

Novel Materials for Prosthetic Liners

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Existing materials for prosthetic liners tend to be thick and airtight, causing perspiration to accumulate inside the liner and potentially causing infection and injury that reduce quality of life. The purpose of this project was to examine the suitability of aerogel for prosthetic liner applications. Three tests were performed on several types of aerogel to assess the properties of each material. Moisture vapor permeability was tested by incubating four aerogel varieties with an artificial sweat solution at 37.0°C and less than 20% relative humidity for 24 hours. Two aerogel varieties were eliminated from the study due to difficulties in handling the material, and further testing proceeded with Pyrogel® in 2.0 and 6.0 mm thicknesses. Force distribution was tested by compressing samples under a load of 4448 N at a rate of 2.5 mm/min. Biofilm formation was tested in a high-shear CDC Biofilm Reactor. Results showed that 2.0 mm Pyrogel® blanket allowed $55.7 \pm 28.7\%$ of an artificial sweat solution to transpire, and $35.5 \pm 27.8\%$ transpired through 6.0 mm Pyrogel® blanket. Samples also outperformed the load-bearing capabilities of existing liner materials. No statistically significant difference was found between the two Pyrogel® thicknesses for either moisture vapor permeability or force distribution. In addition, biofilm formation results showed no change between the two Pyrogel® thicknesses. The breathability and load bearing properties of aerogel make it a suitable material for application to prosthetic liners.

Nomenclature

±	=	plus or minus
<	=	less than
>	=	greater than
λ	=	wavelength
°C	=	degrees Celcius
AODC	=	acridine orange direct count
ASTM	=	American Society for Testing and Materials
BS EN	=	British European Standards Specifications
CDC	=	Center for Disease Control
cm	=	centimeter
g	=	gram
HPC	=	heterotrophic plate counts
ISO	=	International Organization for Standardization
lbf	=	pounds of force
mL	=	milliliter
mm	=	millimeter
N	=	Newton
nm	=	nanometer
R2A	=	R2 agar
rpm	=	revolutions per minute
SLSL	=	Space Life Science Lab
TSB	=	Tryptic Soy Broth

I. Background and Theory

For amputees, the interface between the residual limb and the prosthesis is essential for fit and comfort. The interface is considered the most important aspect of the prosthesis since an amputee will not wear even the most advanced prosthetic if it is uncomfortable.¹⁻² This study investigates the application of aerogel as a novel material for prosthetic liners. Silica aerogel has several remarkable properties that would address current issues with prosthetic liner materials. Aerogel is lightweight; hydrophobic, preventing perspiration from being absorbed and causing odor; and breathable, providing pathways for moisture vapor transmission.³ The aerogel varieties used in this study are environmentally friendly and non-toxic. The Materials Safety Data Sheets indicate the dust from the aerogel can be a mild skin irritant,⁴ so samples were encased in nylon to prevent direct contact with skin.

Perspiration control is a major issue with existing prosthetics and liners. Physiological cooling methods including conduction, radiation, convection, and evaporation are limited in amputees due to reduced circulation and surface area,⁵ and liners can compound the problem. Current prosthetic socks and liners are airtight, causing perspiration to accumulate inside the liner.⁶ In fact, 60-70% of prosthesis users cite perspiration as an issue.⁷ The closed environment created by the prosthetic liner can lead to bacterial infections and allergic reactions, and over a third of prosthetic users have skin problems.⁸ Furthermore, constant skin hydration increases friction between the liner and the skin, causing irritation which can reduce wear time and impact normal activities.⁹ Ulcers, the most common skin ailment related to prosthesis use, often begin as abrasions caused by friction between the prosthetic liner and the residual limb.¹⁰

Multiple studies concluded that tremendous improvement is possible in perspiration control.^{5,11} However, there is limited literature available on the vapor transmission and moisture permeability of prosthetics and liners. Hachisuka, *et al* investigated the moisture permeability of socket and liner materials with distilled water.¹¹ In a clinical trial testing several different liner varieties, Visscher *et al* determined that GORE-TEX® vapor permeable liners reduced skin hydration and friction compared to other liners.⁹ GORE-TEX® is made of expanded polytetrafluoroethylene, which has a microporous structure that allows vapor to transpire while preventing the passage of liquid water.

