Interface pressures and shear stresses: sagittal plane angular alignment effects in three trans-tibial amputee case studies

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Abstract

Interface pressures and shear stresses at different sagittal plane angular alignment settings were measured on 3 trans-tibial amputee subjects ambulating with patellar-tendonbearing total contact prostheses. Substantial socket-shank angular alignment modifications in the sagittal plane had minimal effect on stance phase peak interface pressures, though more substantial effects on stance phase peak resultant shear stresses. No consistent trend of a greater stress at misaligned vs nominally aligned settings was identified. Changes in interface stresses from session to session tended to be greater than those for different alignment settings, suggesting that subjects compensated well for misalignments but less well for session differences.

Introduction

The sagittal plane angular alignment of a lower-limb prosthesis, the angular position of the foot relative to the socket in the sagittal plane, influences the distribution of mechanical stress at the stump-socket interface. However, data reported in the literature vary as to the degree of influence of the alignment on interface stresses. Pearson *et al.* (1973) found that 10 degree flexion adjustments (with no translational compensation) on one subject resulted in pressure changes of 99% (285kPa), 51% (135kPa), 26% (26kPa), and 40% (21kPa) for

All correspondence to be addressed to J. E. Sanders PhD, Associate Professor, Department of Bioengineering, Harris 309, Box 357962, University of Washington, Seattle WA 98195, USA Tel: (+1)206 685-8296. Fax: (+1)206 543-6124 E-mail: sanders@limbs.bioeng.washington.edu the anterior distal tibia, patellar tendon, lateral tibial condyle, and medial tibial condyle sites respectively. Ten degree extension adjustments resulted in pressure changes of 42% (150kPa), 35% (83kPa). 0% (0kPa), and 40% (21kPa), However, Appoldt et al. (1968) on 2 transfemoral amputee subjects found only a small reduction (complete quantitative data not provided) at every test location for 5 degree flexion and extension adjustments (with translational compensation). Winarski and Pearson (1987), on trans-tibial amputee subjects, found 30% (67kPa) pressure changes for 1 subject and 30% (28kPa) changes for a second subject at a patellar tendon site when 10 degree flexion adjustments were made (with no translational compensation). Ten degrees of extension produced changes of 53% (80kPa) and 54% (46kPa) in the same 2 respective subjects.

The purpose of this research was to extend from and add to this database of interface stressalignment investigations. An intent here is inclusion of resultant shear stress data with pressure in the analysis so as to determine if the changes of interface resultant shear stresses to alignment follow similar patterns to those for pressures collected at the same site. It was also intended to compare interface pressure sensitivity to alignment with results reported in the literature adding data to analysis of this important issue.

Methods

Subjects

All subjects were male unilateral trans-tibial amputees who regularly wore total contact patellar-tendon-bearing (PTB) prostheses with sleeve suspensions and had been amputees for at least 1 year. Subject No.1 was 23 years of age,



Fig. 1. An instrumented prosthetic socket. Transducers are positioned in mounts at anterior-medial proximal, anteromedial distal, lateral and posterior proximal sites. Dummy transducer plugs fill mounts at sites that are not monitored.

of mass 65.9kg, and had his right limb amputated 4 years prior to this study as a result of a gunshot wound. His stump was very bony with little soft tissue especially distally and was of length 14.6cm from the patellar tendon to the distal end. He regularly used a PTB total contact socket with a 3-ply wool sock, a Pelite" liner, and a latex or Neoprene sleeve suspension. Subject No.2 was 25 years of age, of mass 68.2kg, and had his right limb amputated 8 years prior to this study as a result of a motorcycle accident. He had a prominent medial distal osteophyte, and his stump was of length 15.2cm. He regularly used a PTB total contact socket with a nylon sheath, a Pelite liner, and a Neoprene sleeve suspension. Subject No.3 was 46 years of age, of mass 86.4kg, and had his right limb amputated 8 years prior to this study as a result of a climbing accident. He had excessive superficial tissue in his stump, a prominent peroneal nerve, and a deep cleft in the antero-distal suture line. He regularly used a PTB total contact socket with a nylon sheath, a Pelite liner, and supracondylar suspension.

