level 2 evidence that VAS sockets increase volume, whereas non-VAS sockets reduce the volume of the residual limb during prosthetic use. There was agreement between two high quality level 2 studies and one low-quality study, which offers grade B evidence that VAS reduces movement on the residual limb. There were two high-quality studies representing level 2 evidence that VAS sockets favorably affect pressure distribution on the residual limb. Two level 2 studies demonstrated improvements in specific functional areas: spatiotemporal gait and balance confidence. A third level 2 study reported a decrease in activity with VAS use. These three studies do not provide consensus in any one functional area. Because of this lack of consistent evidence, more research is needed to determine if use of VAS increases function.
Klute et al. ²⁹	<ul style="list-style-type: none"> No evidence exists to support the notion that a prosthesis can assist in healing wounds with or without VAS. There is little scientific evidence to inform prosthetic liner prescription practices. Research has shown that liners can help distribute loading and reduce pain.
Baars and Geertzen ³⁰	<ul style="list-style-type: none"> Most studies mentioned improved suspension (with silicone liner socket use) compared with the conventional supracondylar fitting. Walking performance improved with less use of walking aides. There were reports of positive but also negative effects on the skin such as excessive perspiration and itching.
<p>*As different authors refer to VAS sockets through a range of acronyms, the term VAS has be substituted within the evidence statements for consistency.</p>	

METHODS

A Medline search was conducted on May 2, 2017, to locate published secondary knowledge sources of evidence statements within the published literature. The following search terms were used: ((prosth*) AND transtibial) AND (socket OR suspension OR interface) AND (systematic review OR meta-analysis). This search originally yielded 17 abstracts. Of these, 9 articles were identified as secondary knowledge sources (i.e., meta-analysis, systematic review, or scoping review) that synthesized published findings of primary knowledge related to transtibial socket design, interface, and suspension.^{3,11,22–28} Two additional publications meeting this standard were referenced within the selected literature and included for consideration and analysis.^{29,30} Collectively, the 11 identified publications included one systematic review and meta-analysis,³ nine systematic reviews,^{11,23–28} and a single scoping review.²²

In more recent publications, where authors provided explicit evidence statements, these were extracted for subsequent synthesis (Table 2). If explicit evidence statements were not provided, well-supported narrative statements were extracted (Table 3). Statements were confined to areas of clinical utility. Extracted statements are summarized in Tables 2 and 3 and addressed the following key considerations:

1. Comparative effectiveness: With regard to socket design, PTB sockets were compared against TSB sockets. Frequently, these comparisons overlapped with interface comparisons,

with foam liners (i.e., Pelite) used in conjunction with PTB sockets, whereas elastomeric liners were used in conjunction with TSB sockets. Suspension comparisons were variable but can be generalized as comparisons between anatomic suspension techniques, mechanical locking liner techniques, and suction techniques, with VAS representing an extreme form of suction that has been extensively studied.

2. Benefits of treatments: Potential benefits found in the extracted evidence statements relate to timeliness of prosthetic fitting, enhanced activity levels, patient satisfaction, reduced movement of the residual limb within the socket (i.e., enhanced suspension), mitigation of forces within the socket, stabilization of limb volume, improved comfort, and better gait symmetry.

3. Harms of treatments: Potential harms found in the extracted evidence statements relate to injury to the residual limb secondary to socket forces, discomfort, heat and perspiration, donning difficulties, and system maintenance requirements.

RECOMMENDATIONS

The extracted evidence statements from Tables 2 and 3 were subsequently synthesized into the six recommendations below, comprising the CPG.

Recommendation 1: The static and dynamic pressure distribution of the residual limb within the socket are essential considerations in patient comfort, function, and well-being.

