

Safari MR, Meier MR. Systematic review of effects of current transtibial prosthetic socket designs—Part 2: Quantitative outcomes. *J Rehabil Res Dev.* 2015;52(5):509–26.

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

| Study | Participants | | | | | | Intervention | | Outcome | Instrument | Main Conclusions |
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| | N (M/F) | Age, yr (mean ± SD [range]) | Inclusion Criteria | Residual Limb Characteristics | Cause of Amputation (n) | Other | Socket Type | Socket Use Before Test | | | |
| Hoskins et al., 2013 [26] | 4 (3/1) | 66.75 (58–73) | Wound present on residual limb; VAS user when wound was still open. | Not clear | Ulcer (2), Trauma (1), Infection (1). | BM: 91.88 kg (79–118); Height: 1.77 m (1.67–1.85); YSA: 4–23. | VAS | Not clear. | Wound size (surface area). | Photography camera. | Average of 161.50 d for wound size of 1.94 cm ² to close; Users were able to ambulate despite presence of wound on residual limb. |
| Eshraghi et al., 2013 [27] | 12 (9/3) | 46.86 ± 12.3 | No ulcer on residual limb; No residual limb volume change; Ability to ambulate without assistance; Residual limb length: ≥11 cm; Prosthesis user for last 6 mo. | L: 14.5 ± 1.2 cm | Diabetes (7), Trauma (5). | BM: 73.60 ± 11.5 kg; Height: 1.7 ± 0.05 m. | TSB + Dermo pin lock, Seal-In X5, and distal magnetic liners. | Not clear. | Interface pressure during swing. | TekScan (F-Socket transducer). | Pin lock liner showed higher interface pressure than distal magnetic liner at proximal region of both anterior and posterior aspects and distal region of anterior aspect of residual limb; Distal magnetic liner showed smallest mean peak pressure over these regions; Mean peak pressure for Seal-In X5 liner was highest of all 3 liners at all 4 sites measured. |
| Brunelli et al., 2013 [28] | 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 ramps without aid; 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. | 18 mo minimum for sleeve suspension; 7 wk minimum for Seal-In liner. | Pistoning; Energy cost of walking. | Photography camera; Metabolimeter. | Lower amount of pistoning was reported for Seal-In X5 liner; No significant difference between 2 systems in terms of energy cost and walking. |
| Eshraghi et | 10 | 42 (30– | Unilateral transtibial | L: 14.5 ± 1.3 cm | Diabetes (5), | BM: 79.5 ± | TSB + Dermo pin lock, | 1 mo for | Pistoning | 7-camera Vicon | Seal-In X5 liner |

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| al., 2012 [29] | (10/0) | 72) | amputation; Activity level: K2 and K3; Residual limb free of wounds 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. | | Trauma (5). | 12.2 kg; Height: 1.7 ± 0.05 m. | Seal-In X5, and distal magnetic liners. | each suspension type. | (static condition). | 612 motion analysis system. | showed least pistoning among 3 systems; Pin lock and magnetic systems had comparable pistoning; Users reported least problem with Seal-In liner and were most satisfied with cosmesis, suspension, and fit of Seal-In X5 liner. |
| 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 and Seal-In X5 liners. | >4 wk | Interface pressure. | TekScan (F-socket transducer). | Mean peak pressure at anterior, posterior, and medial aspect of residual limb was higher for Seal-In X5 liner than Dermo liner; Suspension was scored higher for Seal-In X5 liner. |
| Gholizadeh et al., 2012 [31] | 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 phase. | TSB + Dermo and Seal-In X5 liners. | 2 wk | Pistoning (static condition). | Photography camera. | Seal-In X5 liner decreased amount of pistoning, skin traction, and pain at distal end of residual limb. |
| 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 and Seal-In X5 liners. | 4 wk for each liner | Pistoning (gait). | 7-camera Vicon 612 motion analysis system (MXF20 camera). | Maximum displacement was 5.4 ± 0.6 and 2.5 ± 0.4 mm for Dermo and Seal-In X5 liners, respectively. |
| Boutwell et al., 2012 [33] | 12 (4/7) | $55.9 (43-67)$ | Age: 18–70 yr; Amputation without serious complications; Experience with definitive prosthesis: ≥ 60 mo; Ability to walk ≥ 10 m over level ground without use of walking aids; No medication that could interfere with balance or 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 liner with 3 and 9 mm uniform thickness. | ≥ 2 wk for each socket type. | Interface pressure; Gait characteristics; Comfort and function. | Novel pliance system; 8-camera Eagle Digital RealTime system; Six force platform. | Thicker gel liner reduced pressure over bony prominences of residual limb in users with either padded or bony residual limb with little effect on gait characteristics; Thicker gel liner seems to increase vertical GRF during |

