Safari MR, Meier MR. Systematic review of effects of current transtibial prosthetic socket designs—Part 1: Qualitative outcomes. J Rehabil Res Dev. 2015;52(5):491–508.

Appendix 3. Summary of included studies examining effects of transtibial socket designs.

Study	Participants						Intervention		Outcome	Instrument	Main Conclusions
	N (M/F)	Age, yr (mean ± SD [range])	Inclusion Criteria	Residual Limb Characteristics	Cause of Amputation (*n*)	Other	Socket Type	Socket Use Before Test			
Brunelli et al., 2013 [33]	10 (10/0)	44.9 (24–54)	Unilateral transtibial amputation; Age: 20–65 yr; BM: <116 kg; Carbon fiber foot users; Activity level: K3 or K4; Ability to ascend and descend ramp without aids; Absence of significant clinical disorders.	L: >11 cm	Trauma (8), infection (1), PVD (1).	BM: 81 ± 15.8 kg; height: 1.7 ± 0.7 m.	TSB + Seal-In X5 liner and silicone liner with sleeve suspension.	Minimum of 18 mo for sleeve suspension and 7 wk for Seal-In X5 liner	Perceived QoL; Mobility; Prosthetic-related factors; Task performance.	PEQ, LCI-5, HSQ, TUG.	Improvement in QoL reported by users when using Seal-In X5 liner; More safe and intensive prosthesis use reported in HSQ results as consequence of using Seal-In X5 liner; No difference found in LCI-5, energy cost, and TUG results.
Eshraghi et al., 2012 [35]	10 (10/0)	42 (30–72)	Unilateral transtibial amputation; Activity level: K2 and K3; Residual limb free of wound and pain; No upper limb disability; Experience with silicone liner; No volume fluctuation of residual limb; Ability to ambulate freely; Residual limb length: ≥13 cm.	L: 14.5 ± 1.3 cm	Diabetes (5), trauma (5).	BM: 79.5 ± 12.2 kg; height: 1.7 ± 0.05 m.	TSB + Dermo pin lock, Seal-In X5, and distal magnetic liners.	1 mo for each suspension type	Satisfaction; perceived problems with prosthesis.	PEQ	Users reported least problems with Seal-In X5 liner and were most satisfied with cosmesis, suspension, and fitting of Seal-In X5 liner; Overall satisfaction, satisfaction with noise, and donning and doffing were rated highest for new magnetic liner compared with other two liners.
Ali et al., 2012 [38]	243 (243/0)	44.02 ± 6.26	Prosthesis use for ≥1 yr.	None	Trauma (243).	BM: 85.09 ± 15.54 kg; height: 1.7 ± 0.14 m; Activity level: K2 (43), K3 (154), K4 (46).	TSB + Dermo pin lock and Seal-In liners; PTB.	Average of 21 mo	Prosthetic use; Satisfaction; Perceived problems with prosthesis.	PEQ	TSB and Seal-In liner resulted in higher overall satisfaction and lower problem scores than other two sockets, followed by TSB with Dermo liner; Users scored satisfaction with