Instrumented prostheses

An instrumented prosthesis was designed and manufactured for each subject by certified prosthetists using computer-aided design (ShapeMaker[™]) and manufacturing methods. Sockets were designed to be slightly smaller than those normally used by the subjects because no socks or sheaths were worn with the instrumented prosthesis. Only a Pelite liner, made during vacuum-forming of the socket, was between the socket and stump and it was bonded with a thin layer of epoxy to the inside of the socket. At selected, relatively flat, locations on the anterior, lateral, and posterior surfaces of each socket, holes of diameter 8.73mm were drilled through the socket wall and Pelite liner. Mounts, carefully aligned to be perpendicular to the inside socket surface, were fixed to the outside of the socket with epoxy. The mounts held custom-designed transducers (Sanders and Daly, 1993) of diameter 6.35mm so that their sensing surfaces were flush with the inside Pelite liner surface (Fig. 1). Each transducer surface was a Pelite disk of the same thickness as the surrounding Pelite, thus no foreign material was introduced to the stump. The transducers measured shear stresses in 2 perpendicular directions in the plane of the transducer surface as well as pressure applied perpendicular to the surface. During a data collection session, stresses were monitored at 4 of 7 possible locations at a time (Table 1). It was not possible to monitor all 7 sites simultaneously because of a limited number of channels in the data acquisition system. Mounts of unmonitored sites were filled with dummy transducer plugs.

The prosthesis was completed with a Berkeley alignment unit, an instrumented pylon (Sanders *et al.*, 1994), and a Seattle^T LightFoot. Because of a limited number of data acquisition channels

Site	Abbr.	Description of location
Anterior Lateral Proximal	ALP	at the level of the tibial tubercle, lateral side
Anterior Medial Proximal	AMP	at the level of the tibial tubercle, medial side
Anterior Lateral Distal*	ALD	distal stump, anterior tibial border, lateral side
Anterior Medial Distal	AMD	distal stump, anterior tibial border, medial side
Lateral	L	femoral neck, ~2cm distal distal to the fibular head
Posterior Proximal	PP	mid-calf, on the posterior longitudinal midline
Posterior Distal	PD	distal calf, on the posterior longitudinal midline

Table 1. Transducer locations,

*for Subject No.3, this site was located in the mid-limb region because of excessive scar tissue more distally.

on the computer data collection system (16 channels total), only 4 of 6 shank forces and moments were monitored simultaneously in a session. Axial force was measured in all sessions. Data were collected at a 125Hz sampling rate. The Berkeley alignment unit was modified to include an apparatus for measurement of angular alignment changes (Sanders et al., 1990). The apparatus added minimal mass to the prosthesis. An instrumented prosthesis weighed approximately 3.1kg, typical of a fitting prosthesis (most of the mass was in the Berkeley alignment unit). Subject No.2 used a suprapatellar strap attached to an elastic belt to facilitate suspension. Subject No.1 used a latex sleeve suspension. Subject No.3 used a latex sleeve suspension and supracondylar socket design.

Data collection sessions

Trials were carried out and data collected with the sagittal plane angular alignment at 1 of 3 settings for each subject. Misalignment settings were selected to be the maximum of the available range on the Berkeley unit but within safety ranges acceptable to the research prosthetists. No translational compensations were made for the flexion and extension adjustments. During each trial, the subject walked the length of an 18m hallway at a cadence controlled to between 94 and 99 steps/min using a metronome. The selected value was the closest to the subject's normal self-selected walking rate. Data collection was initiated 1 step after walking was initiated and lasted for 8 s. At least 4 consecutive trials were conducted at each alignment setting, thus the alignment was changed at least twice over the course of a data collection session. Alignment ordering was randomly selected. As many sessions as possible were conducted on each subject over a 1 month period, with a minimum of 2 sessions on each subject. The purpose of the 1 month time restriction was to limit effects of stump changes on socket fit. It was expected that session effects on interface stresses would not be as drastic as alignment effects thus the 4 sites selected for monitoring in each session were selected randomly rather than systematically.