In addition to perspiration control, novel prosthetic liners should distribute stress and friction loads evenly. Using prostheses causes the soft tissues of the residual limb to bear the load of body weight.¹² Liners cushion the transfer of loads from the soft tissue, while assisting the suspension of the prosthetic limb.¹³ In a gait analysis study,

Sanders, *et al* determined that the maximum axial force of a transtibial amputee is in excess of 800 N.¹⁴ A 550 N repeated load study by Covey *et al* of various commercial liners having a thickness of at least 4.1 mm and an averaging 7.5 mm indicated that liners had a residual displacement, or change in thickness, of at least 0.43 mm and averaging 0.75 mm.¹⁵

II. Materials and Methods

A. Moisture Vapor Permeability

Moisture vapor permeability testing of four aerogel varieties was conducted in a controlled environment chamber (Tabai Espec, Platinous Dry Lucifer, Osaka, Japan) at the Kennedy Space Center (KSC) Materials Science Division Physical Testing Lab. Test procedures were adapted from British European Standards Specifications (BS EN) 13726-1:2002 (Test methods for primary wound dressings – Part 1: Aspects of absorbency).¹⁶ Three varieties of aerogel blanket and one variety of aerogel beads were investigated: 2.0 mm Pyrogel® 2250, 6.0 mm Pyrogel® 6250, 10.0 mm Spaceloft® (Aspen Aerogels, Northborough, MA) and Nanogel® 102 beads (Cabot Aerogel, Billerica, MA). Circular samples of aerogel with a diameter of 39.9 mm were encased in nylon (Hanesbrands, Winston-Salem, NC) and sealed with waterproof tape (Johnson & Johnson, Skillman, NJ)(Fig.1). A solution of artificial sweat was prepared according to International Organization for Standardization (ISO) 3160-2:2003 (Watch-cases and accessories - Gold alloy coverings - Part 2: Determination of fineness, thickness, corrosion resistance and adhesion).¹⁷ 15 mL of solution were added to a flanged cylindrical test fixture having a contact area of 12.5 cm². Samples were attached to the test fixture with a hose clamp (Fig. 2) and incubated inverted in a controlled environment chamber at 37.0°C and less than 20% humidity for 24 hours. An independent digital thermo-hygrometer (Omega Engineering, Stamford, CT) was also placed in the chamber for an additional temperature and humidity reading. Three samples of Nanogel® were tested, and then a comparison of one sample of each Pyrogel® and Spaceloft® was conducted. Further testing was performed on the 2.0 mm and 6.0 mm Pyrogel® due to the difficulty of using Nanogel® and Spaceloft®.

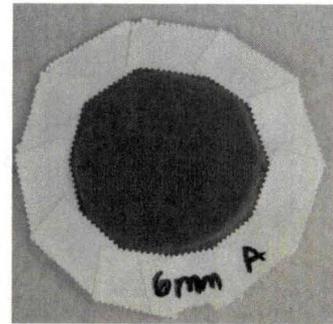


Figure 1. Prepared aerogel sample



Figure 2. Test fixture with sample

B. Compression

Compression testing of the Pyrogel® was performed on an Instron model 4500 (Instron, Norwood MA). A load of 4448N (1000 lbf) was applied to three 3.81 cm square samples of each thickness. Samples were compressed at a rate of 2.5 mm per minute.