											donning and doffing of PTB socket highest of all; Sweat problem was not different for all 3 socket types.
Ali et al., 2012 [30]	9 (7/2)	49.33 ± 15.05	None.	NR	Trauma (3), PVD (2), diabetes (4).	BM: 72.44 ± 16.30 kg; height: 1.7 ± 0.08 m; Activity level: K2–K3 (8), K3–K4 (1).	TSB + Dermo liner and Seal-In X5 liner.	>4 wk	Satisfaction; Perceived problems with prosthesis.	PEQ	Users were most satisfied with Dermo liner and experienced least problems with it; Suspension scored higher for Seal-In X5 liner.
Gholizadeh et al., 2012 [40]	1 (0/1)	51	None.	Bony residual limb with adventitious bursa; No soft tissue at distal end of tibia	PVD.	Pain at distal end of residual limb, particularly during swing.	TSB + Dermo liner and Seal-In X5 liner.	2 wk	Satisfaction.	PEQ	Seal-In X5 liner decreased pain at distal end of residual limb; User was more comfortable with Seal-In X5 liner.
Gholizadeh et al., 2012 [32]	10 (NR)	45.8 (22–71)	Unilateral amputation; No pain or ulcer on residual limb; No volume fluctuation of residual limb; No dependence on assistive devices for ambulation; Good upper limb strength.	L: 14.45 ± 1.30 cm	Diabetes (5), trauma (5).	BM: 73.8 ± 14.19 kg; height: 1.7 ± 0.06 m; Activity level: K2 (4), K3 (6).	TSB + Dermo liner and Seal-In X5 liner.	4 wk for each liner	Satisfaction; Perceived problems.	PEQ	Users were overall more satisfied with Dermo liner than Seal-In X5 liner; Users mentioned more pain and pistoning problems and less walking satisfaction with Dermo liner.
Boutwell et al., 2012 [31]	12 (4/7)	55.9 (43–67)	Age: 18–70 yr; Amputation without serious complications; ≥6 mo experience with definitive prosthesis; Ability to walk ≥10 m over level group without walking aids; No medication that could interfere with balance and gait.	Bony (5), padded (5), average (1)	Trauma (6), PVD (1), other (4).	BM: 88.2 ± 18.2 kg; height: 1.7 ± 0.09 m.	TSB + Alpha gel liner with 3 and 9 mm uniform thicknesses.	At least 2 wk for each socket type	Comfort and function; User preference.	Questionnaire	Thickness of gel liner had effect on user's perception of comfort; Users with residual bony limb preferred thicker liner while those with padded residual limb expressed mixed preference toward both liners.
Ferraro, 2011 [37]	9 (5/4)	NR (23–71+)	Age: ≥18 yr; Normal cognitive abilities; No cardiovascular or health conditions that interfere with ambulation; Activity level: K2; Ability to walk 100 ft continuously with or without assistive devices; >6 mo	NR	PVD (56%).	All used TSB socket with pin lock system.	VAS + electronic vacuum pump; TSB + pin lock liner.	NR	Balance confidence in performing ADLs.	ABC	VAS socket improved balance and may result in lower possibility of future falls.

			postamputation; Use of definitive prosthesis for ≥30 d.								
Sutton et al., 2011 [39]	1 (1/0)	40	None.	Extensive patellar tendon and hamstring group damage; Pain and discomfort at fibular head; Skin dermatitis due to excessive force.	Trauma.	BM: 108 kg; height: 1.65 m; Activity level: K3; 16 yr wearing PTB with ischial weight-bearing socket.	VAS.	Follow-up at 1 wk, 1 mo, and 1 yr	Functional capability; ADL; Mobility; Health of residual and sound limbs; Pain.	LCI-5, IADL, AMPPro, interview	No differences seen in LCI-5 and IADL scores; User showed improvement in balance tasks; Better linkage, no swelling or pain in contralateral limb and residual limb, better gait symmetry as observed by clinicians, hair regrowth, and confidence in stability at work were reported after switching to VAS socket.
Klute et al., 2011 [24]	5 (NR)	56 ± 9	Age: 18–70 yr; Ability to walk on treadmill for 30 min; Prosthesis use: >1 yr with diabetic or dysvascular amputees and >4 mo for all others; No disorder, pain, or injury that interfered with gait.	—	Trauma (4), diabetes (1).	BM: 84 ± 11 kg; height: 1.78 ± 0.1 m; YSA: 13 ± 15.	TSB + pin lock Alpha liner; VAS.	3 wk	Activity level (step count); Residual limb health; Ambulation and frustration.	Step count instrument, PEQ	Activity was twice as much with TSB socket; Users expressed that residual limb was healthier, ambulation was easier, and they had less frustration while using pin lock mechanism compared with VAS socket.
Manucharian, 2011 [42]	EG: 15 (10/5), CG: 21 (12/9)	>40*	Adult; Successful wearer of definitive prosthesis; Unilateral amputation; No wounds on residual limb.	NR	EG: Trauma (2), PVD (13); CG: Trauma (4), PVD (17).	Previous prosthesis—EG: PTB (9), TSB (6); CG: PTB (17), TSB (4).	PTB + silicone sleeve suspension; HS (hydrocast) + Pelite liner and silicone sleeve suspension.	1 mo	Socket comfort.	SCS	SCS at initial socket fitting and after 1 mo was higher for PTB socket; SCS for HS socket decreased after 1 mo; SCS was higher for users who did not change sockets; Users with traumatic amputation required more adjustment and had lower SCS than users with PVD amputation.
Selles et al., 2005 [23]	EG: 12 (NR), CG: 14 (NR)	EG: 67.6 ± 13.5, CG: 57.9 ±	Unilateral transtibial amputation; Age: >18 yr; Prosthesis use: >1 yr; Active walkers with or	NR	EG: Trauma (5),diabetes (7); CG: Trauma (6), diabetes	Phantom limb pain: EG (6), CG (10).	EG: HS (ICEX + pin lock); CG: TSB + Comfort/Two Color liner and pin lock.	3 mo	Satisfaction; Mobility; Pain and phantom	PEQ, Activity monitor	ICEX and TSB socket function similarly to conventional socket

