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Is skin pressure a relevant factor for socket assessment in patients with lower limb amputation?

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Abstract.
BACKGROUND: Prosthetic rehabilitation improves the overall quality of life of patients, despite discomfort and medical complications. No quantitative assessment of prosthesis-patient interaction is used in routine protocols and prosthesis quality still results from the manufacturer's know-how.
OBJECTIVE: Our objective is to investigate whether pressure can be a relevant factor for assessing socket adequacy.
METHODS: A total of 8 transtibial amputee volunteers took part in this experimental study. The protocol included static standing and 2 minutes walking tests while the stump-to-socket interface pressures were measured. Questionnaires on comfort and pain were also conducted.
RESULTS: During static standing test, maximum pressures were recorded in the proximal region of the leg, with a peak value reaching 121.1 $\pm$ 31.6 kPa. During dynamic tests, maximum pressures of 254.1 $\pm$ 61.2 kPa were recorded during the loading phase of the step. A significant correlation was found between the pain score and static maximum recorded pressure ($r = 0.81$).
CONCLUSIONS: The protocol proposed and evaluated in this study is a repeatable, easy-to-set quantified analysis of the patient to socket interaction while standing and walking. This approach is likely to improve feedback for prosthesis manufacturers and consequently the overall design of prostheses.

Keywords: Prosthetic socket, rehabilitation, pain measurement, patient satisfaction, transtibial amputee, gait ability, comfort assessment, transtibial prosthetic socket

1. Introduction

The number of lower limb amputations (LLA) is increasing every year [1,2] and is expected to reach 3.6 million in the USA in 2050 [3]. Main causes for LLA are vascular diseases (54%) (including diabetes and peripheral arterial disease), trauma (45%) and cancer (less than 2%) [3].

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Prosthetic rehabilitation aims at restoring patient's mobility and improves their overall quality of life. It also improves the likelihood of returning to employment [4]. Despite these potential benefits, a substantial number of patients with LLA do not use their prosthesis. More than 35% of patients do not wear their prosthesis for it is uncomfortable [2]. Other reasons can be economic and/or related to possible complications that occur quickly after surgery. Skin integrity issues at the stump are the main source of reported complications [5–7].

A large proportion of amputees also suffer from secondary disabling pain at the stump/prosthesis interface, phantom limb pain, or back pain [8,9]. The walking pattern is substantially modified by the wearing of a prosthesis: reduced walking speed (0.85 vs 1.44 m/s), longer support phase (0.85 vs. 0.67 s), and significantly lower horizontal reaction force [10]. Therefore, the sockets design and the manufacturing process should be further optimized to improve the management of people with LLA.

Nowadays, the care of lower limb amputees differs from one country to another. It is made all the more complex because there is no consensus on the criteria to be adopted to ensure optimal prosthetic design. The manufacturing of lower limb prostheses remains a long and iterative process, which is slow to take advantage of technological progress such as fast machining (stereolitography, 3D printing). As a consequence, the quality of the prosthesis greatly depends on the prosthetist know-how, amongst with many other factors. The ability for the patient to express the pro and cons of a prosthetic device as well as his feeling on the constraint applied by the socket on the stump are taking part in the final design of the prosthesis. Computer assisted approaches are still limited, although mechanical interactions between a stump and the prosthesis were previously predicted using finite element methods [11,12].

The current study aims to investigate how quantitative pressure measurements at the stump/socket interface could offer reliable assessment means to estimate the prosthesis match to the patient's need as well as the patient's satisfaction.

2. Materials and methods

2.1. Patient clinical assessment

Volunteer participants with a below-knee amputation and an ASA Score of 1 (patient in good health, without organic, physiological, biochemical or psychic issue) were included in the study. A mental and physical condition compatible with the planed research protocol was also confirmed by the therapist in charge of the patient at the hospital. All subjects were tested with their own prosthesis, which they had all been wearing for at least six months. All prostheses were of similar design as they were all developed by the same prosthetic manufacturer.

This study was performed in a hospital environment (Department of Physical Medicine) and meets all ethical standards. Patients were informed prior to each trial and consent forms were signed by the patient.