Table 3. Evidence Statements Extracted from Narrative*

Pirouzi et al. ¹¹	<ul style="list-style-type: none"> • Dissatisfaction with prostheses is mainly caused by strains and injuries associated with the socket fit, often due to limb changes that are difficult to control, predict, minimize, or compare.
Gholizadeh et al. ²⁷	<ul style="list-style-type: none"> • Pressure distribution (within the socket) directly and indirectly affects the effective indices of user satisfaction, issues relevant to residual limb interaction, and mechanical and biomechanical variables of the socket. • Suction or VAS systems are capable of diminishing the displacement of the residual limb inside the socket and decreasing gait asymmetry and pain at the distal end of the residual limb compared with other systems • The tasks of donning and doffing can be more difficult with suction or VAS systems. • High perspiration is one of the disadvantages of the TSB socket with a silicone liner, polyurethane, or TEC liner compared with the PTB socket with Pelite insert. • No clinical support is available to suggest a standard (suspension) system for all transtibial amputees. • Thicker liners are more comfortable and can distribute the pressure more evenly over residual limb. However, amputees' instability is increased during walking.
Safari and Meier ²⁵	<ul style="list-style-type: none"> • Results related to outcomes variables such as physical activity and participant preference and satisfaction are similar to, and in some cases, better for TSB sockets than for PTB sockets. • Compared with PTB sockets, TSB sockets lead to greater activity levels and satisfaction in active persons with amputation, those with amputations of traumatic etiology, and younger persons.
Safari and Meier ²⁶	<ul style="list-style-type: none"> • Gait symmetry is influenced by prosthetic socket design, in particular by socket suspension. • Generally, TSB socket with elastomeric liners show reduced pistoning and thus improved suspension. • The VAS socket provides the best suspension of all reported socket designs, followed by a TSB suction socket (Seal-In), a TSB socket with sleeve suspension, and a TSB socket with pin lock liner. The least suspension is provided by a PTB socket with sleeve suspension or a PTB socket with supracondylar design. • Robust evidence shows that the VAS socket resulted in increased step length and stance duration symmetry compared with TSB sockets. • Trends indicate that TSB sockets result in fewer pressure problems than PTB sockets. • VAS sockets seem to improve gait symmetry, control residual limb volume fluctuations, and affect residual limb health positively compared with other socket designs.

*As different authors refer to VAS sockets through a range of acronyms, the term VAS has been substituted within the evidence statements for consistency.

The socket has consistently been described by lower-limb prosthesis users as the most important consideration in their satisfaction with a lower-limb prosthesis.^{1,4,5} When present, dissatisfaction with a transtibial prosthesis is frequently caused by strains, injuries, and discomfort associated with fit of the residual limb within the socket.¹¹ Research has shown that interface liners can help distribute loading and reduce pain.²⁹ The challenge of maintaining a congruent fit is exacerbated by changes to the residual limb that can be difficult to predict or control.¹¹ In addition to the immediate impacts of socket fit on the user's comfort and the health of the residual limb, the fit of the socket over the limb affects biomechanical variables of function and performance.¹¹

Recommendation 2: *Total surface bearing sockets are indicated to decrease fitting times and enable higher activity levels.*

Compared with PTB sockets, TSB sockets may lead to greater activity levels, fewer pressure problems, and improved satisfaction among active prosthesis users,²⁵ a finding epitomized in the work of Yigiter et al.³¹ who cite increased gait symmetry, velocity, cadence, and balance with TSB sockets. This statement is made with a recognition that, within the published evidence, TSB sockets have generally been fabricated over elastic liner interfaces, whereas PTB sockets have generally been fabricated over foam interfaces, and the respective contributions of socket design, interface, and suspension cannot be reasonably inferred from current literature. The generalized statement of the benefits of TSB sockets is countered by the observations of a single small trial of 13 subjects who reported increased wearing time and activity with PTB sockets compared with TSB sockets, an observation similarly confounded by the different interfaces and suspension methods used with each socket design type.³²

From an economic standpoint, although PTB sockets have a lower initial cost, this is offset by the need for patients to spend up to three times longer in the fitting process to achieve a satisfactory socket fit,²² observations supported by two unrelated clinical trials.^{33,34} Highsmith et al.²² summarized that these additional clinic visits, which require increased time commitments and travel costs as well as the risk of potential complications, ultimately increase latent costs of PTB sockets. Conversely, TSB sockets have a higher initial procurement cost, but result in fewer associated visits.²²

Recommendation 3: *Compared with traditional foam-based interfaces, viscoelastic interface liners are indicated to decrease dependence on walking aids, improve suspension, improve load distribution, decrease pain, and increase comfort.*

Systematic reviews of existing clinical studies suggest viscoelastic interface liners offer clinical improvements relative to traditional PTB socket interfaces (i.e., foam and fabric). These improvements include decreased reliance on walking aids, improved load distributions against the residual limb, decreased pain, and increased comfort.^{3,30} These benefits were largely identified in early clinical trials with modest to large study populations of 27 to 83 subjects and included improved walking

function,^{35–37} decreased reliance on upper-limb walking aids,^{33,36} decreased pain,^{37–38} and improved comfort.^{36–38}

