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Silicone, Thermoplastic Elastomer, and Polyurethane Prosthetic Liners: Material-Dependent Biomechanics, Clinical Decision-Making, and Research Priorities - A Critical Narrative Review

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Abstract: ***Background**: Prosthetic liners couple soft residual-limb tissues to a comparatively rigid socket. Their mechanical response may modify loading and suspension, while limited heat and vapor transfer can complicate prolonged wear. Material-family labels are often used in prescription despite marked product-to-product variation. **Objective**: To examine what published comparisons actually establish about silicone, thermoplastic elastomer (TPE), and polyurethane (PU) liners, and to distinguish measurable material differences from unproven clinical assumptions. **Methods**: This critical narrative review integrates selected peer-reviewed investigations of liner compression, shear, tension, friction, and thermal conductivity. Evidence is organized by test domain and clinical relevance. Because no exhaustive database screening or formal risk-of-bias procedure was completed, the synthesis is not described as systematic. **Findings**: In one commercial-product comparison, mean compressive tangent moduli were 310 ± 100 kPa for silicone, 140 ± 30 kPa for TPE, and 300 ± 40 kPa for PU; corresponding shear values were 69 ± 17, 21 ± 5, and 63 ± 3 kPa. Reinforcement strongly affected tensile response, and tested PU products had comparatively low friction. These results describe particular products and protocols, not intrinsic polymer constants or demonstrated patient-outcome advantages. **Conclusion**: A polymer-only ranking cannot guide reliable prescription. Clinical selection requires consideration of construction, socket fit, suspension, tissue condition, activity, moisture, and patient-reported experience. Comparative patient-level studies remain necessary.*

Keywords: Prosthetic liners; socket-interface biomechanics; silicone; thermoplastic elastomers; polyurethane

1. Introduction

The residual limb–prosthetic socket interface must transmit body weight and dynamic loads while accommodating tissues that are not naturally adapted to prolonged enclosure and repetitive loading. Elastomeric liners form a compliant layer between skin and socket and may also participate in suspension. Their influence extends beyond cushioning: liner stretch, surface adhesion, thermal resistance and changes during prolonged use can alter the overall mechanical environment [1–4].

Liner prescription is often discussed in terms of silicone, thermoplastic elastomer (TPE) and polyurethane (PU). These labels identify broad polymer families, not standardized material specifications. Within each category, cross-link density, gel composition, additives, thickness, surface treatment and fabric backing can produce markedly different responses. Consequently, a claim that one material is universally softer, more durable or more protective is unlikely to be defensible without identifying the tested products and conditions [1, 3].

Earlier laboratory studies characterized differences in compressive, tensile and shear behavior among commercial liners [1, 5]. A later review emphasized that evidence linking these measurements to functional outcomes was limited [2]. More recent comparative characterization provides a quantitative basis for describing the three material families but also highlights the effect of fabric construction and differences between historical and contemporary formulations [3]. This article therefore focuses on what the available experiments establish, what remains uncertain clinically, and how future studies could bridge the gap.

2. Scope and Methodological Transparency

2.1 Review Design and Question:

A critical narrative approach was selected to address the question: How do measured mechanical and thermal characteristics of silicone, TPE and PU liners differ, and to what extent can those differences guide clinical prescription? The emphasis is on lower-limb elastomeric liners, particularly commercially tested transtibial products.

2.2 Literature Identification and Selection

The synthesis draws on identifiable peer-reviewed publications examining elastomeric liner characterization,

comparative mechanical testing, thermal conductivity and clinical implications [1–5]. The principal comparative dataset is the 2018 study by Cagle and colleagues [3]. Foundational studies were retained because they establish the history and methods of liner testing.

2.3 Interpretation Framework

Evidence is distinguished across three levels: (i) directly measured material properties under specified laboratory conditions; (ii) mechanistic implications for the coupled limb–liner–socket system; and (iii) demonstrated patient outcomes. A laboratory difference in modulus is evidence of different specimen behavior, not direct evidence of reduced skin injury, improved mobility or greater satisfaction.