A clinical examination of the leg was performed by the medical practitioner to estimate pain, sores and redness. Skin and tissue lesions on the stump were reported. Pain was measured by using a scale derived from the scale created by Wong and Whaley [13]. Such scale ranks the pain from 0 to 10: 0 corresponds to no pain, and 10 to maximum imaginable pain. Additionally, participants were asked to fill in a prosthesis evaluation questionnaire (PEQ) for assessing their psychometric characteristics. The questionnaire was composed of 13 questions organized at three levels or factors: the feeling of discomfort and pain, the overall feeling of well-being, and the areas of pain on the patient's stump. Such questionnaire was derived from [14–16].

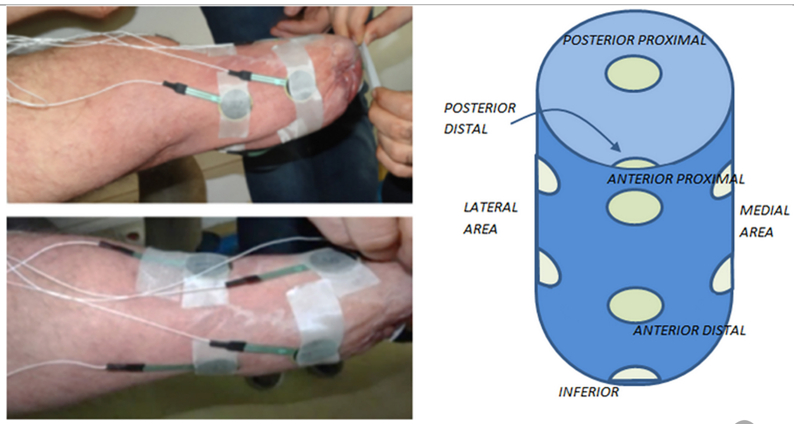

Fig. 1. Sensors located on the subject's stump and experimental protocol for 2 min test. Dynamic test analysis with phasic decomposition of the pressure measurement signal.

2.2. Static and dynamic testing

A total of 9 FSR-type piezo resistive force sensors (Interlink Electronics, CA, USA) previously discussed in [17] were placed on each subject's stump, in anterior, lateral, medial and posterior regions of the proximal and distal stump. An additional sensor was placed in the inferior area of the stump (see Fig. 1). Each subject, initially seated, was first asked to stand 3 times, holding a steady standing position for 5 seconds, before sitting down on the chair. Then, dynamic testing consisted of asking each volunteer to stand up again and walk in round trips during 2 minutes along a 6 m long pathway and sit down again. Pressure measurements were analysed and post-processed with a python script. Static pressure measurements were averaged on 3 consecutive measures. Dynamic analysis consisted of the identification of peak pressures recorded at 5 different phases of the walking gait (loading, mid-stance, terminal stance, toe-off, swing) as illustrated in Fig. 2 on an averaged measured signal of five steps. Pressure results were normalized by the volunteer's weight in order to further compare it between patients. In order to reduce any possible bias due to stump variations (volume, fatigue, sensitivity, sweat), all volunteers were tested during the same time slot (between 10:00 am and 12:00 am).

2.3. Statistics

Correlations were tested using R software (R Foundation for Statistical Computing) and a significant level was reported as p value < 0.5. Reproducibility of the results was assessed on all patients in computing the intra-class coefficient on a second measurement in both static and dynamic case.

3. Results

3.1. Clinical assessment and questionnaire

A total of 8 male volunteers were recruited with the following characteristics: age 43.62 $\pm$ 9.91 years, weight 67.25 $\pm$ 11.40 kg and size 172 $\pm$ 11 cm, BMI of 24.2 $\pm$ 2.88 kg/m^2. In seven patients out of eight, road accidents were the main cause of amputation; for one of the volunteers, the cause of amputation was bone disease.

