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Quantification of prosthetic outcomes: Elastomeric gel liner with locking pin suspension versus polyethylene foam liner with neoprene sleeve suspension

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Abstract—For this randomized crossover trial, we compared two common transtibial socket suspension systems: the Alpha® liner with distal locking pin and the Pe-Lite™ liner with neoprene suspension sleeve. Our original hypotheses asserted that increased ambulatory activity, wear time, comfort, and satisfaction would be found with the elastomeric suspension system. Thirteen subjects completed the study. Following 2.5-month accommodation to each condition, ambulatory activity was recorded (steps/minute for 2 weeks), and subjects completed three questionnaires specific to prosthesis use and pain: the Prosthesis Evaluation Questionnaire (PEQ), a Brief Pain Inventory (BPI) excerpt, and the Socket Comfort Score (SCS). Upon completion, subjects selected their favored system for continued use. Ten subjects preferred the Pe-Lite™ and three the Alpha®. Subjects spent 82% more time wearing the Pe-Lite™ and took 83% more steps per day. Ambulatory intensity distribution did not differ between systems. No statistically significant differences were found in questionnaire results. Subject feedback for each system was both positive and negative.

Key words: Alpha® liner, ambulatory monitoring, elastomeric, lower limb, outcome assessment, Pe-Lite™ liner, prosthesis, questionnaire, socket, transtibial.

INTRODUCTION

Interface and suspension systems for transtibial prosthetic sockets differ markedly in design, durability, function, and price. The choice of system strongly affects the experience of the patient and the cost of ongoing care. Currently, little objective outcomes research exists to guide clinical decisions regarding socket prescription.

The elastomeric gel sleeve used with a total surface-bearing (TSB) socket is a relatively new technology [1,2] that is becoming widely prescribed. The gel liner (silicone or other elastomeric gel) is rolled or slid over the residual

Abbreviations: BPI = Brief Pain Inventory, CAD/CAM = Computer-Aided Design/Computer-Aided Manufacturing, DMERC = Durable Medical Equipment Regional Carrier, PDI = Prosthetic Design, Inc., PEQ = Prosthesis Evaluation Questionnaire, PTB = patellar tendon-bearing, SAM = StepWatch™ activity monitor, SCS = Socket Comfort Score, SD = standard deviation, 3S = Silicome Suction Socket, TSB = total surface-bearing, VA = Department of Veterans Affairs.

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limb. Suction or friction between the gel and the skin holds the liner to the limb. The gel is thought to reduce the shear forces transmitted to the residual limb and, thus, protect the skin. Gel liners can be used simply to interface with the skin or for prosthesis suspension. Various methods can be used for suspension such as a distal locking pin, suction seal, Velcro-type hook adhesion, and cord and lanyard. Tearing or puncturing of the liner can greatly compromise prosthesis suspension [3]. Elastomeric suspension liners tend to be costly and must be replaced often, usually within a year [4].

Another popular system in use since the 1950s is the patellar tendon-bearing (PTB) soft-lined socket. A dense, closed-cell foam liner is molded to fit inside the socket to provide some cushioning for the residual limb. Socks are commonly worn between the residual limb and the liner and are added or removed to compensate for volume changes of the residual limb. Suspension is independent of the liner and can be achieved through a variety of strategies, including supracondylar contouring of the socket, a latex rubber or neoprene suspension sleeve worn over the socket and extending to midthigh, or a suprapatellar strap or cuff. The foam liners are considerably more durable and less expensive than elastomeric gel liners, and they require little maintenance.

Elastomeric Suspension Systems

Despite the popularity of elastomeric suspension systems, few well-controlled prospective studies have been conducted regarding their efficacy. Most studies tracked subjects who have been prescribed and/or have successfully used these systems, but have not concurrently examined an alternative type of system [4–9]. While results have been generally positive, they have not been overwhelmingly so.

Crossover Studies

We found only one published crossover study comparing elastomeric suspension liners with Pe-Lite™ liners. Boonstra et al. [10] conducted a prospective study comparing the Fillauer Silicone Suction Socket (3S) with shuttle-locking mechanism [1] to the supracondylar PTB socket with Pe-Lite™ liners. A new socket was made for each condition and the original foot retained. The accommodation periods were a minimum of 10 weeks. Data collected included preference, a 34-item questionnaire, and open-ended feedback.

Of the eight subjects enrolled, two could not tolerate the 3S system. Four of the remaining six selected the Pe-Lite™ as their preferred system. Traction during swing phase and ease of donning and doffing were positive factors cited with the preference for the Pe-Lite™. Close contact between the 3S system and the limb was a positive factor noted by those who preferred the 3S system.

Alpha® Liner Studies

The only publication we found specific to the Alpha® locking liner reported on a retrospective study by Hatfield and Morrison [4]. Subjects' responses to new prostheses with Alpha® locking liners were compared to their opinions of previous prostheses (n = 40). Their subjects exhibited a similar age (mean and range) and functional level to ours, but amputation level and etiology were mixed. In the Hatfield and Morriston study, 20 subjects reported improved suspension and 10 reported improved comfort with the Alpha® locking liner. On average, each subject was issued 4.5 liners per year. The researchers observed a 20-percent rejection rate of the Alpha® system.