These benefits are offset by reports of difficulties in donning and doffing experienced by some users²⁷ and a temporary increase in perspiration relative to that experienced within foam and fabric interfaces.²⁷ The relative difficulty of donning viscoelastic interface liners has been inconsistent with early trials citing mixed user experiences.^{35,37–38} Temporary increases in perspiration with elastic liners has been reported with greater regularity.^{25,35,37–38} Reviewers have been critical of the quality of research related to transtibial liners and suspension, summarizing that there is insufficient research on user experience to inform specific interface recommendations.^{24,29–30}

Recommendation 4: *Among modern suspension options, vacuum-assisted suspension (VAS) sockets permit the least amount of pistoning within the socket, followed by suction suspension, and then pin lock suspension. The traditional suspension options of supracondylar, cuff, and sleeve suspension provide comparatively compromised suspension.*

Kahle et al. described agreement between two high-quality level 2 studies^{39,40} and one low-quality study,⁴¹ offering grade B evidence that VAS reduces movement of the residual limb within the socket.²⁸ When study findings are aggregated, VAS sockets allow the least amount of movement between the residual limb and the socket. Progressively greater socket displacement is experienced with suction sockets without external vacuum assistance and locking liner suspension.^{26–27} These modern systems provide improved suspension relative to the historical standards of sleeve suspension and supracondylar suspension.^{3,26} However, because of the additional considerations associated with suspension variants, there is no single suspension system currently viewed as the standard for all individuals with transtibial amputation.²⁷

Recommendation 5: *VAS sockets are indicated to decrease daily limb volume changes while facilitating more favorable pressure distribution during gait.*

VAS sockets have been studied extensively in recent years, culminating in a well-defined set of potential benefits associated with this socket-suspension system. These benefits include decreases in daily volume changes and in the peak positive pressures experienced during stance,^{23,28} as well as the maintenance of a better socket fit, improved mobility, comfort, stability, proprioception, overall satisfaction, prosthetic function, and quality of life.²³

In their systematic review on VAS sockets, Kahle et al. asserted that VAS sockets increase volume, whereas non-VAS sockets reduce residual limb volume, citing two studies representing level 2 evidence.²⁸ This finding was also asserted in other systematic reviews.^{3,26–27} This tendency toward limb volume increases is thought to occur as a result of increased negative pressures during swing phase in VAS prostheses.^{42,43}

Kahle et al. also evidenced two high-quality studies^{41,42} representing level 2 evidence that VAS sockets favorably affect pressure distribution on the residual limb,²⁸ an observation

echoed by a similar level 2 evidence statement by Highsmith et al.³ and found in the assertions of Safari et al. that VAS sockets seem to affect residual limb health positively compared with other socket designs and that VAS sockets “seem to improve gait symmetry more than other socket designs.”²⁶

The effect of VAS sockets on the associated constructs of mobility, balance, and function has been viewed differently by different reviewers. Gholizedeh et al.²³ asserted that VAS socket systems improve mobility. Kahle et al. also cite two level 2 studies demonstrating improvements in the specific functional areas of spatiotemporal gait³⁹ and balance confidence,⁴⁴ but also note a third level 2 study reporting a decrease in activity with the use of VAS sockets.⁴⁰

The relationship between favorable pressure distribution, skin irritation, and wound healing has been viewed differently by different authors. Although Gholizedeh suggested that “vacuum systems may reduce skin irritation, reduce pain, and assist in wound healing,”²³ Kahle et al. asserted that, “...no evidence exists to support the notion that a prosthesis can assist in healing wounds with or without VAS.”²⁸ Synthesis between these two views is found in a recognition that reduced pistoning reasonably reduces shearing forces which, in turn, reduces the incidence of skin perturbation and pain. Arresting the movement of the limb within the socket may reduce irritation over both healthy and ulcerated tissues, permitting granulation and healing of existing wounds.²⁸

Recommendation 6: VAS sockets require both awareness and compliance on the part of the end user and are not universally indicated.

Despite the established benefits associated with VAS, it is not universally indicated. Gholizedeh et al. summarized succinctly that “...some patients prefer pin lock systems to vacuum...,” whereas others reduce their activity in VAS.²³ It has been suggested that the attention and skills needed for donning a VAS prosthesis may be difficult for some individual with amputation.²³ In support of this contention, authors have reported upon the possibility of VAS systems creating skin blisters when worn improperly.^{40,45} Consistent with these reports, subject matter expert consensus affirms that vacuum systems require both careful clinical evaluation, can cause blistering if not worn properly, and require that the patient has sufficient cognitive ability to know what to watch for and how to fix problems.²³ Further, it has been observed VAS requires more maintenance than other suspension systems,²³ a reality that should also be weighed when considering its use.

