**Published in Archives of Physical Medicine and Rehabilitation 86(4):pp.641-649** 

#### **REGIONAL DIFFERENCES IN PAIN THRESHOLD AND TOLERANCE OF THE TRANS-TIBIAL RESIDUAL LIMB: INCLUDING THE EFFECTS OF AGE AND INTERFACE MATERIAL**

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The work described in this paper was supported by The Hong Kong Polytechnic University Research Studentship and a grant from the Research Grant Council of Hong Kong (Project No. PolyU 5200/02E).

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### **ABSTRACT**

**Objectives:** To compare the pain threshold (the minimum pressure inducing pain) and pain tolerance (the maximum tolerable pressure) of different regions of the residual limbs among different amputees by indentation method, and to evaluate the interface pressure distribution and distortion of the skin surface upon indentation by finite element (FE) analysis. **Design:** Cross-over trial; FE analysis.

**Setting:** Rehabilitation Engineering Center

**Participants:** Eight trans-tibial amputees for indentation test and one for FE analysis.

**Interventions:** Load indented to the residual limbs through Pelite® or polypropylene indenter attached to a force transducer was increased until they could no longer tolerate the load. A FE model was built to simulate the indentation process with the experimentally recorded pain threshold used to load the indenters against the soft tissues.

**Main Outcome Measures:** Pain threshold and tolerance. Interface pressure and distortion of soft tissues.

**Results:** Patellar tendon and distal end of fibula were the best and worst load tolerant region respectively. Some regions with thicker layer of soft tissue had lower pain threshold and tolerance than those with thinner tissue layer. There was a trend that pain threshold and tolerance decreased with age. The FE model showed that the peak pressure at skin surface was very close when both indenters were loaded against the soft tissue at pain threshold limit. **Conclusions:** Contrary to common believes, regions with thicker layer of soft tissue did not have higher load tolerant ability than thin-skin regions. Pain threshold and tolerance could be age-dependent. The FE model suggests pain is triggered when peak pressure is applied to the residual limb exceeding a certain limit.

**Key Words:** pain threshold, pain tolerance, prosthetics, indentation, finite element analysis

#### **INTRODUCTION**

Surveys have shown that lower-limb amputees considered comfort to be one of the most important issues they face in using a prosthesis.<sup>1</sup> It is not uncommon for amputees to experience pain at the residual limb while wearing their prostheses. $2$  High stresses applied onto the residual limb which is not particularly tolerant to loadings is a major cause of the pain.3 Stress developed at the soft tissue of the residual limb during walking and tissue response to stresses are critical considerations in socket design and fit.

The understanding of the load transfer mechanics between the residual limb and prosthetic socket is the first step to achieve a successful prosthesis fit.<sup>4</sup> Experiments have been conducted to measure the stresses applied onto the residual limb by the prosthetic socket, as reviewed by Mak et al.<sup>3</sup> Finite element (FE) analysis has also been a useful tool for the prediction of the stress distribution at the interface. Parametric analyses using FE models have provided better understanding of the effects of socket modifications,  $5.6$  material properties of the sockets<sup>5,7</sup> and liners<sup>8</sup>, frictional properties at the interface<sup>4</sup> and prosthetic alignment<sup> $6,9$ </sup> on the interfacial stresses.

Experimental measurement and computational simulation can display the stress pattern over the residual limb during walking. However, without an adequate understanding how tissues at various sites respond to stresses, it is difficult to discuss the optimal stress patterns over the residual limb. Knowledge of the pain threshold and tolerance of the soft tissues around the residual limb is needed for the improvement of comfort in prosthetic uses. Pain threshold and tolerance of the residual limb reflects the magnitude of pressure that can be applied to the residual limb by the prosthetic socket without causing discomfort and intolerable pain. It can serve as a guideline for the acceptable stress distribution patterns on the residual limb within a socket. By analyzing the stress patterns and stress tolerant abilities at different regions of the residual limb, assessment of socket fit and optimization of prosthetic design could be rationalized.