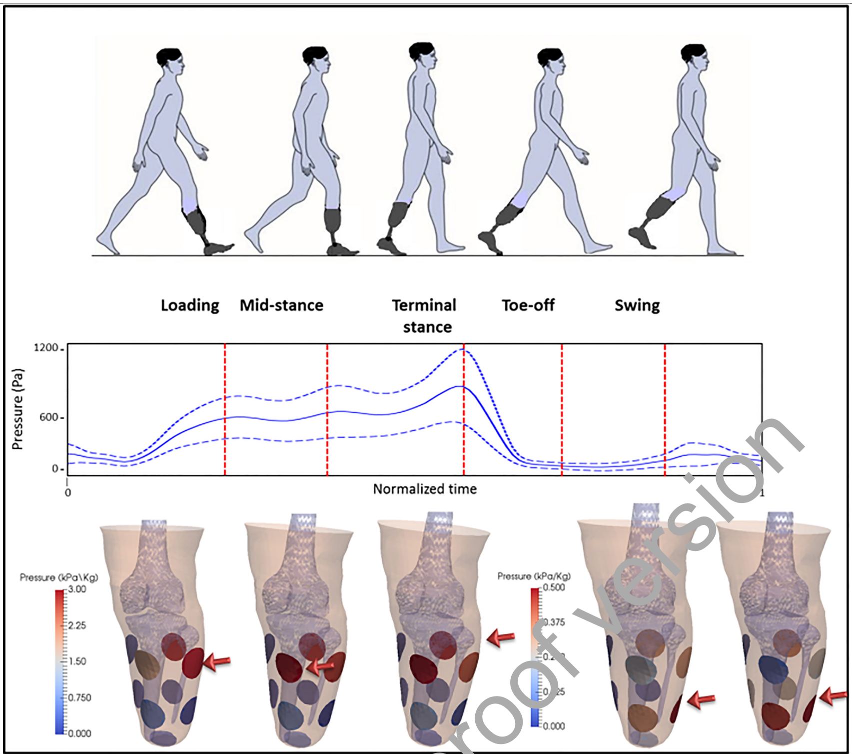

Fig. 2. Dynamic pressure results: phase analysis of the dynamic pressure.

All patients but one reported minor to moderate pain, always limited to the distal region of the stump, and declared feeling fairly to very well with their socket. The last declared that the prosthesis was "not fully satisfying" and reported severe pain while using his prosthesis, mostly in the proximal upper region of the socket (knee region).

3.2. *Peak pressures*

An example of pressure recording in the ambulatory test is illustrated in Fig. 2. During the sit to stand test, on average, maximum pressures were recorded in the proximal area of the stump (see Fig. 1), excluding the medial area, with a maximum value of 121.1 ± 31.6 kPa.

The dynamic pressure measurements showed that maximum pressure levels during walking were found in average in the popliteal area, i.e. the proximal posterior area in Fig. 1. The maximum absolute average value is 254 kPa.

Peak pressure measurements are summarized in Table 1. No signs of excessive sweat or stump volume change were noted before or after the trial. None of the patients declared being tired before or after the trial.

3.3. *Pressure level correlation to questionnaires*

Correlation coefficients were computed between peak pressures recorded both in static and dynamic conditions on the volunteers and questionnaire answers, each of which was considered here as a possible satisfaction assessment criteria.

Table 1
Static and dynamic normalized pressures results according to the location of the sensors

		Distal				Proximal				
	Inferior	Anterior	Lateral	Posterior	Medial	Anterior	Lateral	Posterior	Medial	r2 (p)
SPP (kPa)	27.1 ± 42.4	39.3 ± 28.9	36.6 ± 48.3	6.7 ± 8	14.5 ± 13.4	97.7 ± 76.4	106.9 ± 75.1	121.1 ± 31.6	32.7 ± 58.6	0.14 (0.21)
nSPP (kPa/Kg)	0.52 ± 0.86	0.66 ± 0.54	0.59 ± 0.79	0.1 ± 0.12	0.22 ± 0.18	1.55 ± 1.17	1.73 ± 1.2	1.91 ± 0.7	0.46 ± 0.83	0.57 (0.03)
DPP (kPa)	19.2 ± 50.6	57.9 ± 77.1	34.6 ± 76.5	40.1 ± 89.4	25.8 ± 40.8	199.5 ± 178.5	205.7 ± 142.4	192.6 ± 67.8	254.1 ± 61.2	0.02 (0.58)
nDPP (kPa/Kg)	0.59 ± 1.56	1.06 ± 1.52	0.57 ± 1.28	0.56 ± 1.23	0.36 ± 0.57	3.35 ± 3.64	3.25 ± 2.12	3.59 ± 1.58	3.58 ± 8.62	0.015 (0.49)
Stance phase	Mid stance	Terminal stance	Toe-Off	Terminal stance	Terminal stance	Terminal stance	Loading	Terminal stance	Loading	