3. 3. Materials and Construction

3.1 Silicone Gels and Elastomers

Silicone polymers have a flexible siloxane backbone. Their properties depend on molecular structure, cross-link density and filler content. A soft silicone gel and a firmer silicone elastomer can behave quite differently despite sharing the same chemical family. Sanders et al. reported that the silicone gels in their sample generally exhibited lower stiffness than the silicone elastomers in compression, shear and tension [1]. Fabric backing and thickness profile further alter whole-liner behavior. Therefore, silicone should not be treated as a single stiffness category.

3.2 Thermoplastic Elastomers

TPEs combine deformable polymer domains with physically reinforcing regions. Commercial TPE gel liners can be highly compliant, but formulations and reinforcement vary. In the directly compared 2018 product groups, TPE specimens had lower mean compressive and shear tangent moduli than silicone and PU specimens [3]. Their longitudinal behavior was much more heterogeneous, illustrating that a soft-feeling gel may still have a relatively stiff fabric-backed structure. Long-term creep and aging should be evaluated at product level rather than inferred from polymer identity.

3.3 Polyurethane

PU materials encompass multiple urethane-linked polymer networks with variable soft and hard segments. This chemical flexibility permits wide variation in stiffness and surface response. Earlier reports involving particular urethane products should not be generalized to newer commercial PU liners. Notably, the PU products examined by Cagle et al. showed lower dynamic friction values than many silicone and TPE products in that experimental setup [3]. The finding illustrates formulation dependence rather than an invariant PU advantage.

4. Mechanical mechanisms at the socket interface

4.1 Compression and local load redistribution:

Nominal compressive stress is $\sigma = F/A$, but the actual residual-limb interface has nonuniform contact area and highly variable tissue geometry. Elastomers undergo nonlinear deformation; a tangent modulus defined at a particular loading range is therefore more informative than an unqualified Young modulus. A softer specimen can accommodate a local contour while simultaneously changing displacement elsewhere in the system. Whether peak pressure is reduced depends on socket fit, liner thickness, tissue stiffness, loading history and boundary conditions. It is not valid to equate lower laboratory modulus with lower ulcer risk [1, 3].

4.2 Shear, Friction and Tissue Tolerance

Tangential stress may be expressed as $\tau = Ft/A$. Repeated shear combined with compression and moisture can challenge skin integrity. Lower liner shear stiffness may permit deformation within the material; however, the direction and magnitude of resulting skin stress cannot be inferred without examining both contact surfaces and the socket. Likewise, a higher friction coefficient can improve coupling while increasing the capacity to transmit tangential force. Friction is dependent on the counter-surface, load, sliding velocity, temperature and hydration; bench values obtained against a skin surrogate are not direct in-vivo skin measurements [1, 3].

4.3 Tension, Reinforcement and Suspension

Longitudinal liner deformation can influence perceived security and pistoning, especially when a liner forms part of a locking or suction suspension system. Fabric reinforcement can dominate tensile response. The 2018 characterization reported changes exceeding 200% in tensile stiffness for some backing comparisons [3]. Moreover, tensile tangent moduli were defined over differing ranges for different products, so a numerical group mean must not be mistaken for a standardized intrinsic polymer constant. A clinical suspension conclusion requires measurement of actual relative movement under controlled socket conditions.

4.4 Time-Dependent Response and Near-Incompressibility

Creep, stress relaxation and hysteresis can modify interface behavior during prolonged standing and repetitive gait. Near-incompressibility means that deformation is largely a change of shape rather than a substantial reduction of volume. Cagle et al. reported Poisson ratios close to 0.5 for their tested materials [3]. This distinction is important when describing the apparent flow of gel liners: the observed accommodation does not imply that the polymer can freely escape the constrained socket environment.

5. Comparative Evidence Synthesis

Table 1: Published descriptive product-group results from Cagle et al. [3].