There were few investigations studying the pain response to stresses applied onto the residual limb. Persson and Liedberg<sup>10</sup> reported the maximum weight that could be born at the distal ends of the residual limbs in subjects with different levels of lower limb amputations. Neumann<sup>11</sup> performed analysis on the relation between the magnitude of pressure applied globally to the residual limb and the perception of discomfort by amputees. Kelly<sup>12</sup> examined the relationship between degree of gait alteration and pain intensity. However, load tolerance over different regions of the residual limb, which is important in establishing guidelines for acceptable stress patterns, have not received much attention apparently.

Patellar Tendon Bearing (PTB) socket has been used for more than 40 years. The main principle of PTB socket is that greater pressure is applied to the regions which are believed to have greater ability to tolerate load while some relieves are made for the pressure sensitive regions.13 Patellar tendon and medial tibial flare are the major weight bearing surface. In addition, PTB socket is so designed that relatively higher pressure is applied at the anteromedial and anterolateral tibia, lateral shaft of fibula and posterior compartment. Although the basic principle of PTB socket designs has stood the test of time, there is a lack of quantitative information on the load tolerance at different sites of the residual limb, documenting exactly how pressure-tolerant those areas are.

The objective of this study was to evaluate and compare the tissue stress at pain threshold and tolerance limits over different regions of the residual limb among trans-tibial amputees using an indentation method. Tissue strain and stress distribution upon indentation could provide additional information on pain initiation. With the help of finite element analysis, we have investigated the soft tissue displacement as well as the stress distribution beneath the indenter when the tissue was indented to an extent reaching pain.

#### **METHODS**

Pain threshold and tolerance over eleven different regions of the residual limbs of eight male unilateral trans-tibial amputee subjects were studied. Pain threshold is defined in this paper as the minimum pressure that induces pain and pain tolerance as the maximum pressure a person can tolerate without excessive effort. The subject characteristics are shown in Table 1. None of the subjects had history of diabetic mellitus and symptoms of peripheral neuropathy. Written consent was obtained from all participating subjects. The experiment was conducted in line with the human subject guidelines of the Hong Kong Polytechnic University.

Subjects were asked to sit and rest their residual limbs with extended knee on a table. Indentation test started after about 15-minute rest and briefing of the experiment. Pressure was applied to the test regions perpendicularly to the skin surface through a circular, flatended indenting material of 12mm diameter and 4mm thickness connected to a mechanical force transducer (maximum load=200N, division=2N) until the subjects said "stop". The load rate was manually controlled at about 4N/s. The experimenter can maintain the loading rate 4N/s with ease during the indentation, with 2N division of the force transducer. The subjects were instructed to say in Chinese "painful" when they started feeling pain and said "stop" when they could not stand the pressure any more. Force magnitudes were recorded from the force transducer when the subjects said "painful" and "stop". Pain threshold and tolerance were calculated by dividing the force magnitudes by the initial surface area of the indenter. All subjects were tested by the same experimenter. Special device to hold the residual limb was deemed unnecessary as observed the subjects did not tend to withdraw the residual limb away from the indenter to avoid oncoming pain.

The eleven test regions were those which commonly require relieves at prosthetic sockets including tibial tuberosity, mid-shaft of tibia, fibula head, distal ends of fibula and tibia as well as those where relatively high magnitude of force is usually applied as expected for a PTB socket, including mid-patellar tendon, medial tibial flare, mid-shank of fibula, popliteal muscle (over the medial aspect of the lateral head of the gastrocnemius), anterolateral and anteromedial tibia. Subjects were asked to turn their residual limb so that the test sites were well exposed for the indentation. The order of the test sites being indented was pre-defined with the nearby test sites indented first before switching to test sites at other positions to minimize the numbers of turns of the residual limb by the subjects.

Each site was tested with two different indenting materials, namely Pelite® and polypropylene. Pelite® is a relatively soft material which is often used as liner at the socketresidual limb interface, and polypropylene is a thermoplastic material commonly used for fabrication of prosthetic sockets. The order of the use of indenting materials was randomized. The subjects were not told they were tested with two different indenting materials. Before the test started, all test regions were marked to ensure the indenter was pressing on the same regions for different tests. All sites were tested with the same indenting material (Pelite® or polypropylene) and ten minutes rest was given to each subject before changing to another

indenting material. A new Pelite<sup>®</sup> indenter was used when obvious permanent deformation was noted or a new subject participated in the indentation test. The indentation test was performed twice with at least 10-minute rest in-between and the pressure at each test site were averaged. The whole experiment took about an hour for each subject. Throughout the experiment, the subjects were asked to keep extending and elevating their residual limb on the table to reduce the chance of edema.

