REDUCING SKIN SHEAR & FRICTION FORCES FOR ORTHOTIC & PROSTHETIC USERS. DEVELOPMENT OF THE BURSATEK CONCEPT.

Adrian A. Polliack, Ph.D. and Samuel Scheinberg, M.D.
SAM Medical Products
Portland, Oregon

The treatment of pressure sores and related skin problems due to extrinsic factors such as pressure, shear, friction and moisture at the residual limb-socket and limb-orthosis interface is often debilitating, and time-consuming for both patient and practitioner. Aside from this medical challenge, the economic costs borne with the associated time off work or work disability, add to the already strained psychosocial challenges placed on both the patient and family.

The biomechanics of the coupling between the musculoskeletal residual limb and the lower limb prosthetic socket is an important factor for socket fit (1). Socket fabrication and fit is a highly refined process relying on the prosthetist's skill and experience. It refers to achieving proper biomechanical alignment and load transfer while providing user support, comfort, safe suspension and aesthetics (1,2). Despite major technology improvements to lower limb prosthetic components, socket fit still remains a key issue, especially since the residual limb soft tissues are not suited for loading (3,4). As a result of pressure, shear forces, friction and pistoning, amputees often experience skin breakdown near bony prominences such as over the anterior tibial surface or near the fibular head. Residual limb skin problems typically include discomfort, pain, sweat pooling, edema, contact dermatitis, blisters, cysts, verrucous hyperplasia, pressure ulceration and associated infection such as folliculitis (4-10). These latter conditions can make prosthesis use difficult or preclude its use until the soft tissues are viable once again.

It is clear that friction between the residual limb and the prosthetic socket liner leads to certain effects. On the one hand, shear forces and the friction it can produce on the skin, lead to tissue distortion and damage (11). On the other hand, pressure and shear forces at the residual limb-socket liner interface assist in supporting and suspending the load of the prosthesis, while minimizing slippage during standing and ambulation.

The Bursatek® bandage presented in this study has been modeled after the body's bursal sac, a structure comprising a sac of synovial membrane filled with fluid, and specifically able to relieve shear and friction forces between structures.

Healthy, able-bodied female subjects were selected for testing. The subjects were recruited from established contacts in the local Newport, Oregon area. The skin over the medial tibial cortex, adjacent to the tibial crest, was selected as the site of testing, as used by Sanders et al (3). This represents a flat and bony region that is susceptible to skin breakdown for amputees using a transtibial prosthesis (4, 12-13). Using the level of the tibial tuberosity as a zero reference, tests were performed 10 cm distal to this reference point (14) (Figure 1).

All subjects shaved their legs including the area of the test site on the morning of the test. They were instructed to wash their legs with tap water after shaving, and directed not to apply any lotions at or near the test site. All subjects were instructed not to perform exercise or strenuous activity during the 3-hour period prior to the test session, so that body temperature would remain at baseline levels. They entered the clinical test room 45 minutes prior to the scheduled test time so acclimatization to the room temperature and humidity levels could occur.

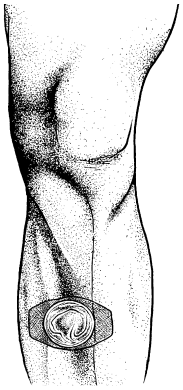

Figure 1. A schematic representing the Bursatek bandage over the medial tibial cortex site at a level approximately 10cm distal to the tibial tuberosity.

The skin test site was prepped with distilled water and wiped dry with a soft dry cloth to remove any dust, dirt, oils or moisture (15). The test room temperature was maintained at 22°C (72F) and at a relative humidity of between 40-50% for all tests (15). Each subject sat on a raised, cushioned chair with one leg extended in front, supported on a lower platform.

Foam wedges and platform adjustment maintained knee flexion at 5° as measured by a goniometer (4) (Figure 10). A level was used to position the medial tibial cortex to an exact level plane. The test site was located by measurement and inspection and was tip-marked using a fine indelible ink pen, allowing for allowing for all tests to be repeated at the exact same location. Skin friction force was measured using a custom apparatus designed by the investigators (Figure 2).