SPP: static peak pressure, nSPP: normalized static peak pressure, DPP: dynamic peak pressure; nDPP: normalized dynamic peak pressure.

Table 2
Static and dynamic weight normalized pressures according to questionnaire assessments

	Nb	Mean SPP (kPa/kg)	Mean DPP (kPa/kg)
Sweat			
No or not annoying	5	0.74 ± 0.34	1.68 ± 1.43
Yes annoying	3	1.16 ± 0.28	3 ± 2.24
Socket changes			
Once or less	3	1.67 ± 0.16	1.82 ± 1.06
More than once	5	0.78 ± 0.4	2.15 ± 1.9
Blister, scratches, bruises, contusions			
Never	3	0.81 ± 0.46	1.38 ± 1.07
Sometimes	5	0.9 ± 0.35	2.56 ± 1.91
Frequency of pain on stump			
Never	3	0.63 ± 0.33	2.27 ± 1.64
Sometimes or often	5	1.03 ± 0.32	1.89 ± 1.83
Frequency of pain in other leg			
Never	2	1.18 ± 0	1.07 ± 0
Sometimes or often	6	0.81 ± 0.37	2.22 ± 1.71
Remove prosthesis due to pain			
Never	5	0.77 ± 0.38	1.97 ± 1.47
Sometimes or often	3	0.98 ± 0.37	2.17 ± 2.14
Adequacy socket stump			
Goes very well	3	0.9 ± 0.35	2.56 ± 1.91
Fairly well or It should be better	5	0.81 ± 0.46	1.38 ± 1.07
Prosthesis weight			
No difficulties	3	0.63 ± 0.33	2.27 ± 1.64
A little heavy	5	1.03 ± 0.32	1.98 ± 1.83
Difficulty for sitting down			
Sometimes	4	0.93 ± 0.22	2.2 ± 1.21
Never	4	0.76 ± 0.55	1.86 ± 2.35
Qualifying mobility			
Can walk freely	3	0.63 ± 0.33	2.27 ± 1.64
Can walk at variable speed and with obstacle	5	1.03 ± 0.32	1.89 ± 1.83
Prosthesis satisfaction			
Moderately	3	0.98 ± 0.37	2.17 ± 2.14
Very happy	5	0.77 ± 0.38	1.97 ± 1.47