Data processing

Data from the transducers and instrumented shank were converted into interface pressures

Table 2. Angular alignment changes for each subject.

Plantarflexion	Dorsiflexion
-12 degrees	4 degrees
-9 degrees	5 degrees
-5 degrees	8 degrees
	Plantarflexion -12 degrees -9 degrees -5 degrees

and shear stresses and shank forces and moments using calibration data. For the transducers, resultant shear stress magnitudes, which were the resultant stresses in the plane of the interface, and pressure magnitudes at each transducer site were calculated. Only data from complete steps were included in the analysis and the first step in a trial was not included because of possible acceleration effects on the results. Steps in which instrumentation problems occurred were not included in analysis. Steps were segmented into stance and swing phases based on a slope threshold of 0.63N/ms for heel contact and -0.63N/ms for toe-off in the shank axial force channel. For stance phase of each step, the peak magnitude pressures and resultant shear stresses were determined. The basis for using the peak magnitude pressure and resultant shear stress data in analysis is that it is expected that these are threatening times for stump soft tissues and thus are of strong clinical interest.

Results

Alignment deviations were at least 4 degrees in each direction (plantarflexion, dorsiflexion) for all subjects. Values reflect the maximal acceptable safety ranges for each subject as established by the research prosthetists. In Table 2 angles are specified relative to the centre of rotation for sagittal plane adjustments on the Berkeley alignment unit at the nominal (zero) alignment setting for each subject.

The coefficient of variance (defined as the standard deviation/mean)(COV) was, in general, less for pressure than for resultant shear stress. For pressure, COV was typically greater than **10% for antero-medial proximal and antero**lateral proximal sites (Table 3) but less than 10% at remaining sites. There was not a trend of greater COV for misaligned vs nominally aligned settings.

Alignment changes had minimal effect on pressure maxima and resultant shear stress maxima at most of the sites for most of the alignment modifications. Data shown in Figure 2 are typical. Absolute value pressure changes

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Table 3. Interface stress magnitudes and coefficients of variance.

Stance phase maximal magnitudes (kPa) and coefficients of variance (%). Site abbreviations are listed in Table 1. Pressure