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| Sanders and Fatone, 2011 [5] | 7 (6/1) | 47 (25–67) | None. | L: 14–23 cm | Trauma (6); Diabetes (1). | BM: 58–102 kg; Height: 1.6–1.88 m; Activity level: K2 (1), K3 (2), K4 (4). | VAS | 3 wk–1 yr | Residual limb in-socket volume. | Bioimpedence. | weight acceptance. VAS socket maintained or increased volume in 6 subjects; Residual limb volume was less affected by VAS socket in users with diabetes or PVD; Results further indicated that subjects showed increased in limb volume with more elevated vacuum. |
| Klute et al., 2011 [21] | 5 (NR) | 56 ± 9 | Age: 18–70 yr; Ability to walk on treadmill for 30 min; Prosthesis use: >1 yr (diabetic or dysvascular), >4 mo (all others); No disorder, pain, or injury interfering 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 | Residual limb volume; Limb pistoning. | Optical scanning; 12-camera motion analysis system. | No significant difference in volume reported; VAS socket showed less pistoning. |
| Gholizadeh et al., 2012 [34] | 6 (NR) | 43 (22–49) | Unilateral amputation; Residual limb length: ≥13 cm; Stable limb volume; Intact upper limb; No pain or wound on residual limb; Mobility without assistive devices. | L: 14.41 ± 1.42 cm | Diabetes (3), Trauma (3). | BM: 77.16 ± 14.95 kg; Activity level: K2–K3. | TSB + Dermo and Seal-In X5 liners. | 4 wk | Pistoning (static condition). | 7-camera Vicon motion analysis system. | Maximum pistoning occurred after adding 90 N distal traction load; Movement of pin lock liner was larger (5 ± 1.5 mm) than with Seal-In X5 liner (2 ± 1 mm); Users expressed less skin stretch and more secure feeling with Seal-In X5 liner. |
| Gerschutz et al., 2010 [35] | 1 (NR) | NR | None. | NR | NR | Residual limb volume fluctuation; New to VAS socket; Diabetes; Activity level: K2. | VAS with 2 different vacuum settings; TSB suction socket. | 15.5 wk | Residual limb volume fluctuation. | OMEGA Tracer (over liner). | VAS resulted in 0.8% volume change compared with 4.9% in TSB socket; 2 different pressure settings (–33.86 and –50.79 kPa) showed similar results; Wound healing was observed; Improvement in volume retentions observed with VAS socket use during 3.5 mo period. |