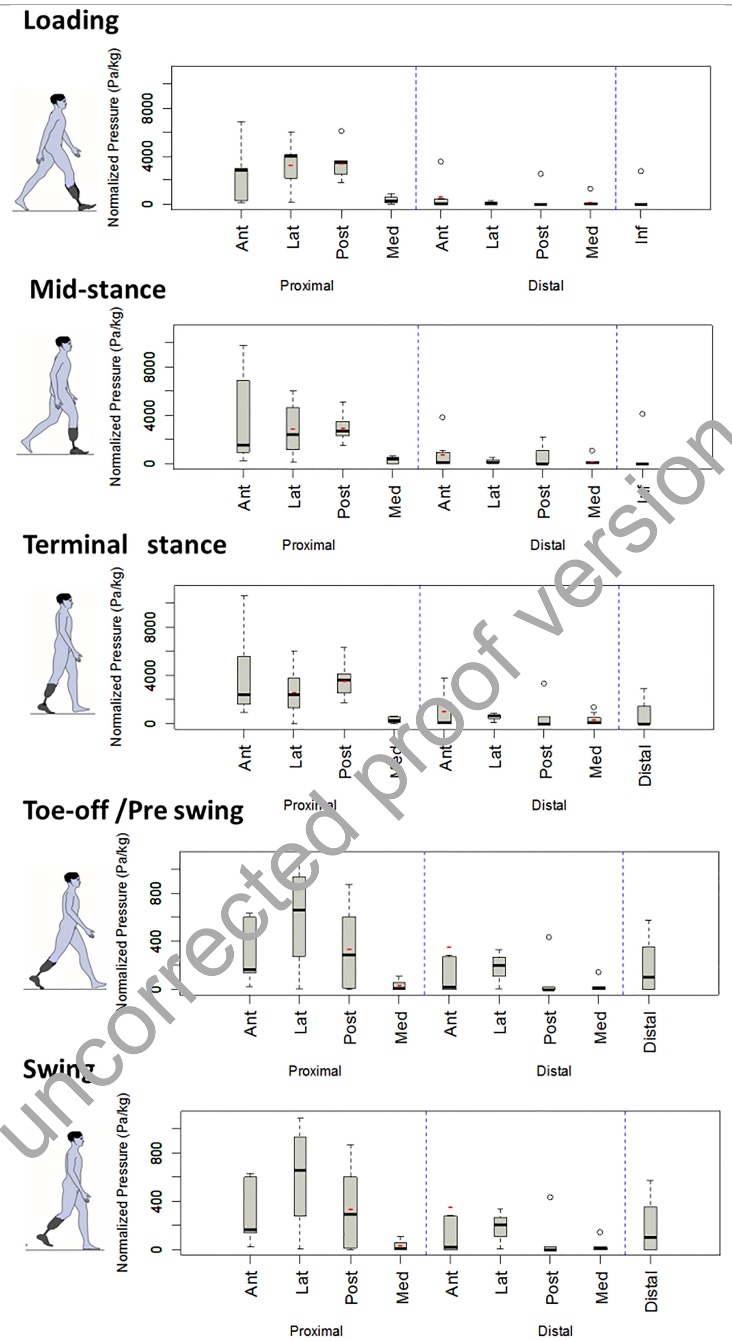

Fig. 3. Static and dynamic pressures boxplot representations according to location of the sensor on the limb.

A correlation was found between static peak pressure and pain score reported by the volunteers ($p = 0.03$). A slight trend of correlation was also found between dynamic peak pressure and pain scores ($p = 0.49$). There was no correlation found between peak pressures and other questionnaire answers (see Table 2).

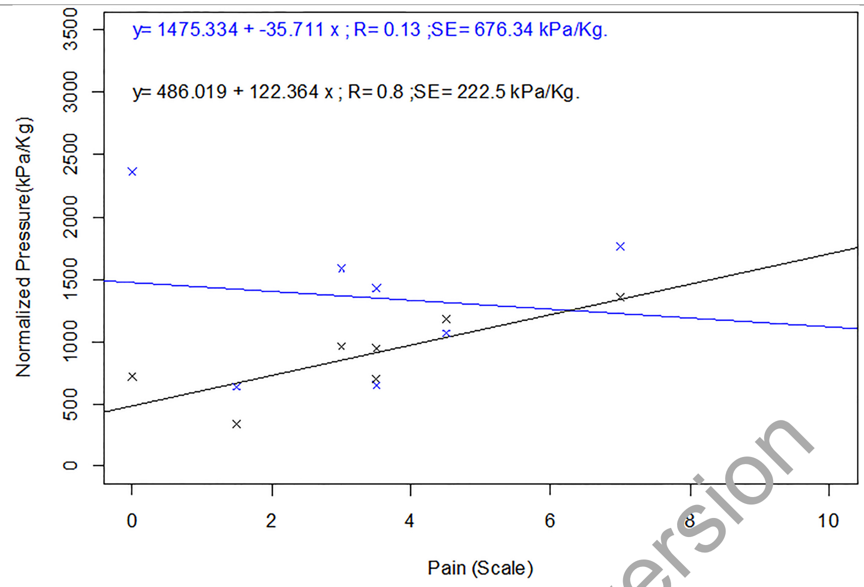

Fig. 4. Correlation between pain score and recorded average peak pressures, in static (black) and dynamic (blue) test conditions.