Statistical analysis was performed using SPSS 10.0. Repeatability of the measured pain threshold and tolerance on repeated indentation tests was assessed by intraclass correlation coefficient (ICC). ICC model (3, 1) was used for single measurement at each trial taken by one experimenter. Pain threshold and pain tolerance among different test regions, indenting materials and subjects were compared using one way analysis of variance (Bonferrori test). Differences were considered significant at the  $p<0.05$  level. Relationships of pain threshold and pain tolerance with age, body weight and years of prosthetic uses were assessed by Pearson product-moment coefficient of correlation.

A finite element model was built, based on the limb geometry and pain threshold recorded in the indentation test of Subject 1 (Table 1), to simulate the indentation process so that the stress distribution and indention depth of the different test sites beneath the indenting material could be studied. Magnetic resonance images (MRI) were obtained from the residual limb of Subject 1 to capture the geometries of skin surface and internal bones. Details of capturing the geometries of the FE model were described elsewhere<sup>14-16</sup>. The FE analysis was performed in ABAQUS version 6.3 (Hibbitt, Karlsson & Sorensen, Inc., Pawtucket, RI). Each site was isolated for FE analysis using a fine mesh. A circular disc of diameter 10mm was created and aligned flat onto each test sites as shown in Figure 2a. The Young's Modulus and Poisson's ratios of different regions of the residual limb and the indenting materials were adopted from the literature<sup>4,17</sup> (Table 2). The soft tissue surrounding was given fixed boundaries. By Saint-Venant's principle, the fixed boundaries had effect on stress/strain distribution only at the nearby regions which was relatively far away from the indenter. Pressure, with magnitude equivalent to the measured pain threshold of each test site, was applied to the indenter to load against the corresponding test site. The number of elements assigned varied among different test sites ranging from 55,966 to 117,883. The mesh densities of the test sites were refined such that convergence of peak stress was within 2% of that of the previous coarser mesh (Figure 2b).

#### **RESULTS**

Good repeatability of the measured data on repeated trials was obtained as shown by the high ICC of 0.85, 082, 0.87 and 0.88 at the four testing conditions respectively which were Pelite® indenter at pain threshold and tolerance levels and polypropylene indenter at threshold and tolerance level. Figure 1 shows the means and standard deviations of pain threshold and pain tolerance over the eleven test regions for all the subjects using indenting materials Pelite® and polypropylene. Among the test regions, mid-patellar tendon tolerated the highest pressure, while distal end of fibula tolerated the lowest. Statistical analysis shows significant difference between mid-patellar tendon and distal end of fibular using Pelite® indenter at both pain threshold ( $p=0.023$ ) and tolerance ( $p=0.003$ ) conditions and using polypropylene indenter at pain tolerance limit  $(p=0.045)$ . The standard deviations show the variations among subjects. Greater value of standard deviations over mid-patellar tendon region was due to that subjects 2 and 7 had particularly higher tolerance at MPT than other subjects. As far as other test regions are concerned, tibial tuberosity, fibular head, medial

tibial flare and mid tibial crest on average had higher pain threshold and tolerance than medial and lateral regions tibial, mid-shank of fibula and popliteal muscles. However, no statistically significant difference was found with these test sites.

Subjects tolerated load better with softer indenting material (Pelite®) at all the sites of the residual limbs than the harder material (polypropylene), as seen in Figure 1 the pain thresholds and tolerances recorded with Pelite® material are higher than those with polypropylene. Statistically significant differences were noted in pain threshold  $(p=0.011)$ and pain tolerance  $(p=0.003)$  between the use of Pelite® and polypropylene indenters.

Pain threshold and tolerance over eleven different test sites were averaged for each subject and compared in Table 3. Statistical analysis reveals that the readings recorded from subject 2 and 7, the youngest among the subjects, were significantly higher than other subjects. There was no significant difference among the other six subjects. Table 4 displays the relationship of pain threshold and tolerance with weight, age and duration of the use of the prosthesis. There is a trend that the load tolerant ability decreased with increasing age. Poor correlation of weight and duration of the use of the prosthesis with the readings is found.