C. Biofilm Formation

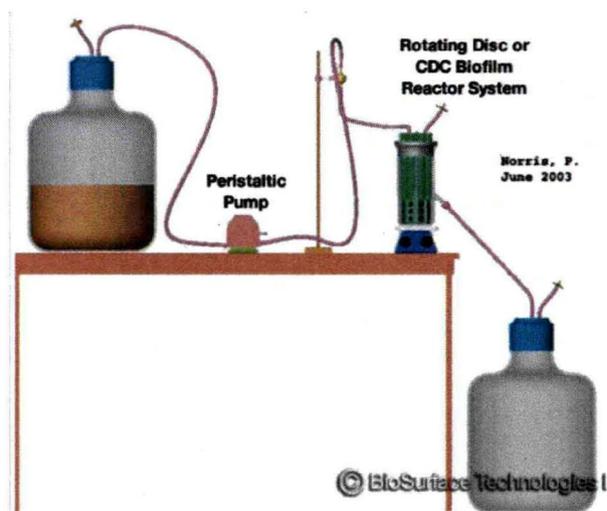


Figure 3. CDC Biofilm Reactor

Bacterial biofilms were cultivated on 12 coupons of each thickness of Pyrogel® in a CDC Biofilm Reactor (Fig. 3); (Biosurface Technologies Inc, Bozeman, MT) at the KSC Space Life Science Lab (SLSL) following ASTM International E 2562-07 (Standard Test Method for Quantification of a *Pseudomonas aeruginosa* Biofilm Grown with High Shear and Continuous Flow Using CDC Biofilm Reactor).¹⁸ The CDC biofilm reactor was set on a magnetic stir plate rotating at 180 rpm. During the first 24 hours of operation, the batch mode,

Pseudomonas aeruginosa was cultured in 500mL of 0.3g/L Tryptic Soy Broth (TSB) (BD, Difco, Franklin Lakes, NJ). For the following 24 hours, the reactor ran in continuously stirred tank reactor (CSTR) mode during which 0.1g/L TSB was added continuously at 11.7mL/min and excess fluid collected in the effluent tank. After 48 hours of operation, the reactor was harvested and each coupon underwent 10 mL of sterile water rinsing, 10 minutes of ice-water bath sonication, followed by 30 seconds of vortex. Each coupon was then analyzed for microbial biofilm content via heterotrophic plate counts (HPC) on R2A ((BD, Difco, Franklin Lakes, NJ) media, and Acridine Orange Direct Counts (AODC) via fluorescent microscopy with a Zeiss Axioskop epi-fluorescent microscope. HPCs indicate the amount of culturable cells via CFU/mL while AODC stains all cells for enumeration (cells/mL). In addition, the inoculum concentrations were also determined by HPCs on R2A media and by AODC. A spectrophotometer was employed to rapidly measure optical density at $\lambda=590$ nm to assist with the determination of initial cellular concentration.

III. Results and Discussion

A. Moisture Vapor Permeability

The results of moisture vapor permeability testing are shown in Table 1. At least one-third of the moisture vapor evaporated through the 2.0 mm Pyrogel®, at least 16% evaporated through the 6.0 mm Pyrogel®, and at least 84% evaporated through the Nanogel®. Standard deviation and range are not available for the samples of 10.0 mm Spaceloft® because only one sample was tested. Spaceloft® was eliminated from further testing since it was significantly more difficult to use. Nanogel® was also eliminated from the study due to difficulty of use. Samples of existing liner materials were not able to be obtained in a timely manner.

Late in testing, it was discovered that one of the test fixtures was not functioning properly and solution was leaking during incubation. Data points where leaking in the chamber was observed and documented have been removed from the study. The faulty test fixture may have failed in other trials, but the leaked solution may have evaporated before the samples were removed from the chamber and so the failure was not known. The non-uniform performance between the test fixtures could account for the high variance within the 2.0 mm and 6.0 mm Pyrogel® groups. The difference between the Nanogel® beads and the different types of blanket tested can be explained by the large amount of space between the beads, allowing for solution to evaporate more freely than through the denser blankets.

Table 1. Moisture vapor permeability

Material	Moisture Vapor Lost (g)	Moisture Vapor Lost (%)
Nanogel® Beads	-12.8	84.7
	-12.3	86.9
	-12.9	85.7
2.0 mm Pyrogel®	-13.4	88.4
	-5.19	34.8
	-6.55	43.8
6.0 mm Pyrogel®	-2.43	16.1
	-3.48	23.0
10.0 mm Spaceloft®	-10.1	67.3
	-6.27	41.4