INCONCLUSIVE AREAS OF EVIDENCE

Although the recommendations above summarize the best available evidence, limitations to this evidence base result in several areas of inconclusive findings. Foremost among these is that the related elements of socket design, interface materials, and suspension are largely integral to one another, precluding a precise understanding of their individual contributions to comfort and function.

Note: Clinical practice guidelines are “guides” only and may not apply to all patients and all clinical situations. Thus, they are not intended to replace clinical judgment but rather to supplement clinical practice decision making.

REFERENCES

- Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. *Am J Phys Med Rehabil* 2001;80:563–571.
- Ziegler-Graham K, MacKenzie EJ, Ephraim PL, et al. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil* 2008;89(3):422–429.
- Highsmith MJ, Kahle JT, Miro RM, et al. Prosthetic interventions for people with transtibial amputation: systematic review and meta-analysis of high-quality prospective literature and systematic reviews. *J Rehabil Res Devel* 2016;52:157–184.
- Legro MW, Reiber G, del Aguila M, et al. Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehabil Res Dev* 1999;36(3):155–163.
- Klute GK, Kantor C, Darrouzet C, et al. Lower-limb amputee needs assessment using multistakeholder focus-group approach. *J Rehabil Res Dev* 2009;46(3):293–304.
- Radcliffe CW, Foort J, Inman VT, Eberhart H. The patellar-tendon-bearing below-knee prosthesis. *Biomechanics Laboratory University of California*.
- Staats TB, Lundt J. The UCLA total surface bearing socket below-knee prosthesis. *Clin Prosthet Orthot* 1987;11(3):118–130.
- Sewell P, Noroozi S, Vinney J, Andrews S. Developments in the trans-tibial prosthetic socket fitting process: a review of past and present research. *Prosthet Orthot Int* 2000;24:97–107.
- Fillauer CE, Pritham CH, Fillauer KD. Evolution and development of the Silicone Suction Socket (3S) for below-knee prostheses. *J Prosthet Orthot* 1989;1:92–103.
- Kristensson O. The ICEROSS concept: a discussion of a philosophy. *Prosthet Orthot Int* 1993;17:49–55.
- Pirouzi G, Abu Osman NA, Eshraghi A, et al. Review of the socket design and interface pressure measurement for transtibial prosthesis. *ScientificWorldJournal* 2014;2014:849073.
- Childers WL, Wurdeman SR. Transtibial amputation: prosthetic management. In: Krajbich JI, Pinzur MS, Potter BK, Stevens PM, eds. *Atlas of Amputations and Limb Deficiencies: Surgical, Prosthetic, and Rehabilitation Principles*. 4th Ed. Rosemont, IL: American Academy of Orthopedic Surgeons; 2015:493–508.
- US Department of Health and Human Services; Agency for Healthcare Quality and Research; National Guideline Clearinghouse. Accessed at: <https://www.guideline.gov/browse/clinical-specialty> on 9/8/2017.
- Lin RS, Stevens PM, Winger M, Castiglione CL. Orthotic management of deformational plagiocephaly: consensus clinical standards of care. *Cleft Pal Craniofac J* 2016;53(4):394–403.
- Stevens P, Rheinstein J, Campbell J. Acute postoperative care of the residual limb following transtibial amputation: a clinical practice guideline. *Arch Phys Med Rehabil* 2016;10:e21.