Literature Summary

The efficacy of elastomeric suspension liners has been the topic of much debate. Individual opinion and manufacturers' claims are often central to the dialogue. Differences in study design and the complexity of factors involved make it difficult to draw firm conclusions from the small body of peer-reviewed literature. To facilitate understanding and to provide perspective for the results of our study, a summary of literature on elastomeric suspension systems is provided in the **Appendix** (found in the online version only).

METHODS

Socket Suspension Systems Studied

For this study, we examined patient satisfaction, pain, socket comfort, daily ambulatory function, physical changes, and patient comments associated with use of two systems for the interface and suspension of transtibial prostheses. The Alpha® suspension liner with distal locking pin was compared to the Pe-Lite™ liner with neoprene suspension sleeve.

*Alpha®**

The Alpha® system uses a mineral oil-based thermoplastic elastomeric gel to interface with the residual limb. The manufacturer states that the gel absorbs shear, abrasive, and impact forces, providing a superior level of comfort and protection for the wearer [11]. The outside of the liner is covered with a slippery fabric to increase durability and facilitate donning and doffing. The Alpha® liner selected was a suspension type, which uses a stainless steel pin at the distal end to secure the liner to the socket via a shuttle lock in the distal end of the socket (**Figure 1**). A button on the outside of the socket releases the pin (and the liner) from the shuttle lock (and the socket). Liners are supplied in pairs, and the manufacturer recommends that users alternate the liners daily. A pair of liners normally lasts 4 to 9 months [4].

Pe-Lite™†

The Pe-Lite™ system consists of a liner molded from medium-density polyethylene foam thermoformed to fit the contours of the socket. Subjects in this study wore prosthetic socks inside the liner and a fabric-lined neoprene sleeve pulled over the socket and extending to midthigh to suspend the prosthesis (**Figure 2**). A Pe-Lite™ liner lasts several years.

Cost, charge, and financial reimbursement data for the use of specific prosthetic components can be complex and variable, which makes comparison difficult. As a reasonable point of comparison, the Washington State Medicaid 2001 allowable reimbursement for replacement of a pair of Alpha® liners was $945. Reimbursement for replacement of a Pe-Lite™ liner was $280.

Research Design

Randomized Crossover Trial

Subjects were required to be at least one year past unilateral transtibial amputation of traumatic origin, be stable in their current prosthesis, and exhibit no major preexisting health problems. Minimum ambulatory function for enrollment was based on Durable Medical Equipment Regional Carrier (DMERC) Level 2 criteria [12]: "has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator." DMERC levels range from 0 to 4, and define eligibility for Medicare reimbursement of specific prosthetic systems in the United States.

Fourteen subjects were enrolled. All provided written informed consent prior to enrollment. One subject withdrew from the study due to elective revision amputation to excise bone spurs present prior to enrollment. Thirteen subjects completed the protocol. Each wore one system for 3 months after a stable comfortable fit was achieved, then switched to the other using the same procedure. For control of seasonal variability, pairs were simultaneously entered into the protocol in opposite conditions, with the assignment of conditions randomized and enrollment distributed throughout the seasons. Subjects retained their original limb for use if needed during both conditions, but were instructed to wear the study limbs as much as possible.

Clinical Methods

A new socket was fabricated for each condition. All were formed from thermoplastic polypropylene preforms. Distal end pads were not used in either condition. In the Pe-Lite™ condition, medium-density cones of Fillauer Pe-Lite™ polyethylene were thermoformed over the positive model for the socket, and then the polypropylene socket was formed over the Pe-Lite™. Two staff research prosthetists designed the total-contact PTB sockets for this condition. Clear check sockets were used to verify that the sockets provided total contact. The sockets were designed for use with 3-ply prosthetic socks.

To ensure proper design and fitting of sockets for the Alpha® condition, the manufacturer's staff prosthetist visited the laboratory to train the study prosthetists, cast the subjects' residual limbs, and participate in design of the total surface-bearing sockets. Uniform thickness 6 mm Alpha® liners with distal locking pins were used in conjunction with Prosthetic Design, Inc. (PDI) shuttle locks. The sockets were designed for use without prosthetic socks, although wearing socks between the liner and socket was permitted if necessary to accommodate volume reduction. Several subjects occasionally used socks in this manner.

Alignment was controlled. In each subject's first condition, the limb was dynamically aligned. For the second condition, an Otto Bock laser alignment system was used

*Manufactured by Ohio Willow Wood, 15441 Scioto Darby Road, Mount Sterling, OH 43143; USA.

†Manufactured by Fillauer, Inc., 2710 Amnicola Highway, Chattanooga, TN 37406; USA.