Subj.		No. of	Al	MP	A	LP	AN	4D	AL	.D	1		Р	Р	Р	D	A	x
Sess	Alig	steps	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV
1.1	zero	20	88.0	22.9%	92.4	6.1%			100.9	5.6%			119.4	10.2%			860.2	4.4%
	dflex pflex	20 19	60.2 89.7	23.0% 16.0%	92.9 88.9	10.5% 7.5%			97.7 100.7	5.4% 6.1%			111.4	6.9% 9.4%			813.3	5.2% 3.4%
1.2	zero	20	66.6	11.5%	114.1	7.0%			87,7	4.6%					72,2	2.9%	796.9	3.2%
	dflex	20	67.0	13.8%	117.9	15.4%			88.8	7.2%					68.5	7.0%	792,1	2.5%
	pflex	20	78.2	15.0%	112,9	7.9%			89,1	8.1%					69.4	3.8%	774.9	2.5%
2.1	zero	16			57.4	10.0%			98.0	6.2%			92.2	9.1%	83,9	9.9%	784.8	3.0%
	dflex	17			60.0	8.4%			98.0	5.1%			93,9	6.1%	79.7	5.4%	758.3	3.5%
	pflex	16			73,1	13.9%			85.3	8.3%			97.6	4.8%	93,2	4.1%	822,7	3.9%
2.2	zero	10					53.4	21.2%	98.6	3.7%	101.1	3.3%	101.2	4.5%			798.t	3.4%
	dflex	12					53.2	15.6%	95.3	6.2%	106.0	5.4%	112.3	4.9%			784.6	2.3%
	pflex	11					52.5	9.5%	93.4	9.8%	105.9	6.0%	103.1	3.2%			8.39.4	3.5%
2,3	zero	19	91.6	9.0%	97,7	2.8%							108.5	5.0%	82.9	3.9%	783.3	3.0%
. /	dflex	23	98.2	12.2%	97.5	4.8%							111.9	8.1%	79.5	5.0%	778.6	3.2%
	pflex	26	13.5	10.0%	91.7	5.3%							111.0	2.9%	102,4	3.5%	862.1	2.8%
3,1	zero	5	58.0	5.2%			124.8	6.7%			183,5	3.2%	99,0	2.1%			926.1	3.4%
	dflex	5	70,1	6.8%			124.9	2.6%			166.5	4.1%	93.2	3.3%			929.7	3.5%
	pflex	13	51.4	4.3%	-		130.1	3.7%			185.9	5.6%	104.0	2.4%			950.0	1.8%
3.2	zero	8			23.7	26.7%			111.9	2.2%			78.3	1.9%	79.1	3.4%	930.9	2.6%
	dflex	25			28.2	28.9%			105.5	2.9%			78.8	2.8%	77.5	2.7%	905.0	2.3%
	pflex	1			25.9	37.1%			121.7	6.2%	-	_	85.1	1.6%	83,4	2.8%	933,2	1.4%
3.3	zero	16			33.1	20.3%	154.1	3.6%		1	164.3	9.4%			82.0	3.0%	950,4	2.4%
	dflex	16			29.9	17.9%	134.0	5.1%			156.4	4.8%			76.0	3.9%	882.1	2.6%
-	pnex	1/			31.2	30.3%	141.0	5.8%		-	1/1.2	8.5%	-		89.4	3.2%	969.8	3.3%
3.4	zero	16	52.8	5.0%	35.9	20.4%					159.3	4.2%	107.3	2.0%			931.3	2.2%
	dflex	16	59.1	6.5%	38,1	23.8%					148.3	4.7%	99,3	2.0%			875.5	2.7%
	ptlex	20	48.9	5.5%	36,6	14.5%					167.0	4.5%	110,8	2.2%		_	946.6	2.2%

Resultant shear stress

Subj.		No, of		lo, of AMP		ALP		AMD		LD		L	PP		I	PD
Sess	Alig	steps	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV	Mag	COV
1,1	zero dflex pflex	20 20 19	7.7 8.0 8.2	33.0% 15.7% 23.4%	13.5 13.7 13.0	10.3% 8.7% 12.5%			31.7 33.1 32.6	9.5% 6.3% 9.5%			40.7 38.0 39.8	3.9% 6.2% 3.6%		
1,2	zero dflex pflex	20 20 20	8,2 6,4 10,8	30.6% 31.5% 32.8%	18,9 20,6 17,4	17.0% 18.3% 18.7%			29.2 29.0 27.7	16.1% 12.2% 20.4%					8.1 7.7 8.5	6.6% 7.3% 9.4%
2,1	zero dflex pflex	16 17 16			22,1 22,7 19,6	18.7% 24.2% 16.8%			29.9 29.3 39.6	12.9% 17.3% 9.7%			35.9 40.4 36.4	6.8% 9.6% 10.3%	23,5 16,0 15,4	46.7% 59.6% 41.8%
2.2	zero dflex pflex	10 12 11					20,7 22,0 22,2	20.1% 15.2% 8.8%	16.7 18,7 22,1	12.1% 10.6% 10.9%	11,0 11,3 12,3	7.4% 9.9% 13.3%	16,6 18,6 16,5	7.3% 6.3% 7.1%		
2,3	zero dflex pflex	19 23 26	11.3 12,2 8.5	24.9% 25.9% 22.1%	22,2 20,7 34,8	12.1% 10.3% 17.9%							19.7 20.8 16.2	5.2% 4.7% 6.3%	11,8 13,2 17,4	22.0% 15.8% 31.4%
3.1	zero dflex pflex	5 5 13	5.7 9.6 5.8	13.9% 20.9% 23.8%			40,3 36,2 40,4	9.0% 13.7% 16.0%			43.8 44.4 45.7	4.4% 5.6% 7.4%	10,7 10.4 11,2	7.8% 8.0% 12.1%		
3.2	zero dflex pflex	8 25 7			14,0 12,6 13,3	24.2% 18.3% 27.3%			9.2 7.2 13.7	10.7% 14.0% 43.8%			8.2 8.4 8.2	7.8% 6.6% 10.5%	5.0 8,2 7,2	36.8% 19.2% 20.8%
3,3	zero dflex pflex	16 16 17			7,8 9,7 6,2	13.5% 15.5% 14.6%	39,0 37.6 47,3	14.4% 14.1% 15.3%			31.8 33.0 33.9	10.2% 6.2% 8.5%			6,8 6.3 8,6	10.0% 14.0% 13.5%
3.4	zero dflex pflex	16 16 20	5.6 6.8 6.3	15.5% 13.2% 14.6%	10,8 10,6 11,5	13.9% 11.0% 11.1%					36.2 34.3 37.4	3.7% 3.5% 11.2%	13,5 13,0 13,1	6.1% 7.2% 6.0%		