This apparatus is comprised of a frame with an attached ball-bearing slide block, to which a vertical rod was secured. A lightweight, hollowed, rigid plastic end-probe (indenter) incorporated a cylindrical brass bushing which fit flush over the end of the vertical rod (Figure 3). This allowed the end-probe to glide freely in the normal plane. The end-probe tip diameter was 1cm. Normal load was achieved by placing weights on top of the end-probe (Figure 3 and 4). A weight rack attached on the side of the apparatus was connected over a pulley to the vertical rod by a cable. A load applied to this side rack applies a shear force to the end-probe.

For each test, a 228g (0.506 lb) axial load was applied to the skin test site via the end probe (Figure 8 and 10). The end probe was placed on and exactly perpendicular to the medial tibial cortex (Figure 10). Small incremental weights (between 10-20g [0.022-0.044 lbs]) were carefully applied to the side rack by the investigator in order to create a shear load (Figure 2-4). As weights were added, a second investigator observed for movement of the indenter. This second investigator was unaware of the timing or amount of additional weight added to the side rack. A 5-second pause was made after each weight addition to allow observation for movement. If no movement was observed, another weight was added. At the instant movement of the end-probe was observed, the test was stopped. The coefficient of friction (μ) was then calculated as the ratio of the shear load (F) to the normal load (N).

Three tests were performed on the skin test site. After each test, the loading probe was removed and then re-applied in the same location to begin the next test. The skin test site was prepped each time before the test was repeated by cleaning with water, drying the site and waiting 2 minutes. Using the loading probe, three additional tests were performed with the Bursatek bandage attached to the same skin test site (a single bandage was used in this step). It was applied prior to the first test and removed only after all three tests were completed.

Twenty-one able-bodied female subjects were recruited for this study. Six of these subjects were omitted from the study due to patient non-compliance, contrary to protocol. Table 1 shows a summary of the data collected from 15 subjects. Mean age was 35 years (range 18-40), with an mean weight of 151 lbs (range 125-241) and a height of 65" (range 62-68). The temperature mean was 73°F with a mean relative humidity of 49%. No subjects showed any signs of sweating or discomfort during the tests.