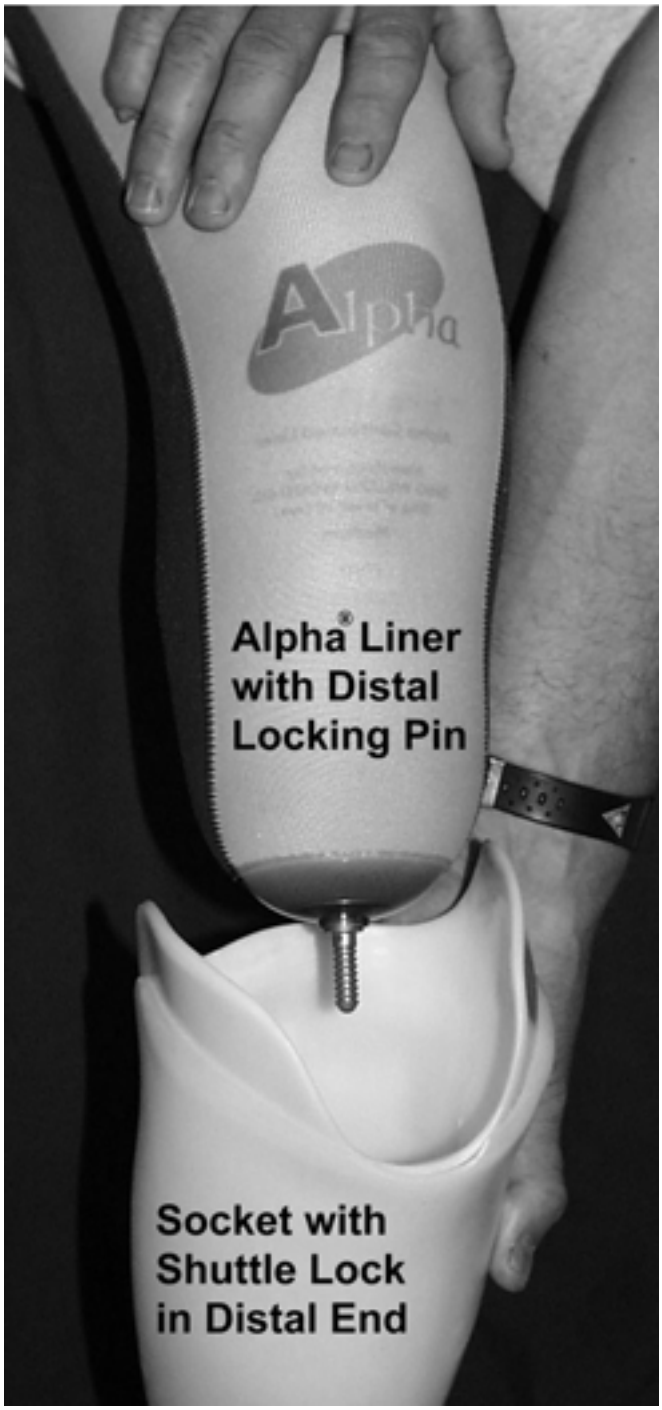

Figure 1.
The Alpha® liner system.

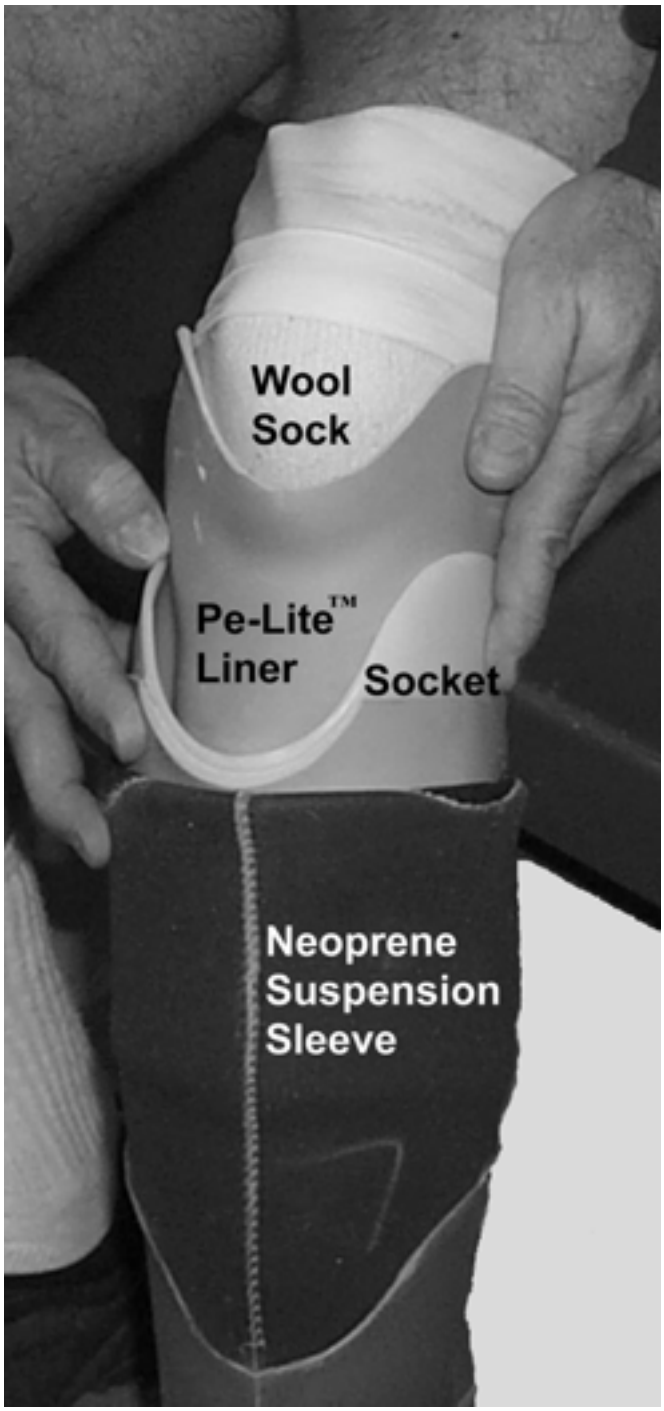

Figure 2.
The Pe-Lite™ liner system.

to reproduce the alignment of the first condition for initial setup. Later, if necessary because of differences in socket design, the alignment was slightly adjusted. Usually, no changes were necessary.