		15.6	without walking aids; No recent residual limb problems; Capable of residual limb distal weight-bearing; No known problems using silicone liner.		(3), PVD (4), other (1).				pain; Prosthetic function; ADL.		in terms of satisfaction and ADLs.
Van de Weg and Van der Windt, 2005 [36]	220 (132/88)	62.1 ± 17.5	None.	NR	PVD (83), trauma (93), other(33), NR (11).	Pelite (62), silicone liner (94), urethane liner (62).	PTB; TSB + silicone/urethane liner.	Not clear	Satisfaction and perceived problems with prosthesis; Overall satisfaction; Use, maintenance, and durability of prosthesis.	PEQ, Numerical scale for satisfaction, questionnaire.	No significant difference between liners in terms of use, satisfaction, and perceived problems; Users with PTB sockets compared with liner users showed significantly higher satisfaction on uneven terrain, walking, and sitting; PTB sockets were associated with more sweating.
Astrom and Stenstrom, 2004 [43]	29 (24/5)	39.77 (7–78)	Good fit of conventional suspension with or without silicone liner; Ability to walk indoors; Prosthesis use: >1 yr; Capable of answering questionnaire.	Long (6), ordinary (20), short (3)	Trauma (15), tumor (1), infection (2), diabetes (3), PVD (8).	No problems (5); Residual limb problems (20); Pain as limiting factor for ambulation (18); Foot or knee problems (3); Arm amputation (1).	TSB + polyurethane liner; TSB (ICEROSS/EVA/suction socket).	>2 mo	Physical activity; Socket comfort; Walking distance; Perception of advantages and disadvantages to socket; Residual limb pain and problems.	Self-administered questionnaire, Interview	62% of users experienced better/more comfort with TSB socket and polyurethane liner; 67% had better or much better physical capacity with polyurethane liner; 9% reported better physical activity with previous socket; At 3 and 5 yr follow-up, majority of users preferred comfort of urethane liner, but use of ointment for donning was disadvantage.
Coleman et al., 2004 [34]	13 (10/3)	49.4 (31–66)	>1 yr postamputation; Traumatic amputation; Stable in current prosthesis; No major health problems; Minimum ambulatory function: level 2 (DMERC).	None	Trauma.	YSA: 24.4 (4.7–39.3); DMERC score: 3.23 ± 0.6.	PTB; TSB + Alpha liner with pin lock.	3 mo	Ambulatory activity; PEQ subscales; Pain and socket comfort; User preference and view.	Step-Watch Activity Monitor, PEQ, SCS, BPI, Interview.	Users were able to walk with same intensity in both liners, but spent more time in PTB sockets; No significant differences in PEQ scores, SCS, and pain between 2 socket