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| Dumbleton et al., 2009 [36] | EG: 24 (20/4); CG: 24 (20/4) | EG: 50.04 (25–69); CG: 60.54 (29–89) | ≥1 yr postamputation; Use of prosthesis for ADLs for ≥6 mo. | L: 14.1 cm (10.5–17.5) (EG); 12.3 cm (7–18) (CG) | EG: PVD (4), Trauma (20); CG: PVD (8), Trauma (18). | NR | HS (ICECAST) + silicone liner; PTB (suspension NR). | >6 mo | Interface pressure. | 6 channel F-scan system and shoe sensors. | Uniform pressure distribution of HS socket was not confirmed; Pressure distribution showed consistent pattern between 2 sockets; Interface pressure was higher for HS socket and had narrower SD; PTB socket showed steeper pressure gradients. |
| Lenka et al., 2008 [37] | 14 (NR) | EG: 71 ± 5; CG: 24 ± 3.8 | No orthopedic or neurological disorders. | NR | NR | BM: 22.17 ± 3.02 kg (EG), 19.35 ± 3.09 kg (CG); Height: 1.64 ± 0.05 m (EG), 1.7 ± 0.03 m (CG). | PTB | EG: >3 yr; CG: >2 yr | Gait parameters; Dynamic weight-bearing distribution. | Computer dynamography; Foot sensors. | Younger users walked faster, had higher cadence, and better step length symmetry than older users; GRF at early stance in younger users was small than for older users; Load at posterior heel was larger in younger users. |
| Rogers et al., 2008 [38] | 1 (1/0) | 41 | None. | NR | NR | BM: 85 kg; Height: 1.8 m; Activity level: K4. | VAS with 3 different compliant socket walls. | Subject wore conventional socket for 1 yr | Interface pressure; Gait parameters. | TekScan F-scan mobile system; 6-camera Vicon 370 3D motion analysis system. | Interface pressure over tibular head and distal tibia were higher in conventional VAS socket than for those of compliance sockets; GRF was not different in sockets, but walking was faster with compliant sockets. |
| Dou et al., 2006 [39] | 1 (1/0) | 25 | None. | NR | NR | Ability to walk ≥500 m without any dyskinesia. | TSB + silicone liner. | NR | Interface pressure. | Novel pliance measurement system. | In natural gait conditions, maximum mean pressure occurred at patella tendon and popliteal area; Pressure at medial and anterior distal tibia was also high. |
| Selles et al., 2005 [24] | EG: 12 (NR); CG: 14 | EG: 67.6 ± 13.5; CG: | Unilateral transtibial amputation; Age: ≥18 yr; Prosthesis use: ≥1 yr; | NR | EG: Trauma (5), Diabetes (7); CG: | Phantom pain: 6 (EG), 10 (CG). | EG: HS (ICEX + pin lock); CG: TSB + comfort/two color liner | 3 mo | Gait analysis; Cost and time of socket | 3-camera ProReflex infrared system. | ICEX and TSB sockets function similarly to |

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| | (NR) | 57.9 ± 15.6 | Active walkers with/without walking aid; No recent residual limb problems; Capable of residual limb distal weight-bearing; No known problems using silicone liners. | | Trauma (6), Diabetes (3), PVD (4), Other (1). | | and pin lock. | | manufacturing. | | conventional socket in terms of gait characteristics; ICEX socket manufacturing was less time consuming, but cost of materials was higher than for TSB socket; Number of postdelivery visits was higher for ICEX socket. |
| Aström and Stenström, 2004 [40] | 29 (24/5) | 39.77 (7–78) | Good fit of conventional suspension with or without silicone liners; 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); Stump problems (20), with pain as limiting factor (18); Foot or knee problems (3); Arm amputation (1). | TSB + polyurethane liner; TSB (ICEROSS/EVA/suction socket). | >2 mo | Gait symmetry (8). | Vicon 370 3D motion analysis system. | No gait parameters showed better symmetry with any type of socket. |
| Beil and Street, 2004 [41] | 8 (NR) | 46 (33–65) | NR | NR | No PVD. | YSA: 18 (6–32). | TSB + urethane liner (pin lock or sleeve suspension). | Not clear. | Average positive and negative pressure during gait; Pressure impulse during swing. | Force sensing pressure sensors; Air pressure sensor. | Stance phase average pressure was not significantly different between 2 sockets; Overall positive pressure, impulse value, average positive pressure, and distal negative pressure during swing were significantly higher in TSB and pin lock sockets. |
| Datta et al., 2004 [22] | EG: 11 (11/0); CG: 10 (8/2) | EG: 47.8 ± 16.9; CG: 52.2 ± 16.2 | Attending routine medical or prosthetic review or repairs; Endolite PTB socket with Pelite liner, cuff suspension, and Multiflex ankle/foot mechanism; Ability to walk without aids (e.g., sticks or crutches); Health contralateral limb; No gait problems as result of socket | — | EG: PVD (3), Trauma (7), Other (1); CG: PVD (4), Trauma (3), Other (3). | BM: 85.4 ± 11.5 kg (EG), 82.4 ± 15.9 (CG); Height: 1.73 ± 0.04 m (EG), 1.71 ± 0.06 m (CG); YSA: 11.6 ± 11.8 (EG), 8.6 ± 15.9 (CG). | HS (ICEX); PTB. | >6 wk | Gait parameters; Symmetry index. | Vicon 370 3D motion analysis system. | No significant differences between EG and CG demonstrated for any measured variables. |