The stress distribution and indention depth of the different test sites beneath the indenting material was studied in the FE model. Figure 3 (a, b) shows the stress distribution pattern at the mid-patellar tendon region of Subject 1 with two indenting materials when pain was initiated. High interface pressure appeared around the edge of the indenting material. Figure 3c shows the magnitude of pressure at the skin surface from the center towards the edge of the indenting material. It can be observed that interface pressure was distributed more evenly with pelite® than polypropylene indenting material. The pressure distribution pattern was similar among different test regions but differed in peak stress values. Table 5 shows the peak interface pressure at skin surface and indentation depth when each test sites was indented with load equivalent to pain threshold. Peak interface pressure was defined as the average pressure of five elements having the highest magnitude of pressure over the test site at skin surface, to reduce the effects of MRI and FE modeling artifacts. It is observed that the peak stresses over the same test site indented by Pelite® and polypropylene with load initiating pain were very close. Although the difference of peak stresses were small at the same site indented with different stiffness of material, there were obvious differences of applied load, indentation depth and stress distribution at the same test sites using the two indenting materials.

#### **DISCUSSION**

Pain threshold (the minimum pressure inducing pain) and pain tolerance (the maximum tolerable pressure) had been measured over different regions of the body in previous studies and the measuring method was similar to that employed in this study. Fischer<sup>18</sup> measured the pain tolerance at the thumb, mid-tibia, supraspinatus and deltoid of healthy subjects by applying pressure to the test regions through a rubber disc attached to a force gauge until the subject said "stop" indicating that the subject could not stand the pressure any longer. Neumann et al.<sup>19</sup> and Pickering et al.<sup>20</sup> used a pressure algometer to apply pressure gradually onto the phalanx of fingers of healthy subjects until the subjects could no longer tolerate the pain to measure pain threshold and tolerance. There are methods to quantitatively estimate the intensity of perceived pain using visual analogue, verbal and numerical rating scales. However, we did not attempt to ask the subjects to report the intensity of the pain according to the pain scales during the indentation process as the duration of the indentation was short,

usually within 20 seconds. Subjects were only required to report verbally the onset of pain and the pain that they cannot tolerate.

In this investigation, focus was put on the residual limb measuring the pain threshold and tolerance of different regions of the residual limbs of trans-tibial amputees. Pain threshold and tolerance of the residual limb could provide useful information for prosthetic design. A prosthesis can be considered totally unacceptable if the socket applies load exceeding the pain tolerance of the residual limb. Throughout the process of prosthetic design optimization, a prosthesis should be made to prevent the applied loads at the socket-limb interface during the gait cycle exceeding a level with reference to its pain threshold. Considering that longer exposure can likely reduce the load level that the tissue can tolerate<sup>21</sup>, the pain tolerance and threshold can be taken as a maximum allowable stress that can be applied onto the residual limb such that pain and discomfort would not be initiated. The dependence of the tolerance level on load exposure duration deserves further investigation in the future.

Mid-patellar tendon and medial tibial flare were shown having better tolerance to load than other regions of the residual limb. Distal end of the fibula, on the contrary, had the least ability to tolerant load. This quantitative finding is consistent with the qualitative description of Radcliff and Foort<sup>13</sup> who identified mid-patellar tendon and medial tibial flare as pressure tolerant areas and distal end of fibula as pressure sensitive area. As mid-patellar tendon and medial tibial flare are pressure tolerant regions, PTB socket is designed to have undercuts at the mid-patellar tendon and medial tibial flare regions. Distal end of the residual limb, being pressure sensitive, usually requires relief during the cast modification process.