Upon receipt of each study socket, subjects were encouraged to return to the laboratory for adjustments if any problems arose. An orthopedic surgeon evaluated and treated all subjects who experienced complications

of the residual limb. Subjects did not enter the 2.5-month accommodation period preceding measurements until a comfortable socket fit was achieved (i.e., no further adjustments were sought).

Measures

Midcondition telephone interviews were conducted to identify pertinent issues and emerging problems. At the end of each condition, ambulatory activity was recorded as the number of steps taken on the prosthesis each minute for 2 continuous weeks with the StepWatch™ activity monitor (SAM) [13]. The SAM is a pager-sized instrument that was attached to the "ankle" of the prosthesis. We attuned the sensitivity to the gait style of each subject, and the settings were verified by inspection of a test light on the SAM that can be set to blink each time a step is identified. We observed the light as the subjects walked at slow, normal, and fast speeds. If the light did not blink once per step, the SAM settings were adjusted. The light did not blink during data collection. Previous studies have found the SAM accuracy to consistently exceed 99 percent in this population [13,14].

The Prosthesis Evaluation Questionnaire (PEQ) [15], a validated instrument to measure satisfaction with prosthesis-specific issues, was administered 2 weeks before the end of each condition. An excerpt of the Brief Pain Inventory (BPI) [16] and the Socket Fit Comfort Score (SCS) [17] were also completed. The questionnaires were administered at this point to reduce potential for bias at the end of conditions when subjects anticipate the change to a different prosthesis.

Pursuant to clinical debate as to whether limb volume changes with the use of elastomeric gel liners, limb volume was measured before and after the Alpha® condition with the use of cast volume methods. The internal shape of the residual-limb cast was recorded with a Provel cast digitizer, then transferred to a desktop computer and imported into ShapeMaker Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM) software [18]. We calculated the cast volume below the midpatellar tendon with ShapeMaker software [19].

Upon completion of the second condition, subjects selected their preferred system for continued use. We then conducted an exit interview.

RESULTS

Subject Characteristics

Ten males and three females with unilateral transtibial amputation of traumatic origin completed the study. One subject functioned at DMERC Level 2, eight were at Level 3, and four were at Level 4. Three subjects used elastomeric suspension systems in their baseline legs, two subjects used hard sockets, and eight subjects used PTB sockets with Pe-Lite™ liners. Full history of prosthetic socket system use was not collected. Exclusion criteria did not include use of any specific socket system. The majority of subjects had experience with different socket types, including Pe-Lite™ liners and elastomeric systems. Subject characteristics are shown in **Table 1**.

Step Activity

We analyzed step activity results using a paired, two-tailed Student's *t*-test. Stride length did not differ between the Alpha® and Pe-Lite™ conditions (1.379 vs. 1.381 m; $p = 0.9048$). Step monitoring data showed that subjects achieved 83 percent more steps per day (4,135 vs. 2,262; $p = 0.002$) with the Pe-Lite™ limb. Subjects spent 82 percent more time wearing the Pe-Lite™ (13.3 vs. 7.3 hours/day; $p = 0.018$) and 72 percent more time (27.1 vs. 15.8 minutes/day; $p = 0.002$) in high-intensity activity (>30 steps/minute) (**Table 2**). Step counts reflect only steps taken on the prosthetic leg. There were no significant differences in step activity between the baseline and Pe-Lite™ conditions. Differences between the Alpha® and baseline conditions were similar to those seen between the Alpha® and Pe-Lite™.

During the time subjects were active in each liner, the intensity distribution did not differ between the Alpha® and Pe-Lite™ systems (**Table 2**). Thus, the difference in overall activity reflects differences in the amount of time

Table 1.
Subject characteristics ($n = 13$).

Measure	Mean ± SD	Range
Age (yr)	49.4 ± 9.6	31.5–65.8
Body Mass (kg)	85.6 ± 17.8	60.0–113.6
Height (m)	1.78 ± 0.08	1.60–1.88
Years Since Amputation	24.4 ± 11.0	4.7–39.3
Activity Level*	3.23 ± 0.60	2.0–4.0

*Durable Medical Equipment Regional Carrier (DMERC) activity levels range from 0 to 4. See *Methods* for explanation.
SD = standard deviation

Table 2.
Step activity results (n = 13).