Outcome	Silicone	TPE	Polyurethane
Compressive tangent modulus (kPa)	310 ± 100	140 ± 30	300 ± 40
Shear tangent modulus (kPa)	69 ± 17	21 ± 5	63 ± 3
Tensile tangent modulus (kPa)*	210 ± 70	1,460 ± 1,790	170 ± 50
Dynamic coefficient of friction	1.4–3.1	0.8 to >3.0	0.4–0.7
Thermal conductivity (W/m·K)	0.16 ± 0.02	0.13 ± 0.01	0.16 ± 0.02

*Tensile tangent moduli were calculated using different loading intervals for some products; fabric backing contributes substantially to variability. Numerical values must be interpreted with the original study protocol.

The strongest direct comparative finding is lower average compression and shear stiffness among the tested TPE products. In contrast, the very wide TPE tensile variability cautions against ranking longitudinal stability by polymer family. The PU friction range illustrates that contemporary products can differ materially from historical descriptions. Importantly, no measure in Table 1 is a direct clinical endpoint such as pain, skin injury, activity or wearing time.

Table 2: Evidence map for the core publications

Source	Study type / material	Contribution	Key limitation
Sanders et al., 2004 [1]	Laboratory tests of 15 elastomeric products	Established variability in compression, shear, tension and friction	Older commercial formulations; no direct patient outcome comparison
Klute et al., 2010 [2]	Review of liner literature	Identified gaps in evidence-based clinical prescription	Historical review; does not reflect all later products
Cagle et al., 2018 [3]	Laboratory comparison across silicone, TPE and PU	Direct product-group modulus, friction and conductivity data	Bench specimens and test-specific conditions; no clinical superiority inference
Klute et al., 2007 [4]	Thermal testing of socket/liner materials	Quantified low conductivity of conventional liner materials	Conductivity is not equivalent to patient thermal comfort
Emrich & Slater, 1998 [5]	Comparative material assessment	Early comparison of liner materials	Older materials and methods

6. Thermal Behavior and the Residual-Limb Microclimate

The liner is one layer in a thermal system that includes the skin, air gaps, textile coverings and socket wall. In an idealized homogeneous layer, conductive heat transfer follows $\dot{Q} = kA\Delta T/L$, where k is thermal conductivity and L is thickness. This relation shows why material thickness can alter thermal resistance even when intrinsic conductivity is unchanged. However, real use involves transient heat generation, perspiration and constrained evaporation, so a conductivity measurement cannot fully characterize comfort.

Klute et al. reported thermal conductivities between approximately 0.085 and 0.266 W/m·K for the liners evaluated [4]. The later comparison found broadly similar mean conductivities across the three polymer families, with values near 0.13–0.16 W/m·K [3]. A difference in these means does not establish that one category is consistently cooler in use. Environmental temperature, relative humidity, physical activity, water-vapor permeability and suspension design must be considered alongside material composition.

The microclimate question is particularly relevant to hot and humid regions, where reduced evaporative cooling may exacerbate perspiration and perceived discomfort. Studies should distinguish measured temperature from subjective heat sensation, record interface humidity, and report skin outcomes and wearing time. The present literature does not justify a universal hot-climate preference for silicone, TPE or PU.

7. Clinical Implications: What can and cannot be Recommended

For a residual limb with prominent bony anatomy, a clinician may evaluate a more compliant product to improve local accommodation, but socket modification remains essential. For highly mobile soft tissue or problematic pistoning, controlled longitudinal behavior and the suspension system may be more relevant than compressive softness. For recurrent skin irritation, clinicians should assess pressure distribution, alignment, liner condition, hygiene, moisture, fit and possible contact sensitivity before attributing the problem to polymer chemistry.

A useful prescription sequence is: characterize residual-limb tissue and volume; identify suspension requirements; evaluate liner thickness and backing; trial product-specific options; assess static and dynamic socket fit; and document comfort, skin response and functional use at follow-up. This is a pragmatic clinical framework, not a validated algorithm proven to favor one polymer family.