Some bony portions of the residual limb such as tibial tuberosity, fibular head, mid tibial crest on average tolerated higher load than some areas with more soft-tissue, such as anteromedial and anterolateral tibia, mid shank of fibula and popliteal muscle. This is contrary to common believes that skin-thin regions and soft-tissue regions are pressure sensitive and pressure tolerant regions respectively<sup>13,22</sup>. This contradiction, however, is not opposed to the design of PTB prosthetic socket. Rectifications of PTB socket are described in terms of displacements instead of force/pressure, for example 25 mm undercut is usually suggested for the socket at patellar tendon region. Since the mechanical properties of the bony regions with thin layer of soft tissue are much stiffer than the fleshy regions covered with thicker soft tissue<sup>4,23</sup>, for a given magnitude of displacement, the stress produced in skin-thin regions would be greater than the fleshy regions. In other words, fleshy regions could tolerate displacement better than skin-thin regions without pressure significantly shooting up. It is the basic principle of PTB socket to allow more deformation applied at regions with more soft tissue. However, fleshy regions are commonly described as "pressure tolerant" leading to confusion that those regions could tolerate higher pressure than other regions of the limb, which is contrary to the results of this study. "Deformation tolerant" could be a more appropriate term than "pressure tolerant" for regions with thick layer of soft tissues. Similarly, "deformation sensitive" could be preferred to "pressure sensitive".

There was a trend that the amputee subjects have lower load tolerant ability with increasing age. This is consistent with the findings of Pickering et al.<sup>20</sup> who reported that the healthy elderly subjects had significantly lower pain tolerance than the healthy young subjects. In addition to age, gender could also have impact on pain tolerance. It has been shown that male subjects exhibited higher load tolerance than female subjects.<sup>18,20,24</sup> The relationships, however, were contradictory to Antonaci et al.<sup>25</sup> who showed that age and sex played little

role on load tolerance. In this study, we have not been able to establish any significant correlation between load tolerance and body weight and duration of prosthetic use.

In addition to average pressure that the tissue can withstand, the pressure distribution underlying the indenter and the soft tissue distortion when pain was just initiated were studied using FE modeling. The FE model shows that the peak interface pressure at the same test site indented with different stiffness of material were very close at the point when pain is triggered. It suggests each test site may bear a threshold which is pressure-related and the thresholds are site-dependent. Pain is initiated if the induced pressure exceeds those thresholds. Inclusion of larger sample size and validation of the FE model using high precision and resolution sensor sheet are required to justify the argument suggested in this paper about the relationship of peak interface stress and initiation of pain.

The results that the subjects could withstand higher force with Pelite<sup>®</sup> than polypropylene can be explained in terms of stress. Softer Pelite® indenting material has the ability to deform when mild to high loading is applied. The deformation can reduce tissue stress by increasing the actual contact area with the tissue and spreading more uniformly the stress applied to the skin. The effects of the sharp edge of the indenting material could also be attenuated by the deformability of Pelite®. The relatively stiff polypropylene indenter, however, deformed very little. The average stress actually applied to the tissue by polypropylene indenter should be higher than that by Pelite® indenter with the same amount of load applied because of the comparatively less contact area of the polypropylene with the tissue. Under the Dunnell effect<sup>26</sup>, the stresses in the soft tissue at the edge of the stiff polypropylene indenter are several times higher in magnitude than those at the center of the indenter. The subjects could tolerate greater load with Pelite® because it induces less average pressure, and more importantly the peak pressure, at the skin surface and around the edge of indenter, hence allowing higher indenting load to be applied before the peak pressure reaches the threshold. The ability of a soft liner in reducing tissue stress has been shown in experiments<sup>27,28</sup>and FE analysis<sup>29</sup>

There are certain limitations in this study which warrant further investigation and validation. Concerning the indentation test method, loading applied to the residual limb by indentation of a small circular disc could be different from that applied from the prosthetic socket experienced during walking. Small area of the indenter can induce some shear stresses at the edge of the indenter especially over the regions covering more soft tissue which may modify pain threshold and tolerance. As concerned with the FE model, there are some assumptions used to simplify the FE model, such as linearly elastic, homogeneous and non-viscoelastic material property and geometrical linearity. Better characterization of material property of different locations of the residual limb considering the viscoelastic and non-linear material properties of the soft tissue will be pursued. In addition to stress at the skin surface, stress developed deep within the tissues is also an important parameter when discussing pain. A more sophisticated model with different structures such as skin, subcutaneous tissue, muscle, tendon and ligament, requiring advanced computational resources and imaging techniques, is desired. Geometrical nonlinearity, taking into account the stiffness changes of the soft tissue upon large deformations, has been attempted. However, with the current algorithms the solution convergence was poor.