Variable	Alpha® Mean	Pe-Lite™ Mean	% Diff. ([P – A]/A)	p-Value (2-Tailed)
All Days Monitored				
Steps/Day	2,262	4,135	83	0.0022*
Inactive Hours/Day	20.6	18.2	–12	0.0093*
Hours Low Activity	2.5	4.2	69	0.0202*
Minutes Moderate Activity	40.5	71.6	77	0.0080*
Minutes High Activity	11.3	24.7	118	0.0003*
Days Liner was Worn				
Steps/Day	3,009	4,498	49	0.0076*
Inactive Hours/Day	19.5	17.7	–9	0.0249*
Hours Low Activity	3.3	4.6	NS	0.0533
Minutes Moderate Activity	53.1	77.9	47	0.0274*
Minutes High Activity	15.8	27.1	72	0.0025*
Average Hours/Day Socket Worn (All monitoring days included)	7.3	13.3	82	0.0186*
Average Hours/Day Socket Worn (On days socket was worn)	11.0	14.7	33	0.0265*
Intensity Distribution of Active Time				
% Low Activity	74.4	72.5	NS	0.4475
% Moderate Activity	19.8	20.2	NS	0.8230
% High Activity	5.8	7.3	NS	0.0891

*Indicates statistical significance at $p < 0.05$ level.
NS = no statistically significant difference
P = Pe-Lite™
A = Alpha® liner

which subjects wore the study limbs. **Figures 3** and **4** illustrate typical wear patterns for the two conditions. Subjects wore the Pe-Lite™ liner for the full day in 86 percent of days monitored (**Figure 4**). The Alpha® liner tended to be worn more sporadically, with some partial days and some skipped days (**Figure 3**). It was worn the full day in only 55 percent of days monitored.

Questionnaires

No differences were found in any of the nine PEQ scales or the in the SCS (**Table 3**). The PEQ scales are calculated from groups of related questions presented in visual analog format. The possible score for each question and each scale ranges from 0 (most unfavorable response) to 100 (most favorable response). PEQ results were analyzed using a two-tailed Wilcoxon matched pairs, signed, ranked test.

The SCS is a single question in which subjects are asked to rate the comfort of their socket fit by circling a number from 0 to 10, where 0 is "most uncomfortable" and 10 is "completely comfortable." SCS results were analyzed with the use of a two-tailed Wilcoxon matched pairs, signed, ranked test. There were no differences in the SCS score between baseline and either condition.

The excerpt of the BPI used in this study was a series of individually scored questions. The first item was enlisted to determine whether or not the subjects would proceed to the other questions by asking whether the subject had experienced any pain in the past week other than normal "everyday" kinds of pain such as headaches. Subjects responding affirmatively answered 11 more questions (on a 1–10 scale) pertaining to the intensity of the pain and how much the pain interfered with various aspects of life. BPI results were analyzed with the use of a chi-square distribution test. No difference was found in any of the BPI

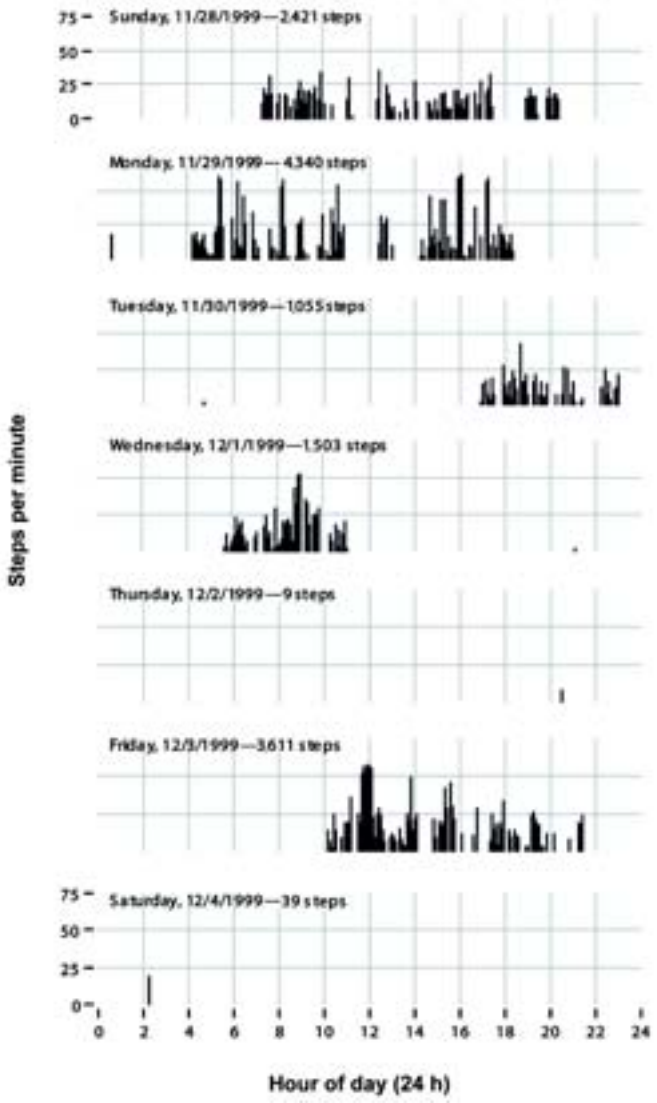

Figure 3.
Typical use pattern for Alpha® condition (Subject 1).