Interface stress and alignment

Table 4 Effects of changes in alignment of interface stresses.

Changes in interface stresses for dorsiflexion (dflex) and plantarflexion (pflex) alignments relative to the nominal (zero) alignment

Magnitudes (kPa) and fractions of the mean (%). Site abbreviations are listed in Table 1.

Pressi	ıre																
Subj.	Alia	A	AMP Mag Er Mn		ALP Fr Mn	A	MD Fe Ma	, A	ALD Er Ma		L	PP Mag. Es Ma		PD Max Fr Ma		AX	
3635	Ang	Mag	FI MIN	Mag	FI MI	Mag	Pr Mn	Mag	rr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn
1.1	dflex	-27.8	-37.6%	0.5	0.5%			-3.2	-3.2%			-8.0	-6.9%			-46.9	-5.6%
	priex	1.0	1.8%	-3,3	-3.8%			-0.2	-0.2%	-		0.0	0.5%			-14.1	-1.7%
1.2	dflex	0,4	0.6%	3.9	3.3%			1.2	1.3%					-3.8	-5.3%	-4.7	-0.6%
	pflex	11.5	15.9%	-1.2	-1.0%			1.4	1.6%					-2.8	-3.9%	-22.0	-2.8%
2.1	dflex			2.5	4.3%			0.0	0.0%			1.7	1.9%	-4.2	-5.1%	-26.5	-3.4%
	pflex		-	15.7	24.1%			-12.7	-13.8%			5.3	5.6%	9.3	10.5%	37.8	4.7%
2.2	dflex				10	-0.2	-0.3%	-3.3	-3.4%	4,9	4.8%	11.1	10.4%			-13.5	-1.7%
	pflex					-0.9	-1.6%	-5,2	-5.4%	4.8	4.7%	1,9	1.9%			41.3	5.0%
2.3	dflex	6.6	7.0%	-0,2	-0.2%		-					3.3	3.0%	-3.4	-4.2%	-4,6	-0.6%
	pflex	-18.1	-21.9%	-6.0	-6.4%							2,5	2.2%	19,5	21.0%	78.8	9.6%
3.1	dflex	12.1	18.9%			0,1	0.1%			-16.9	-9.7%	-5.8	-6.0%			3.6	0.4%
	pflex	-6.6	-12.1%			5.3	4.2%			2.4	1.3%	5.0	4.9%			23.9	2.5%
3.2	dflex			4.5	17.4%			-6,5	-5.9%			0.5	0.6%	-1.6	-2.1%	-25.9	-2.8%
	pflex			2.3	9.2%			9,7	8.3%			6.7	8.3%	4.3	5.3%	2.2	0.2%
3.3	dflex			-3.2	-10.1%	-20.2	-14.0%			-7.9	-4.9%		1	-6.0	-7.7%	-68.3	-7.5%
	pflex			-1.9	-5.8%	-13.1	-8.9%			6.9	4.1%			7.4	8.6%	19,4	2.0%
3.4	dflex	6.4	11.4%	2.2	5.9%					-10.9	-7.1%	-8.0	-7.8%			-55.7	-6.2%
	pflex	-3.8	-7.6%	0.7	1.9%					7.8	4.8%	3.5	3.2%			15.3	1.6%