16. Stevens P, Rheinstein J, Wurdeman S. Prosthetic foot selection for individuals with lower limb amputation: a clinical practice guideline. *Arch Phys Med Rehabil* 2016;10:e21–e22.
17. Sedki I, Fisher K. Developing prescribing guidelines for microprocessor-controlled prosthetic knees in the South East England. *Prosthet Orthot Int* 2015;39(3):250–254.
18. Geertzen J, van der Linde H, Rosenbrand K, et al. Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: amputation surgery and postoperative management. Part 1. *Prosthet Orthot Int* 2015;39(5):351–360.
19. Geertzen J, van der Linde H, Rosenbrand K, et al. Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: rehabilitation process and prosthetics. Part 2. *Prosthet Orthot Int* 2015;39(5):361–371.
20. Qaseem A, Snow V, Owens DK, et al. The development of clinical practice guidelines and guidance statements of the American College of Physicians: Summary of Methods. *Ann Intern Med* 2010;153:194–199.
21. Qaseem A, Humphrey LL, Forcica MA, et al. Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2015;162:370–379.
22. Highsmith MJ, Kahle JT, Lewandowski A, et al. Economic evaluations of interventions for transtibial amputees: a scoping review of comparative studies. *Technol Innov* 2016;18:85–98.
23. Gholizadeh H, Lemaire ED, Eshraghi A. The evidence-base for elevated vacuum in lower limb prosthetics: literature review and professional feedback. *Clin Biomech* 2016;37:108–116.
24. Richardson A, Dillon MP. User experience of transtibial prosthetic liners: a systematic review. *Prosthet Orthot Int* 2017;41:6–18.
25. Safari MR, Meier MR. Systematic review of effects of current transtibial prosthetic socket designs—Part 1: qualitative outcomes. *J Rehabil Res Dev* 2015;52:491–508.
26. Safari MR, Meier MR. Systematic review of effects of current transtibial prosthetic socket designs—Part 2: quantitative outcomes. *J Rehabil Res Dev* 2015;52:509–526.
27. Gholizadeh H, Abu Osman NA, Eshraghi A, et al. Transtibial prosthesis suspension systems: systematic review of literature. *Clin Biomech (Bristol, Avon)* 2014;29:87–97.
28. Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. *Tech Innov* 2014;15(4):333–341.
29. Klute G, Glaister BC, Berge JS. Prosthetic liners for lower limb amputees: a review of the literature. *Prosthet Orthot Int* 2010;34:146–153.
30. Baars EC, Geertzen JH. Literature review of the possible advantages of silicon liner socket use in trans-tibial prostheses. *Prosthet Orthot Int* 2005;29(1):27–37.
31. Yigiter K, Sener G, Bayar K. Comparison of the effects of patellar tendon bearing and total surface bearing sockets on prosthetic fitting and rehabilitation. *Prosthet Orthot Int* 2002;26(3):206–212.
32. Coleman KL, Boone DA, Laing LS, et al. Quantification of prosthetic outcomes: elastomeric gel liner with locking pin suspension versus polyethylene foam liner with neoprene sleeve suspension. *J Rehabil Res Dev* 2004;41(4):591–502.
33. Datta D, Harris I, Heller B, et al. Gait, cost and time implications for changing from PTB to ICEX® sockets. *Prosthet Orthot Int* 2004;28(2):114–120.
34. Selles RW, Janssens PJ, Jongenengel CD, Busmann JB. A randomized controlled trial comparing functional outcome and cost efficiency of a total surface-bearing socket versus a conventional patellar tendon-bearing socket in transtibial amputees. *Arch Phys Med Rehabil* 2005;86(1):154–161.
35. Cluitmans J, Geboers M, Deckers J, Rings F. Experiences with respect to the ICEROSS system for transt-tibial prosthesis. *Prosthet Orthot Int* 1994;18:78–83.
36. Dasgupta AK, McCluskie PJ, Patel VS, Robins L. The performance of the ICEROSS prostheses amongst transtibial amputees with a special reference to the workplace—a preliminary study. Icelandic Roll on Silicone Socket. *Occup Med (Lond)* 1997;47:228–236.
37. Hachisuka K, Dozono K, Ogata H, et al. Total surface bearing below-knee prosthesis: advantages, disadvantages, and clinical implications. *Arch Phys Med Rehabil* 1998;79:783–789.
38. Datta D, Vaidya SK, Howitt J, Gopalan L. Outcome of fitting an ICEROSS prosthesis: views of trans-tibial amputees. *Prosthet Orthot Int* 1996;20:111–115.
39. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthet Orthot Int* 2001;25(3):202–209.
40. Klute GK, Berge JS, Biggs W, et al. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. *Arch Phys Med Rehabil* 2011;92:1570–1575.
41. Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum assisted suspension comparison of hip kinematics, socket position, contact pressure and preference: ischial containment versus brimless. *J Rehabil Res Dev* 2013;50(9):1241–1252.
42. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. *J Rehabil Res Dev* 2002;39:693–700.
43. Sanders JE, Fatone S. Residual limb volume change: systematic review of measurement and management. *J Rehabil Res Dev* 2011;48:949–986.
44. Ferraro C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. *J Prosthet Orthot* 2011;23(2):78–81.
45. Traballesi M, Delussu AS, Fusco A, et al. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. *Eur J Phys Rehabil* 2012;48:613–623.