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| | | | discomfort. | | | | | | | | |
| Goswami et al., 2003 [42] | 7 (NR) | 45 (27–66) | Cause of limb loss: trauma or birth defect. | L: 10.3 cm (4.5–17.5) | Trauma and congenital. | BM: 83 kg (59–107). | VAS + urethane liner (undersized, natural, and oversized sockets). | Not clear | Residual limb volume. | Alginate casting and water casting. | Subjects lost average of 2% residual limb volume in 15% undersized socket; In natural-sized sockets, users gained 5%; In oversized sockets, users gained 11%; No pain, discomfort, or reddening of skin were reported as result of residual limb volume gain. |
| Beil et al., 2002 [14] | 9 (NR) | 46 (33–65) | None. | L: 13 cm (8–20) | NR | YSA: 8 (6–32); No vascular complications. | VAS + urethane liner with and without vacuum. | Not clear | Average peak positive and negative pressure; Pressure impulse for stance and swing; Overall average pressure. | Force sensing pressure sensors; Air pressure sensor. | During stance, pressure impulse variation and average peak pressure were significantly lower with VAS socket; During swing phase, impulse value and average and peak negative pressure were significantly greater in VAS socket. |
| Yiğiter et al., 2002 [43] | 20 (13/7) | 27.8 (15–37) | Attending first prosthetic fitting; Residual limb muscle strength: ≥ 4 ; No joint limitation, muscle shortening, residual limb edema, pain, or problems with residual limb shape; Ability to stand within parallel bars and 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 | Weight-bearing capabilities of residual limb and balance; Time-distance parameter of gait, including walking speed; Pistoning; Prosthesis mass, socket, and volume. | Juxtaposed scales; Footprints; Gruendel method. | Improved balance and time distance parameters reported with TSB socket; Pistoning was smaller and ascending and descending stairs and inclines were faster with TSB socket; No correlation found between suspension and other ambulatory activities. |
| Tanner and Berke, 2001 [44] | 1 (1/0) | 37 | NR | Short, conical residual limb with moderate soft tissue distal to tibia. | Trauma | None. | TSB + 3S with pin lock. | Several months | Vertical tibia/soft tissue movement. | X-ray. | Vertical tibia and soft tissue movement between full weight-bearing and non-weight-bearing was 31 and 2 mm, respectively. |
| Board et al., 2001 [13] | 11 (NR) | 45 (32–64) | Amputation caused by trauma; Ability to walk | Not clear | Trauma | BM: 83 kg (56.2–95.3); | VAS + urethane liner with and without | Not clear | Pistoning; Gait symmetry; | X-ray; 2 60 Hz cameras; | Vacuum results in less pistoning, |

30 min on treadmill.

Height: 1.67 m (1.40–1.83); YSA: 15.2 (6–41).

vacuum.

Residual limb volume change.

Casting and water displacement.

increased gait symmetry (step length and stance duration), and residual limb volume gain after 30 min of treadmill walking.

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| Isakov et al., 2000 [45] | 14 (14/0) | 45.07 (32–57) | None. | Not clear. | Trauma | — | PTB | Not clear | Time-distance parameters of gait; Knee kinematic; EMG. | Electronic walkway (GaitRight); High-speed video camera; MEGA portable EMG logger. | Stance time and single support time were shorter in amputated limb, whereas swing time, step time, and step length were shorter in intact limb; Prosthetic limb had more flexed knee and higher ratio of biceps femoris/vastus lateralis activity at heel strike. |
| Zhang et al., 1998 [46] | 5 (NR) | 65 (43–75) | Regular use of PTB prosthesis. | Bony residual limbs (2); More soft tissue over residual limb (1); Not stated (1) | Not clear | — | PTB + cuff/SC suspension. | Not clear | Interface pressure; Shear stress. | Transducer based on strain-gauge diaphragm technique. | Maximum interface pressure was 320 kPa during walking and occurred at popliteal area; Popliteal area, medial and lateral tibia, and anterior distal tibia were all high pressure areas; Maximum shear stress was 61 kPa measured at medial tibial area. |

3D = three-dimensional, 3S = silicone suction socket, ADL = activity of daily living, BM = body mass, CG = control group, EG = experiment group, EMG = electromyography, EVA = ethylene vinyl acetate, F = female, GRF = ground reaction force, HS = hydrostatic, L = length, M = male, NR = not reported, PTB = patellar tendon bearing, PVD = peripheral vascular disease, SC = supracondylar, SD = standard deviation, TSB = total surface bearing, VAS = vacuum-assisted suction, YSA = years since amputation.