Resultant shear stress

Subj.		AMP		ALP		A	MD	P	LD		L		PP	PD	
Sess	Alig	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn
1.1	dflex pflex	0.2 0.5	2.6% 5.8%	0.2 -0.5	1.4% -3.7%			1.4 0.9	4.4% 2.7%			-2.7 -0.9	-6.9% -2.2%		
1,2	dflex pflex	-1.9 2.6	-25.6% 27.2%	1.7 -1.5	8.5% -8.2%			-0.2 -1.5	-0.8% -5.2%					-0,4 0,4	-5.0% 4.5%
2,1	dflex pflex			0.7 -2.5	2.9% -12.0%			-0.5 9.8	-1.8% 28.1%			4,5 0,5	11.8% 1.5%	-7.6 -8.2	-38.3% -41.9%
2.2	dflex pflex					1.3 1.5	6.2% 6.7%	2.0 5.4	11.3% 24.5%	0.3 1.3	2.8% 10.5%	2.0 -0.1	11.1% -0.7%		
2.3	dflex pflex	0.9 -2.8	7.8% -28.8%	-1.5 12.6	-6.8% 44.2%							1.1 -3,5	5.3% -19.7%	1.4 5.6	11.1% 38.4%
3,1	dflex pflex	4.0 0.1	52.0% 2.6%			-4.2 0.0	-10.9% 0.1%			0.6 1.9	1.3% 4.2%	-0,3 0,5	-3.1% 4.2%		
3.2	dflex pflex			-1.3 -0.6	-9.9% -4.5%			-2.0 4.5	-24.1% 39.2%			0.3 0.1	3.2% 0.6%	3.2 2.2	48.0% 36.3%
3.3	dflex pflex			1.9 -1.6	21.3% -22.3%	-1.4 8.3	-3.8% 19.2%			1.1 2.1	3.4% 6.3%			-0.5 1.7	-7.8% 22.4%
3,4	dflex pflex	1.3 0,7	20.5% 12.5%	-0.2 0.7	-2.1% 6.6%					-2.0 1.2	-5.6% 3.3%	-0,6 -0,4	-4.3% -2.9%		

were less than 10% of the mean in 14 of 16 cases for Subject No.1; 18 of 24 cases for Subject No.2; and 26 of 32 cases for Subject No.3 (Table 4). Pressure changes were larger than 20% of the mean in 1 of 16 cases for Subject No.1; 3 of 24 cases for Subject No.2; and 0 of 32 cases for Subject No.3. Axial force changes were less than 10% for all subjects for all misalignment settings.

Resultant shear stresses (kPa) showed lower absolute magnitude changes than pressures in all cases but greater percentage changes. Resultant shear stress changes for different alignments were less than 10% in 14 of 16 cases for Subject No.1; 10 of 24 cases for Subject No.2; and 20 of 32 cases for Subject No.3. Resultant shear stress changes were larger than 20% in 2 of 16 cases for Subject No.1; 7 of 24 cases for Subject No.2; and 9 of 32 cases for Subject No.3.

Typically a change of more than 10% in pressure was accompanied by a corresponding greater than 10% change in resultant shear stress at the same site. This occurred in 1 of 2 cases for Subject No.1; 6 of 6 cases for Subject No.2; and 3 of 6 cases for Subject No.3. However, in a number of cases a greater than 10% change in resultant shear stress occurred without a correspondingly greater than 10% change in pressure. This occurred in 1 of 2 cases for Subject No.1; 8 of 14 cases for Subject No.2; and 9 of 12 cases for Subject No.3.