We have established a FE model<sup> $14-16$ </sup> to investigate the load transfer at the limb-socket interface. By performing parametric analysis, the model could be further used to predict stress distribution pattern at the limb under different prosthetic designs. In future studies, socket design will be assessed by incorporating the load threshold/tolerance data with the FE model demanding that no regions will experience stresses exceeding the site-specific thresholds. In current practice, the quality of a prosthesis is assessed based on the subjective observation of the prosthetist and the subjective perception of the patient after the socket is fabricated and fitted. Re-fabrication of the prosthesis is needed if the fitting is deemed unsatisfactory. The use of FE model with an understanding of the site-specific load thresholds could serve as an objective and quantitative means of assessing prosthetic design before the fabrication of the prosthesis.

## **CONCLUSION**

This study aims to investigate the differences in pain threshold and tolerance among different regions of the residual limb and different amputee subjects by indentation method with the uses of different stiffness of indenting material. Results suggested that age and indenting material both play an important role in pain threshold and tolerance. Notable differences in pain threshold and tolerance were found among different test regions of the residual limb. It is also the aim of this study to look into the pressure distribution and indentation depth upon indentation by FE modeling and explore if there is any relationship between pressure/ tissue distortion and onset of pain. The FE model suggests pain is triggered when peak pressure applied to the residual limb exceeds a certain limit.

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## **CAPTIONS**

- **Figure 1.** Means and standard deviations for the average applied pressure (surface stress) measured at pain threshold (PTh) and pain tolerance (PTo) levels at eleven test sites for all subjects.
- **Figure 2.** (a) Finite element mesh (59,874 elements) of soft tissue around mid-patellar tendon region and indenter; (b) Peak stress value shows the tendency to converge as the number of elements increases, with the soft tissue at the mid-patellar tendon being indented to an extent that pain was just initiated.
- **Figure 3.** Pressure distribution using (a) Pelite and (b) polypropylene indenting material, and (c) the magnitude of pressure from the center towards the edge of the indentor, over mid-patellar tendon region at pain threshold level
- **Figure 4**. Sagittal plane sectional view of tissue at mid-patellar tendon region showing its deformation under indentation by polypropylene indenter at pain threshold level



**Figure 1**



**Figure 2** 



**Figure 3** 



**Figure 4**

**Table 1.** Subject characteristics (# distance measured from the mid-patellar tendon to the distal end of the stump)

Subject	Age	<b>Mass</b>	Height	Side of	Cause of	Stump	Year of
No.		(kg)	(m)	amputation	amputation	length	prosthetic
						$(cm)$ #	use
	56	86	1.59	Right	Trauma	14.7	29
2	43	76	1.68	Left	Trauma	12	37
3	54	59	1.71	Right	Trauma	15.5	14
4	55	46	1.60	Right	Vascular	11.2	9
					disease		
5	68	57	1.68	Right	Trauma	13.3	17
6	59	50	1.70	Left	Osteosarcoma	13.1	6
7	41	65	1.69	Right	Vascular	7.6	7
					disease		
8	48	73	1.65	Right	Trauma	9.5	$\overline{2}$

**Table 2.** Young's Moduli and Poisson's ratios of the indenting materials and the soft tissues used in the FE models of the various test sites

		Young's Modulus (MPa)	Poisson's ratio
Indenter material	Pelite	0.38	0.30
	Polypropylene	1500	0.30
Soft tissue	Mid-patellar tendon	0.26	0.45
	(MPT)		
	Popliteal muscle (PM) and	0.16	0.45
	anteromedial tibia (AMT)		
	Regions other than MPT,	0.20	0.45
	PM and AMT		

# **Table 3.** Means and standard deviations of pain threshold and tolerance (MPa) of each subject. (\* significantly different from other subjects at 0.05 level.)



**Table 4.** Pearson coefficient of correlation indicates correlation among load tolerance, body mass, age and years of prosthetic uses (\* significant at 0.05 level.)





**Table 5.** Indentation depth and peak pressure at skin surface at pain threshold level of Subject 1