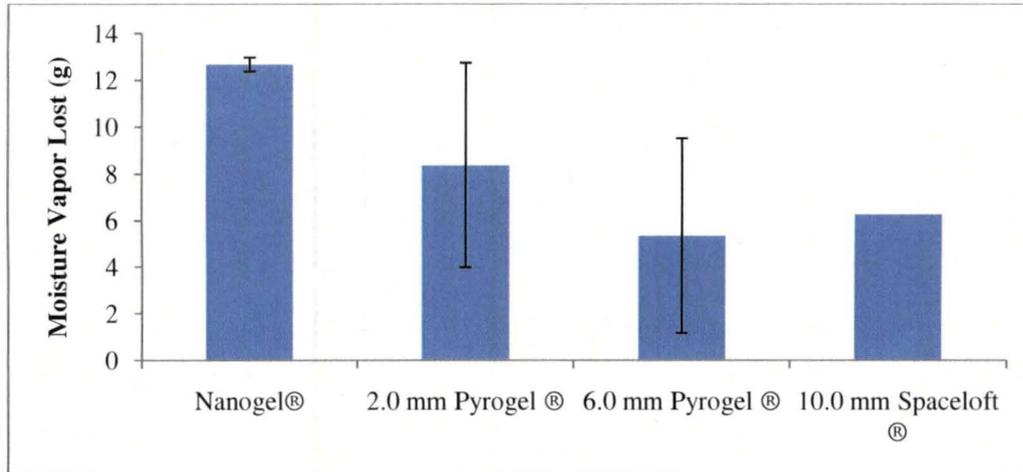


Figure 4. Moisture vapor loss in grams

B. Compression

The findings from the compression test are shown in Table 2, and force displacement curves for the Pyrogel® samples are seen in Fig. 5. At 1000 N, slightly greater than the estimated force generated by a transtibial amputee during ambulation, the samples had less than 78% strain, and an average of 58.5% strain. The loss in thickness following compression with a maximum load of 4448 N for the 2.0 mm samples was -0.466 ± 0.03 mm or $-20.9 \pm 1.02\%$, and for the 6.0 mm samples the loss in thickness was -0.660 ± 0.27 mm or $-10.8 \pm 4.33\%$. The variance between the two groups was low, suggesting that regardless of the thickness of Pyrogel® used the loss in thickness will be about the same. Previous studies indicated that after repeated compression with a 550N load, existing liner materials have a residual displacement of -0.75 mm on average.¹⁵ Aerogel therefore performs as well as or better than the average prosthetic liner in force distribution, even under a load eight times greater than those previously tested.

Table 2. Compression test data

Material	Initial Thickness (mm)	Compression at 1000 N (mm)	Strain at 1000 N (%)	Loss in Thickness (mm)	Loss in Thickness (%)
2.0 mm Pyrogel®	2.11	1.74	77.4	-0.432	-20.5
	2.18	1.32	51.9	-0.483	-22.1
	2.39	1.45	44.6	-0.483	-20.2
6.0 mm Pyrogel®	5.94	3.78	64.5	-0.356	-5.98
	6.02	3.64	60.2	-0.737	-12.2
	6.22	3.47	52.2	-0.889	-14.3