Pressure changes for alignment modifications in the dorsiflexion direction were not always opposite of those for the plantarflexion direction, i.e. there was a maximum or minimum at the zero alignment relative to the dorsiflexion and plantarflexion values. This result occurred in 4 of 8 cases for Subject No.1; 8 of 12 cases for Subject No.2; and 6 of 16 cases for Subject No.3. For resultant shear stress, there was a maximum or minimum at the zero alignment relative to the dorsiflexion or plantarflexion alignments in 4 of 8 cases for Subject No.1; 6 of 12 cases for Subject No.2; and 8 of 16 cases for Subject No.3.

Inspection of Tables 3 and 4 also demonstrates that the magnitude changes between sessions were in some cases substantial compared with those for different alignments within a session. Investigation of session to session differences was not an aim at the outset of the study. The study protocol was not designed to make these



Fig. 2. Changes in pressure (pr) and resultant shear stress (rs) for different alignments. Stance phase peak stresses for Subject 2, session 2 are shown.

comparisons thus only limited data are available. However, analysis of available data demonstrated substantial session to session changes. For pressure, 2 of 3 cases for Subject No.1 had changes greater than 20%; 1 of 6 cases for Subject No.2; 5 of 12 for Subject No.3 (Table 5). For resultant shear stress 1 of 3 for Subject No.1 had changes greater than 20%; 4 of 6 for Subject No.2; and 8 of 12 for Subject No.3. Thus for all subjects session to session changes had a greater proportion of cases with changes greater than 20% than did alignment modifications. Data comparing alignment and session to session changes for Subject 1 are shown in Figure 3. Axial force changes between sessions were less than 10% for all possible pairs

of sessions within a subject. The results suggest a more complete investigation of session to session differences on interface stresses is warranted.

Discussion

Interface pressure data presented here are consistent with those reported by Appoldt *et al.* (1968). Alignment effects on interface pressures were low. For each subject, very few sites demonstrated changes greater than 20% for pressure.

The minimal effects of alignment are inconsistent with the results of Pearson *et al.* (1973) and Winarski and Pearson (1987), where substantial changes in interface pressures for

Table 5. Effects of changes in session on interface stresses. Changes in interface stresses from session to session. Magnitudes (kPa) and fraction of the mean (%). Site abbreviations are listed in Table 1.

Pressure

Subj.	Time btwn	AMP		A	LP	AMD		ALD		L		PP		PD			٩X
Sess	Sess (d)	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn
1.1 v 1.2	0*	21,4	27.7%	-21.7	-21.0%			13,2	14.0%							63.4	7.6%
2.1 v 2.2	12							-0.6	-0.6%		140	-9.0	-9.3%			-13.3	-1.7%
2.2 v 2,3	19											-7.3	-7.0%			14,8	-1.9%
2.1 v 2.3	31			-40,3	-51.9%							-16,3	-16.3%	1,0	1.2%	1,6	0.2%
3.1 v 3.2	5											20.7	23.3%			-4,8	-0.5%
3.1 v 3.3	9					-29,4	-21.0%			19,2	11.0%					-24,3	-2.6%
3,1 v 3,4	9	5.2	9.4%							24,2	14.1%	-8,3	-8.0%			-5,2	-0.6%
3.2 v 3.3	4			-9.4	-33.2%	-				1				-2.9	-3.6%	-19.5	-2.1%
3.2 v 3.4	4			-12,3	-41.2%							-29.0	-31.2%		1	-0,3	0.0%
3,3 v 3,4	0			-2,8	-8.3%					5.0	3.1%					19,1	2.0%

* '0' days indicates that morning and afternoon session were conducted on the same day