											types; 8 users preferred PTB socket; 4 preferred TSB socket but mentioned that it was more cumbersome and inconsistent compared with PTB socket.
Yiğiter et al, 2002 [29]	20 (13/7)	27.8 (15–37)	Attending first prosthetic fitting; Residual limb muscle strength: "≥4"; No joint limitation, muscle shortening, or edema; No pain within residual limb; No problems in residual limb shape; Able to stand up in parallel bars and able to walk with Canadian crutches.	L: 12.5–17.5 cm	Trauma.	BM: 62.5 ± 8.9 kg; height: 1.69 ± 0.09 m.	PTB; TSB (type of liners not indicated).	Not clear	Ambulatory activities.	Task-oriented test	Donning and doffing TSB socket was faster; Ambulatory activities improved while wearing TSB socket; 75% of users chose TSB at end of study as their permanent socket.
Hachisuka et al., 2001 [21]	83 (65/18)	53.4 ± 14.4	Using or past use of TSB socket with silicone liner within previous 5 yr.	Short residual limb (25), average (19), residual limb stump (39)	Trauma (49), tumor (10), PVD (11), diabetes (12), congenital (1).	YSA: 14.8 ± 15.2.	TSB + silicone liner.	2.9 ± 15 yr	Hygiene problems.	Self-report questionnaire	Itching, odor, perspiration, and eruption were hygiene problems experienced by >40% while using silicone liner; Perspiration was less with women, eruption was more with older users, and itching and odor were more with younger users; Washing liner was associated with less eruption.
Hachisuka et al., 1998 [41]	32 (27/5)	44.5 ± 16.0	Ability to walk with TSB prosthesis; Experience with both PTB (or KBM) and TSB sockets; Voluntary enrollment in clinical investigation.	L: 45.5% ± 14.0%	Trauma (21), diabetes (4), PVD (3), other (4).	—	TSB + laminated silicone liner and pin lock; PTB.	9 patients who received both PTB and TSB used it alternately 3–4 d for 2 mo	Satisfaction with TSB and 13 items related to prosthesis use.	Questionnaire	Comfort, less pistoning, and less excess pressure were reasons for users to generally prefer TSB socket; Ease of donning PTB socket was preferred by users; Perspiration, odor, and greasy staining of socket were disadvantages of TSB sockets.
Datta et al., 2004 [22]	EG: 11 (11/0),	EG: 47.8 ± 16.9,	Attending for routine medical or prosthetic	—	EG: PVD (3), trauma (7),	EG: BM: 85.4 ± 11.5	HS Icex; PTB.	>6 wk	Socket comfort.	SCS	Higher SCS reported for HS Icex (mean:

CG: 10 (8/2)	CG: 52.2 ± 16.2	review or repairs; Endolite PTB socket with Pelite liner, cuff suspension, and multiflex ankle/foot mechanism; Walking without any walking aids (e.g., sticks, crutches); Health contralateral limb; No gait problems as result of socket discomfort.	other (1); CG: PVD (4), trauma (3), other (3).	kg; height: 1.73 ± 0.04 m; YSA: 11.6 ± 11.8. CG: BM: 82.4 ± 15.9 kg; height: 1.71 ± 0.08 m; YSA: 8.6 ± 15.9.	8.2, range: 6–10) than for previous PTB socket (mean: 7.2, range: 5–9).

*Majority of participants.

ABC = Activity Balance Confidence scale, ADL = activity of daily living, AMPPro = Amputee Mobility Predictor with Prosthesis, BM = body mass, BPI = Brief Pain Inventory, CG = control group, DMERC = Durable Medical Equipment Regional Carrier, EG = experiment group, EVA = ethylene vinyl acetate, F = female, HS = hydrostatic, HSQ = Houghton Scale Questionnaire, IADL = Instrumental Activity of Daily Living scale, ICEROSS = Icelandic Roll-On Suction Socket, KBM = Kondylen Bettung Münster, L = length, LCI-5 = Locomotor Capability Index, M = male, NR = not reported, PEQ = Prosthetic Evaluation Questionnaire, PTB = patellar tendon bearing, PVD = peripheral vascular disease, QoL = quality of life, SCS = Socket Comfort Score, SD = standard deviation, TSB = total surface bearing, TUG = Timed “Up and Go” test, VAS = vacuum-assisted suction, YSA = years since amputation.