Table 3: Clinical translation of material evidence

Clinical question	Evidence-informed interpretation	Avoid claiming
Which material cushions best?	Compare product-specific compression and geometry	TPE always prevents pressure injury
Which limits pistoning?	Assess fabric-backed tensile behavior and actual suspension	A polymer label predicts suspension security
Which is safest for skin?	Examine pressure, shear, moisture, fit and skin response	A low-friction liner always protects skin
Which is coolest?	Measure temperature, humidity, thickness and ventilation	One polymer is universally best in tropical climates

A pragmatic selection framework can proceed in three stages: first identify the dominant patient problem (e.g., localized intolerance, suspension instability, moisture, or donning difficulty); next examine product-level evidence and the socket–suspension configuration; finally evaluate the actual fit and skin response during progressive use. This framework is a reasoned clinical proposal, not a validated decision rule.

An evidence-to-decision distinction is essential. Bench compression tests describe resistance to prescribed deformation; they do not establish the spatial pressure map within a living residual limb. Friction tests describe a specific contact pair; they do not establish whether the same liner causes less skin trauma during walking. Thermal conductivity is a bulk transport property; it does not capture evaporation, sweat retention, or subjective warmth. Accordingly, each laboratory measure should be linked to a clinically testable hypothesis rather than presented as a treatment recommendation [1–4].

8. Research gaps and future directions

8.1 Comparative Clinical Studies

The central unanswered question is whether measured laboratory differences produce meaningful changes in patient outcomes. Future trials should control socket design, suspension, liner thickness, wear time and accommodation periods. Outcomes should include standardized interface pressure and shear, pistoning, skin events, patient-reported comfort, mobility and device use. Investigators should predefine a primary endpoint and calculate sample size accordingly.

8.2 Durability, Aging and Real- World Exposure

Repeated cycles of compression, stretching, cleaning, sweat exposure and temperature variation may alter mechanical properties. Bench fatigue testing should be paired with in-use follow-up, documenting material deterioration and replacement intervals. Product-level reporting is essential because the polymer family is too broad to capture formulation differences.

8.3 Thermal and Moisture-Engineered Interfaces

Breathable constructions, engineered channels, regionally tailored thickness and other thermal strategies deserve evaluation, but must be tested for mechanical stability and skin safety. Laboratory improvements in conductivity or vapor transport should be linked to actual temperature, humidity, tissue condition and comfort outcomes.

8.4 Digital Measurement and Computational Modeling

Pressure and temperature sensors may support longitudinal assessment of the socket microenvironment, while finite-element models can explore local stress distributions. Such models require validated tissue constitutive laws, realistic boundary conditions and experimentally measured material parameters. Neither simulation nor sensor signals alone substitute for clinically meaningful endpoints.

The review also faces potential selection bias because its cited core studies are concentrated in foundational material-characterization literature. Recent product generations and clinical comparative trials may be underrepresented. For journal-quality evidence mapping, the authors should independently repeat database searches, record exact search dates and hit counts, and document inclusion decisions before claiming comprehensive coverage.

8.5 Relevance to Resource-Limited Settings

Affordability, supply continuity, hygiene, repairability and climate exposure are particularly relevant to rehabilitation services in low-resource settings. Comparative economic and clinical effectiveness studies should report both acquisition and replacement costs, alongside functional and skin-related outcomes.

9. Strengths and limitations of this review

A strength of this manuscript is its separation of quantitative bench observations from mechanistic interpretation and patient outcomes. It avoids treating three broad polymer families as internally homogeneous and identifies fabric reinforcement as an important confounder. However, this is a focused narrative review based on a limited set of foundational publications. The literature search was not exhaustive, screening was not performed independently, and formal quality appraisal was not undertaken. The quantitative table draws primarily from one comparative investigation and should not be mistaken for a meta-analysis. Before submission to a journal requiring comprehensive contemporary coverage, a documented search update and incorporation of additional eligible clinical studies are necessary.

10. Conclusion

Silicone, TPE and PU prosthetic liners show meaningful differences in measured behavior, but those differences are specific to formulation, reinforcement and testing conditions. Among commercial products evaluated in a major comparative study, TPE liners were more compliant in compression and shear; tensile behavior varied substantially with backing, and PU friction measurements challenged older material stereotypes. Thermal conductivities were broadly similar. None of these observations establishes universal clinical superiority. Future progress depends on product-level characterization linked to well-controlled, patient-centered clinical outcomes. Until such evidence is available, individualized liner selection and careful socket assessment remain the most defensible approach.

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