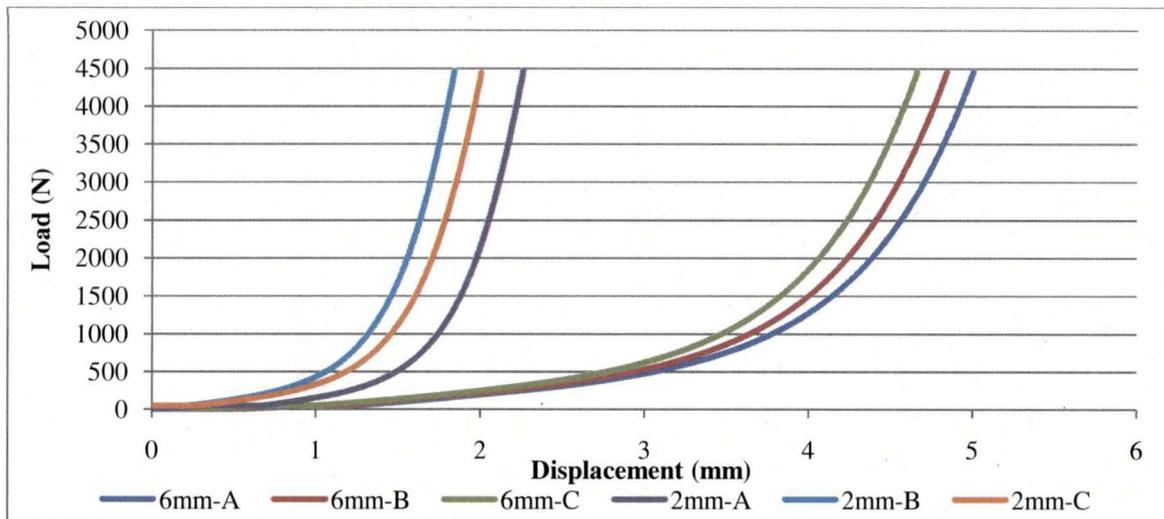


Figure 5. Load versus displacement curve for 2.0 mm and 6.0 mm Pyrogel®

C. Biofilm Formation

Results from the HPCs and AODCs indicate that no change occurred in microbial content between the 2 mm or 6 mm Pyrogel® samples under the high-shear conditions of the CDC Biofilm Reactor. Alternative test methods will be explored for future analysis.

IV. Conclusions

Preliminary investigations of the vapor permeability and load bearing properties indicate that the use of aerogel blanket as an alternative to existing prosthetic liners is favorable. The 2.0 mm Pyrogel® blanket allowed over 34% of an artificial sweat solution to evaporate through it and its load-bearing capabilities are comparable to existing liners even under eight times the load. Future testing on aerogel blankets for application to prosthetic liners would include repeated or cyclic load bearing tests, frictional load bearing tests, additional testing on breathability with existing materials and uniformly performing test fixtures, additional methods for evaluating microbial presence, and designing an aerogel liner prototype for clinical testing.