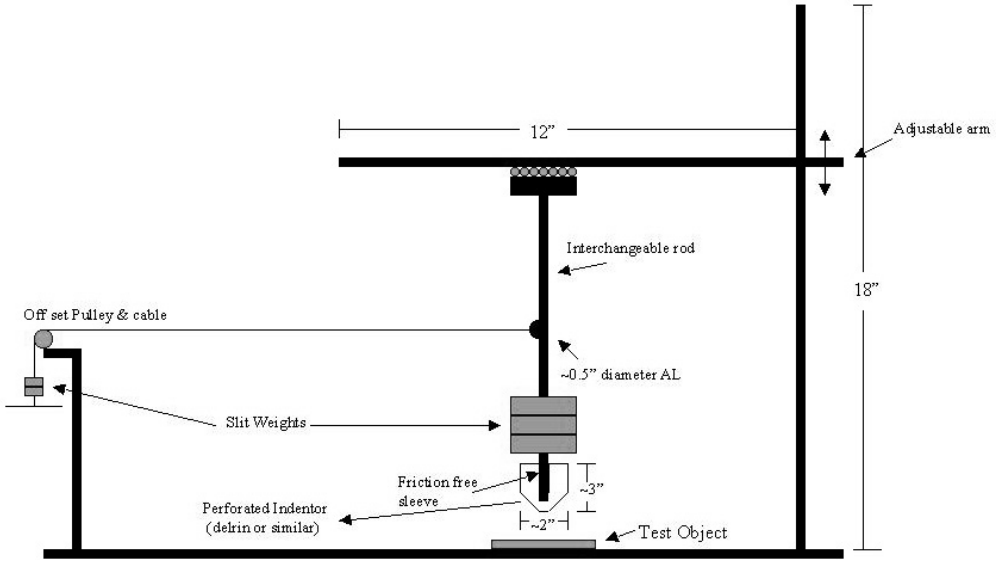

Figure 2: A schematic of the custom-made friction measurement apparatus

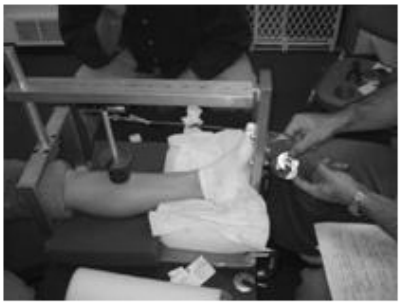

Figure 3 (left): Subject testing. Two investigators sat perpendicular to each other. The one investigator applied small incremental weights to create a shear force (right side of photograph) while the other observed a scale for movement (top of photo).

Figure 4 (right): The end probe indenter contacting the medial tibial cortex at a perpendicular angle during a test. A 228g axial load was achieved by placing a weight on top of the end probe.

The mean coefficient of friction measured on the skin site was 0.327 (SD 0.078). The mean coefficient of friction measured with the Bursatek bandage over the skin site location was 0.225 (SD 0.090) or 31% lower. A two-tailed, paired T-test indicated a statistically significant difference of $P<0.001$.

SUBJ NO.	TESTING DATE	AGE	WEIGHT (lbs)	HEIGHT (inches)	RACE	TEMP (F)	HUMIDITY %RH	Mean SKIN CoF	Mean BlistoBan CoF
4	6/10/2003	33	168	63	Native American	75	46	0.478	0.349
5	6/10/2003	34	125	63	Caucasian	77	45	0.300	0.239
7	6/10/2003	33	135	65	Caucasian	77	45	0.349	0.347
8	6/10/2003	39	159	66	Caucasian	75	45	0.487	0.432
9	6/12/2003	40	241	64	Caucasian	71	54	0.327	0.248
11	6/12/2003	30	125	61	Hispanic	73	50	0.373	0.250
12	6/12/2003	37	140	67	Caucasian	73	49	0.378	0.210
13	6/12/2003	31	150	62	Black	73	48	0.264	0.199
14	6/12/2003	27	230	66	Caucasian	73	51	0.253	0.149
15	6/12/2003	36	130	68	Caucasian	73	46	0.321	0.231
16	6/12/2003	34	220	66	Native American	73	47	0.259	0.146
17	6/12/2003	25	135	66	Caucasian	73	47	0.340	0.165
18	6/12/2003	39	148	62	Asian	73	47	0.349	0.249
19	6/12/2003	18	130	66	Caucasian	71	53	0.208	0.153
20	6/12/2003	18	140	66	Caucasian	71	52	0.242	0.095
n=15	**AVERAGES**	**34.9**	**150.9**	**64.8**		**73.3**	**48.6**	**0.327**	**0.225**
	Std Dev	**12.82**	**44.12**	**2.02**		**1.91**	**3.05**	**0.078**	**0.090**
	RANGES	**18-40**	**125-241**	**62-68**		**71-77**	**45-54**	**0.208 - 0.478**	**0.095 - 0.432**

Table 1: Summary of clinical tests on able-bodied female subjects

This study involved the measurement of friction over the medial tibial cortex with the Bursatek device in place and without it. Data were successfully collected from fifteen female subjects who met the protocol requirements. Results indicated that the Bursatek device reduced the coefficient of friction at the medial tibial cortex by 31% compared to skin alone, which is a statistically significant finding. Moreover, intra-variation of normal and shear load measures between tests for each subject were small and consistent, which validated the reproducibility of the test procedure and the sensitivity of the apparatus. Overall, the data collected from 15 able-bodied female subjects demonstrated feasibility of the Bursatek bandage in reducing the nominal skin coefficient of friction.

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