Resultant shear stress

Subj.	Time btwn	AMP		ALP		AMD		ALD		L		PP		PD	
Sess	Sess (d)	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mn	Mag	Fr Mŋ	Mag	Fr Mn	Mag	Fr Mn
1.1 v 1.2	0	-0.5	-6.0%	-5,4	-33.1%			2,5	8.2%						
2.1 v 2.2	12							13.2	56.5%			19.2	73.3%		
2.1 v 2.3	19			-0.1	-0.5%							16,2	58.2%	11.7	66.3%
2,2 v 2,3	31							_				-3,1	-16.9%		
3,1 v 3,2	5											2,6	27.1%		
3,1 v 3,3	9					1,3	3.3%			12.0	31.6%				
3.1 v 3.4	9	0.1	1.9%							7.6	19.0%	-2.8	-22.9%		
3.2 v 3.3	4			6.1	56.4%									-1,8	-31.2%
3.2 v 3.4	4			3.2	25.7%							-5.3	49.2%		
3.3 v 3,4	0			-3.0	-31.9%	1				-4.4	-12.9%				



Fig. 3. Changes in pressure and resultant shear stress for different alignments and different sessions. Stance phase peak stresses for Subject 1, sessions 1 and 2 are shown.

alignment changes in trans-tibial amputees were reported. Differences could reflect protocol differences, subject variations, or amputation level differences. Another possibility that all the data supports, however, is that in cases in which the transducers were flush with the interface (Appoldt et al. (1968) and this study) results showed substantially lower pressure changes for misaligned vs nominally aligned trials compared with studies in which the transducers protruded into the skin (Pearson et al. 1973; Winarski and Pearson, 1987). Effects of sensor protrusion on interface pressure measurement have been investigated (Appoldt et al., 1969; Patterson and Fisher, 1979) and shown to have an important influence on measurement repeatability, particularly at sites with thin skin over bone. Thus data from Pearson's and Winarski and Pearson's studies may reflect instrumentation design limitations.

The coefficients of variance, in general, were higher for resultant shear stress than for pressure, Thus resultant shear stress is less consistent from step to step than is pressure. Fluctuations in frictional coefficient with changes in skin temperature and surface moisture could be part of the reason. Frictional coefficient sensitivity to temperature has been reported (Naylor, 1955).

The percentage changes in pressure magnitude reported here for the different alignments are comparable in magnitude to the coefficients of variance expressed as a percentage for steps at a setting within a session. Thus compared to the variability from trial to trial, misalignment effects were not substantial. It is important to note that the alignment changes were extreme, the maximal range of the Berkeley alignment unit at which alignments were considered safe. More subtle changes, as would be typical during a fitting session would be expected to have a reduced impact on changes in interface stresses. It is important to note, however, that the 3 subjects evaluated in this study were experienced prosthesis users; they adapted their gaits well to the alignment changes, based in part presumably on interface stress sensations on their stumps. It is interesting to note that, a greater number of sites showed greater than 10% changes for resultant shear stress than for pressure, suggesting that alignment changes influenced resultant shear stress more than they did pressure. Possibly the subjects used pressure sensation more than resultant shear stress sensation as feedback to compensate for the alignment modifications, resulting in more

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consistent pressure values than resultant shear stress values.

Though not part of the original study design, analysis of session to session differences showed that session changes had a greater impact on interface stresses at a greater proportion of sites than did alignment changes within a session. Differences from session to session were not accompanied by greater changes in shank axial force. Possibly, changes in stump shape or material properties were responsible for the session to session differences. To investigate their relative influence, further studies need to be conducted in which stump shape and/or material properties as well as interface stresses are measured. Appoldt et al. (1968) also noted significant session to session differences but he reported for the 2 subjects tested that only in sessions weeks or months apart were the effects significant. Day to day variations were typically within the larger of ± 7 kPa or $\pm 20\%$. It is clear from Appoldt's results and those presented here that the relative influence of session to session effects compared with alignment changes or other modifications to the prosthesis is an area worthy of further investigation. If session to session changes were shown to be more influential on interface stress magnitude changes, then more intensive design and fitting concentration on techniques to overcome shape changes would be warranted.

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