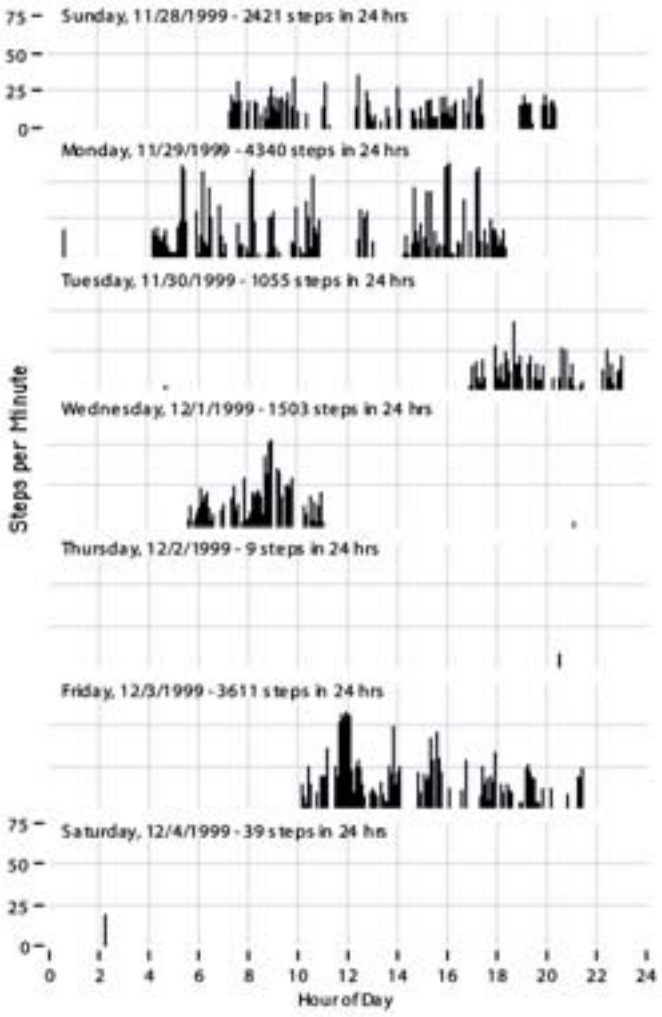

Figure 4.
Typical use pattern for the Pe-Lite™ condition (Subject 1).

scores (**Table 4**). For the Alpha® and Pe-Lite™ conditions, respectively, six and seven subjects reported experiencing no nonnormal pain, so subsequent question results reflect only half of the subjects. No *p*-value could be calculated for the question assessing pain "intensity at least during the past week" because the higher (more intense) rankings of pain contained all zeros.

Residual-Limb Volume

Residual-limb volume results were inconclusive. No difference in volume was found following use of the gel liner, but the variability in the method was so large that physiologically realistic changes might not have been detected.

Subject Preference

At the end of the study, eight subjects selected the Pe-Lite™ liner for continued wear, while four chose the Alpha® and one returned to the original socket. Of the eight selecting to use the Pe-Lite™ system, six had been using a Pe-Lite™ system prior to the study, one used an elastomeric suspension system, and one used a hard socket. Of the four subjects selecting the Alpha limb for continued use, two had been wearing an elastomeric

Table 3.
Prosthesis Evaluation Questionnaire (PEQ) and Socket Comfort Score (SCS) results (n = 13).

Measure	Alpha® Mean ± SD	Pe-Lite™ Mean ± SD	%Diff ([P – A]/A)	p-Value (2-Tailed)
PEQ Scale				
Ambulation	71.6 ± 24.0	78.6 ± 17.5	NS	0.4143
Appearance	84.7 ± 14.1	78.7 ± 17.4	NS	0.0942
Frustration	63.2 ± 27.1	71.1 ± 34.0	NS	0.6377
Perceived Response	88.7 ± 13.1	89.6 ± 13.5	NS	0.6355
Residual-Limb Health	65.1 ± 19.8	64.5 ± 23.1	NS	0.8926
Social Burden	82.1 ± 17.2	82.0 ± 24.3	NS	0.9697
Sounds	63.4 ± 31.6	72.8 ± 32.7	NS	0.3396
Utility of Prosthesis	62.8 ± 25.4	70.7 ± 23.7	NS	0.3054
Well-Being	80.5 ± 18.9	82.4 ± 16.7	NS	0.7910
Socket Comfort Score	6.84 ± 3.0	7.23 ± 2.5	NS	0.7344

PEQ range = 0–100; SCS range = 1–10. Higher scores are more favorable for both instruments.
NS = no statistically significant difference
P = Pe-Lite™
A = Alpha® liner

Table 4.
Brief Pain Inventory (BPI) statistical comparison results (n = 13).

Question	p-Value
Pain other than normal (e.g., headache) during past week? (Yes/No)	0.9025
Intensity at worst during past week	0.9926
Intensity at least during past week	—
Intensity on average	0.9941
Intensity now	0.8752
Level of interference pain caused during past week?	—
General activity	0.6676
Mood	0.8645
Walking ability	0.9266
Normal work (out of home & housework)	0.6676
Relations with other people	0.9631
Sleep	0.7879
Enjoyment of life	0.9703

suspension system and two had been wearing a Pe-Lite™ system. The one subject electing to return to the original socket had been using a hard socket.