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References

- [1] Marks, L. J., and Michael, J. W., "Artificial limbs," *Biomedical Journal*, Vol. 323, No. 7315, 2001, pp. 732-735.
- [2] Fairley, M. "Seeking the perfect marriage in prosthetic liners." *The O&P Edge*, Vol. 7, No. 2, 2008, URL: http://www.oandp.com/articles/2008-02_01.asp [cited 12 July 2011]
- [3] Aspen Aerogels, "Pyrogel® 6250 Data Sheet," 2010, URL: http://www.aerogel.com/products/pdf/Pyrogel_6250_DS.pdf [cited 15 July 2011]
- [4] *Pyrogel® 2250, 3250, 6250, 9250*; MSDS No. ____; Aspen Aerogels; Northborough, MA, 10 April 2008. http://www.aerogel.com/products/pdf/Pyrogel_x250_MSDS.pdf [cited 15 July 2011]
- [5] Klute, G. K., Rowe, G. I., Mamishev, A. V., and Ledoux, W. R., "The thermal conductivity of prosthetic socks and liners," *Prosthetics and Orthotics International*, Vol. 31, No. 3, 2007, pp. 292-299.
- [6] Uellendahl, J. E. "Prosthetic socks and liners." *First Step: A Guide for Adapting to Limb Loss*. Amputee Coalition. Vol. 2, 2001, URL: http://www.amputee-coalition.org/first_step/firststepv2_s2a09.html [cited 12 July 2011]
- [7] Hachisuka, K., Nakamura, T., Ohmine, S., Shitama, H., and Shinkoda, K., "Hygiene problems of residual limb and silicone liners in transtibial amputees wearing the total surface bearing socket," *Archives of Physical Medicine and Rehabilitation*, Vol. 82, No. 9, 2001, pp. 1286-1290.
- [8] Dudek, N.L., Marks, M.B., Marshall, S.C., and Chardon, J.P., "Dermatologic conditions associated with use of a lower extremity prosthesis," *Archives of Physical Medicine and Rehabilitation*, Vol. 86, No. 4, 2005, pp. 659-663.
- [9] Visscher, M. O., Robinson, M., Fugit, B., Rosenberg, R. J., Hoath, S. B., and Wickett, R. R., "Amputee skin condition: occlusion, stratum corneum hydration and free amino acid levels," *Archives of Dermatological Research*, Vol. 303, pp. 117-124.
- [10] Meulenbelt, H.E., Geertzen, J.H., Dijkstra, P.U., and Jonkman, M.F., "Skin problems in lower limb amputees: An overview by case reports," *Journal of the European Academy of Dermatology and Venereology*, Vol. 21, No. 2, 2007, pp. 147-155.
- [11] Hachisuka, K., Matsushima, Y., Ohmine, S., Shitama, H., and Shinkoda, K., "Moisture permeability of the total surface bearing prosthetic socket with a silicone liner: Is it superior to the patella-tendon bearing prosthetic socket?" *Journal of UOEH*, Vol. 23, No. 3, 2001, pp. 225-232.
- [12] Jia, X., Zhang, M., and Lee, W. C., "Load transfer mechanics between trans-tibial prosthetic socket and residual limb—dynamic effects," *Journal of Biomechanics*, Vol. 37, 2004, pp. 1371-1377.
- [13] Klute, G. K., Glaister, B. C., and Berge, J. S., "Prosthetic liners for lower limb amputees: A review of the literature," *Prosthetics and Orthotics International*, Vol. 34, No. 2, 2010, pp. 146-153.
- [14] Sanders, J.E., Daly, C.H., Cummings, W.R., Reed, R.D., and Marks, R.J., "A measurement device to assist amputee prosthetic fitting," *Journal of Clinical Engineering*, Vol. 19, No. 1, 1994, pp. 63-71.
- [15] Covey, S.J., Muonio J., and Street, G.M., "Flow constraint and loading rate effects on prosthetic liner material and human tissue mechanical response," *Journal of Prosthetics and Orthotics*, Vol. 12, No. 1, 2000, pp. 15-41.
- [16] BS EN 13726-1:2002: Test methods for primary wound dressings – Part 1: Aspects of absorbency.
- [17] ISO 3160-2:2003: Watch-cases and accessories - Gold alloy coverings - Part 2: Determination of fineness, thickness, corrosion resistance and adhesion
- [18] ASTM Designation 2562-07: Standard Test Method for Quantification of *Pseudomonas aeruginosa* Grown with High Shear and Continuous Flow using a CDC Biofilm Reactor.

Experiences at KSC – Carolina Ragolta

In addition to working on my project, I had many other learning experiences during my internship at Kennedy Space Center (KSC). I began with rotations in the Materials Science Division and toured labs and facilities throughout KSC. I was astounded by the array of jobs that the scientists perform, and how every task contributes greatly to mission success. I learned about metrology, failure analysis, corrosion, and physical testing, while getting my hands dirty making a carbon fiber bucket drum in the Prototype Lab. I also spent a couple days with the Biomedical Engineering group learning about physiological testing, space shuttle equipment calibration, and life support projects.

In addition to the rotations, I was able to go on several tours of various sites on KSC and Cape Canaveral Air Force Station (CCAFS). Touring the launch complexes on ICBM Road at CCAFS brought the history of the space program to life. I also toured Launch Complex 39A, getting a close look at space shuttle Atlantis before her final voyage and speaking with Mission Specialist Sandy Magnus. I visited Flight Crew Equipment, where I learned about the process of preparing all the tools the astronauts require during their mission. I was also able to spend a day in Firing Room 4 listening in on the Payload Interface Verification Test (IVT) for STS-135. In the final days of my internship, I toured the flight deck of space shuttle Endeavour as well as the Mobile Launch Platform (MLP) for the Ares rockets.

Among all the opportunities I had this summer, there is one experience that far outshines the rest: the chance to witness the last launch of the Space Shuttle program. I had never seen a launch in person before, and the opportunity to bring my family with me to watch on the Causeway only a few miles away was truly unforgettable. It has been humbling to be at KSC during this period of transition, looking with hope towards the future while standing in the shadow of giants. I am honored to have spent my summer as an intern at KSC, and I sincerely appreciate the time and talents of all those who made experience so memorable.