4. Discussion

The normalised maximal peak pressure recorded in this study, whatever the stump area and the test conditions, is 3.59 kPa/kg. This value is in good agreement with previously reported peak pressures. Performing similar tests on a total of 5 subjects, [18] recorded a maximum peak pressure of 320 kPa in the popliteal region of the stump, with no indication of subject's body weight. In a more recent study, [19] reported maximum pressure values of 183 kPa in the popliteal region again, on a single 57 kg patient, i.e. 3.2 kPa/Kg once normalised against subject's body weight.

Areas on the stump identified as the most subject to high pressures during walking gait are, in descending order, the popliteal area (proximal posterior in Fig. 1), the proximal medial and the patellar tendon (proximal anterior in Fig. 1) areas. These results are in good agreement with those reported by Ali et al. [20]. It can be noticed that variability is much greater in the knee region (proximal stump, as illustrated in Fig. 3).

These results may be affected by two main limitations. First of all, the number of recruited patients is small [8], for obvious reasons related to their critical condition. As a result, variability is high and trueness of averaged peak pressures consequently low. Second, FSR pressure sensors reliability is poor: pre conditioning and calibration prior to each new subject is critical and results reliability should be considered as low. Prior to the study, repeatability of pressure sensors was assessed in conditions similar to those of the tests and was found in reasonable agreement with those reported in the sensor datasheet [21] and discussed in [17].

Many questionnaire methods have been developed to evaluate the artificial limbs to see how satisfied users may be [15,22,23] and [16]. Clinical examination and questionnaires are complementary to experimental measures to enhance feedback on users' comfort and satisfaction of prosthetic sockets. In literature, pressure is reported as being related to patient's comfort [24,25] and its monitoring is efficiently providing additional valuable information to the clinical assessment of the prosthesis [26]. Therefore, a correlation between peak pressures and subjective criteria of satisfaction (pain scores, skin issues or more severe complications, excessive sweating, etc.) was expected in this study. Such a correlation was found on pain score only, and more markedly while volunteer were in static standing up conditions (see Fig. 4).

This suggests that pressure monitoring in the proximal posterior area of the stump (Patellar tendon region) is a relevant, although not necessarily sufficient, criteria for patient's further satisfaction assessment. However, the small number of patients included in this study and their heterogeneous characteristics led to a low statistical power of this result. Also, as recently reported, such a criteria should not be limited to one single measure but rather monitored on a long term basis, with some adequate embedded measuring tool, as it is admitted that pressure distribution in the residual limb and the socket interface change over time [27], as does the risk of injuries [28].

The number of patients is limited. Therefore, statistical analysis should be taken carefully. Averaging on 5 steps as well as filtering of the pressure measurements data is enabled to reduce the bias relative to the walking 'biomechanics'. Additionally, questionnaires' reproducibility could be discussed as highly subjective and dependent on the patient. No quantitative measurements of swelling and sweating could be added in such a protocol and reproducibility should be tested over several days.

5. Conclusion

This study aims to solve a problem encountered by many lower limb amputees: discomfort, pain, and possibly medical complications experienced during the use of their prostheses, which may be slight skin lesions in the best case, or more serious medical issues often leading to patients not to wear their prostheses.

This experimental study describes the interaction in both static and dynamic conditions between the prosthetic socket and the stump of patients. Our results suggest that the maximum pressure in the proximal-posterior region of the stump is a good candidate as an indicator of the adequacy of the prosthesis. A normalised pressure value of less than 0.9 kPa/kg offers the best chance of long-term satisfaction for the patient. In addition, the measurements performed in a simple static position revealed the strongest correlation with the pain during the subsequent use of the prosthesis. Pressure measurements are a step forward in optimizing the design of the socket.

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Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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