When asked which of the study systems they would select if it were to be used as their sole prosthesis, 10 subjects indicated they would choose the Pe-Lite™ liner and 3 stated they would choose the Alpha® liner.

Subject Feedback

The comments made by subjects in the final interview, midcondition telephone interviews, and unstructured conversation during visits to the laboratory were recorded, categorized, and tallied. **Table 5** shows the percentage of subjects who made at least one positive or negative comment about the Alpha® or Pe-Lite™ system.

Table 5.
Open-ended feedback: percentage of subjects who made at least one positive or negative comment (n = 13).

Topic	Comments on Alpha®		Comments on Pe-Lite™	
	Positive (%)	Negative (%)	Positive (%)	Negative (%)
Donning	15	69	54	15
Suspension	46	23	31	38
Function in Specific Activities	54	46	23	15
Ability to Wear for Long Periods	23	62	23	23
Care/Maintenance	23	69	15	8
Skin Irritation	8	54	0	23
Comfort (Short or Long Term)	38	8	23	15
Durability	0	46	15	23*
Perspiration	8	46	0	15
Appearance	23	23	0	8

*15% remarked on the neoprene sleeve; 15% referred to the Pe-Lite™ liner. One subject referred to both, so the total is 23% rather than 30%.

Comments are arranged by topic, according to the total number of subjects across both conditions who made at least one comment pertaining to an issue. Subjects who made multiple comments of the same value (positive or negative) for a given condition were counted only once in the tally, but were counted twice if they made both a positive and a negative comment in reference to the same condition.

Specific feedback from subjects on the Alpha® system included the fact that donning (both pulling the liner onto the limb and achieving proper pin alignment for insertion into the shuttle lock) was difficult and time consuming. The ability to quickly release the liner from the socket was appreciated. Suspension was secure. Function was preferable for some activities but not for others; overall, function was not as versatile. Comfort was good over short periods of time but reduced over longer periods. The liner pulled on the skin while sitting, causing discomfort. Maintenance, care, and hygiene were burdensome. The liner tended to cause skin irritation, frequently at the proximal edge but elsewhere as well. Durability and cost of replacement were a concern. Perspiration increased. The profile under clothing was very trim. Most subjects felt that the Alpha® liner offered some positive advantages (the specifics of which differed between subjects) not provided by the Pe-Lite™ liner, and that the Alpha® would be a welcomed option if it could be used in combination with an alternative leg.

Specific feedback on the Pe-Lite™ system noted that donning was quick and simple. Subjects appreciated this convenience, and some mentioned feeling more personally secure (able to respond quickly to demands or emergencies). There was more “play” in the suspension (seen by most as negative, but by some as positive). Function was not as good for some activities and not as bad for others. Comfort was more consistent over long periods of time. Maintenance and hygiene were less burdensome, although some subjects disliked having to launder the prosthetic socks. Skin irritation, perspiration, and liner durability were less of an issue. Durability of the neoprene suspension sleeve was seen by some as poor, but replacement was not a serious concern because of the relatively low cost and good availability. Most subjects felt that the Pe-Lite™ liner system did not offer the optimum function across all variables related to prosthetic use, but it did provide a combination of features and function that was more versatile for continuous daily use.

DISCUSSION

The results of this study are complex to integrate, but are not inconsistent with the literature. Feedback from our subjects reflected the same set of positive and negative issues reported by virtually all studies of elastomeric suspension liners (**Appendix**, found online only).

Our results are similar to those of Boonstra et al. [10], the only other crossover study on the topic. Their subjects were similar to ours in age and amputation etiology, but differed in that all of Boonstra’s subjects were

experiencing persistent residual-limb skin problems at the time of enrollment (sores or folliculitis) and none had previously used elastomeric liners. In Boonstra's study, 67 percent of subjects (four of six completing the protocol) preferred the Pe-Lite™ system. In our study, 77 percent of subjects preferred the Pe-Lite™ system, and 62 percent selected the Pe-Lite™ study limb for continued use.

The findings of both crossover studies appear considerably less positive toward elastomeric liner suspension systems than those of studies that followed subjects who changed to and/or were successful in these systems. However, it is important to note that studies comparing a new socket to a previous socket without employing either a crossover design (where subjects receive new sockets in two or more conditions) or a multiple-arm design (where a large number of subjects are followed after they receive one of two or more types of sockets) are not able to distinguish the extent to which results are attributed to receiving a new socket versus the specific characteristics of the socket system. The fact that only one of our subjects elected to return to the baseline limb suggests that receiving a new socket has a positive influence.

Another study design issue to consider is whether previous experience with socket type influences results. Although our study observed crossover between the baseline type and the preferred type in both directions, the baseline distribution was not equal and the number of subjects was too small to draw conclusions pertaining to previous experience. Of value would be a study enrolling subjects equally divided by baseline system type.

Despite the negative outcome toward elastomeric suspension liners suggested by step activity records, our subjects did not respond more negatively to the Alpha® condition in the questionnaires and did not report greater pain or less socket comfort. Indeed, these results demonstrate choices made when controlling for comfort and pain. Controlling for comfort and pain does not mean that the two socket systems were equal in this regard for each individual, but that overall across the subjects, comfort and pain were not different between the systems.

Subjects took 83 percent more steps in the Pe-Lite™ limb, apparently because most were unwilling to wear the Alpha® prosthesis as regularly as they did the Pe-Lite™ (7.3 vs. 13.3 hours per day, respectively), even though they had been asked to do so. When active in the Alpha® prosthesis, the intensity distribution of ambulation showed no difference from that of the Pe-Lite™, which suggests that subjects were able to meet similar ambulatory demands with both limbs. The PEQ results showed an equal level of satisfaction with the two prostheses across all scales, but the final preference heavily favored the Pe-Lite™ condition limb.

Midcondition comments and final interview responses help explain the preference results. Subjects clearly expressed that the two systems were different and there were aspects of each that were preferable. They tended to react more strongly—both positively and negatively—to the Alpha® condition. Frequently, subjects indicated that some aspects of the Alpha® limb performance were superior (such as security of suspension, short-term comfort, trim profile), but that use of the limb (donning, hygiene/maintenance, skin irritation) was considerably more cumbersome. Subjects often reported that the Pe-Lite™ limb did not perform as well or as poorly in specific situations, was less encumbering to everyday life, and provided more consistency in comfort during extended periods of wear.

Large standard deviation (SD) and lack of significant differences in all PEQ scales indicate there was considerable variability between subjects in the experience of and emphasis placed on the various characteristics of the two systems. Clearly, each individual balances a range of factors when determining preference. Factors related to ease-of-use (donning, care/maintenance) were the most frequently mentioned issues and appeared to have a large influence over subjects' acceptance of and willingness to use the limbs. Sample size calculations based on selected PEQ measures from this study suggest that, for studies of similar design, approximately 90 subjects would be needed to show significant differences in PEQ scales at the $p < 0.05$ level (mean difference = 7.5; SD = 25; paired data; 2-tailed *t*-test; 80% power level).

It is unknown whether our results would have been more favorable toward the elastomeric liner if a cushion liner (vs. a locking or suspension liner) had been studied. Subjects tended to like the security of suspension provided by the locking pin, but difficulties properly aligning the pin and discomfort associated with pulling on the skin or "milking" of the limb due to pin suspension may have outweighed the suspension benefits. However, as with virtually every other reported study involving elastomeric liner systems, feedback from our subjects indicated that issues of skin irritation and perspiration were problematic. It has been suggested that regional weather conditions (humidity in particular) may contribute to the incidence of skin problems via perspiration effects [8].

Unfortunately, the majority of studies on elastomeric suspension liners have been conducted in locations with fairly similar weather conditions—the UK, the Netherlands, and Seattle—where temperatures are generally cool and mild and rain is frequent.

Subject feedback regarding discomfort with the Alpha® liner pulling on the skin (during sitting and walking) is of interest because gel liners are commonly thought to reduce shear forces transmitted to the residual limb. This topic requires further study.

Some researchers have reported that perspiration decreases after several weeks or months [5,6]. Feedback from our subjects did not support this, but we did not formally assess perspiration.

Overall, the balance between positive and negative aspects of elastomeric liner use remains to be resolved. The answer may well depend on patient characteristics, liner type, regional conditions, and previous experience with alternative socket systems.

Many subjects expressed desire to keep both study limbs. This feedback supports the finding that subjects generally responded positively to both limbs and suggests that access to more than one system may be preferable to having one prosthesis. Certainly this is common practice with footwear, where different shoe designs put different stresses on the feet and more proximal structures. Alternating between various well-fitting shoes may help prevent repetitive stresses from developing into chronic pain and injury. Like a shoe, the prosthetic socket directly interfaces with the person during ambulation. Alternating between limb systems might help preserve the integrity of the residual limb. Furthermore, as with shoes, the two socket systems studied offered differences such as appearance, security of suspension, and effort of donning and doffing that were important for some daily circumstances but not for others. The short-term economics of obtaining and maintaining two well-fitting prostheses may appear prohibitive, but it is worth considering whether the benefits of a multiple prosthesis situation for persons with a mature residual limb and stable body weight might outweigh the costs over the long term.

CONCLUSION

Subject preference and overall ambulatory activity heavily favored the Pe-Lite™ system over the Alpha® system. No differences were found in satisfaction, pain, or comfort results. Ambulatory intensity profiles during bouts of activity did not differ between conditions. Subject feedback for each system was both positive and negative, and illustrated the multiplicity of factors influencing the experience with a prosthetic socket. A summary of literature on elastomeric liners is provided to assist with interpretation and planning of future studies (**Appendix**, found in the online version only).

The results of this study and the questions that remain illustrate the need for further outcomes research by independent parties to provide context for evaluation, reference for clinical care, justification for third-party payer policy, and guidance for component improvement. Rigorous clinical trials are rarely conducted because the research is time-consuming, costly, and often not a funding priority. Our hope is that cooperative efforts to combine resources from federal, industry, third-party payer, and educational sources will provide means for such research.

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