Development and Validation of a Tactile Sensitivity Scale for Peripheral Neuropathy Screening

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Abstract— **One of the difficult of the hands peripheral neuropathy screening uncertainty is that the current diagnosis is based not on assessments obtained by accurate and repeatable devices, but mostly on the clinical examination. So, in this paper the authors present a tactile pins-array scale determined with well-defined parameters assessed by non-invasive DITA device (Dynamic Investigation Test-rig on hAptics). This high resolution scale permits to screen the gradual tactile sensory deficit of patients affected by neuropathic diseases. The work has started with an experiment on healthy subjects penalizing their bare finger tactile sensitivity with five different pins-arrays. So, a pins-array scale divided in six levels (grouped in three ranges: low, uncertain and normal tactile sensitivity) was created. The scale was validated with a pilot study on six subjects affected by neuropathic disease. Results show an important role of the scale, supporting the clinical screening and reducing the uncertainty.**

I. INTRODUCTION

The vital role of the sense of touch, involved in many physical interactions between humans and the environment, is well known. Every day, manipulation, grasping and exploration of objects produce touch sensations. These sensations are generated by the activation of mechano-receptors located in the human's skin in response to mechanical or temperature stimuli.

Several works in the literature have studied the relationship between stimulus, receptor, afferent nerve fiber and subjective tactile sensation [1]. Diseases as diabetes, carpal tunnel syndrome, etc., which cause loss of sensation and weakness in subject's touch sensitivity are named peripheral neuropathy; one of the results is that the damaged nerve affect the subject's limbs [2]. This kind of illness can be detected by physical inspections, but the screening is affected by 50% of uncertainty especially at the early stage of the disease. That is due, above all, because the currently first diagnosis is based not on device assessments with high accuracy and repeatability, but on the neurological examination [3]. In spite of everything, during the last decades, it was possible to establish a tactile sensitivity neuropathy scale, but only with four levels: 0-healthy, 1-mild, 2-moderate, 3-severe neuropathy [4]. As it is easy to figure out, the largest part of the uncertainty is to determine whether the patient illness level is 0 or 1, because that means the patient is in healthy or further investigations are necessary, respectively. Moreover, when the diseases are in very early stage, it is difficult to detect it and that causes large time consuming. In the inverse, for the other levels, specific exams as ElectroMiography (EMG), Sensory Evoked Potential (SEP) and Nerve Conduction Velocity (NCV), permit to reduce the level of uncertainty until to 5%. Thus, considering the importance of the touch, it is understandable why researchers as Blix [5], Donaldson [6], Goldschneider [7] and Von Frey [8] designed and built tactile stimulators to investigate sense of touch by means of light touch, pain, vibration or warmth and cold sensation [9]. Unfortunately several nervous system disorders or injuries can cause impaired tactile sensibility and this makes the clinical diagnosis difficult. So, even if they are widely operated with good results [10][11], they have a relevant limit. For instance, a recent study that reviewed 173 works, confirms that despite the mono-filament is easy-to-use and portable, depending on the testing method, gives very different results [12].

Based on this aforementioned screening limits due to the tool low accuracy and due to use of clinical experience with low repeatability, authors think that improving the resolution of current neuropathy scale (mostly between the 0 and 1 levels) is the right method to reduce the uncertain of the tactile sensory deficit. So, the contribution of this paper is to create a higher resolution standard scale for evaluating the gradual tactile sensory deficit of patient affected by neuropathic illness at the early stage. Five levels for improving the resolution on the first range of the neuropathy scale, currently in use, were created. To do this, several experiments were carried out on thirty healthy subjects, penalizing their tactile sensitivity by means of five pins-arrays with different resolution of pins. Results show an important role of the new pins-array scale: it was validate during a pilot study on six subjects affected by neuropathic peripheral disease. To accomplish this study, the authors used the DITA (Dynamic Investigation Test-rig on hAptics) device [13][14].

This paper is organized as follows. Section II describes the device used; Section III shows the experiments carried out to evaluate the tactile performance of the subjects. Results are depicted in Section IV. Finally, Section V addresses to Discussion and Conclusion.

II. TACTILE SENSITIVITY DEVICE: D.I.T.A.

Experiment tests were carried out with DITA (Dynamic Investigation Test-rig on hAptics) as shown in Fig. 1, a device that allows to diagnose the gradual tactile sensory deficit of patients affected by neuropathic illness.

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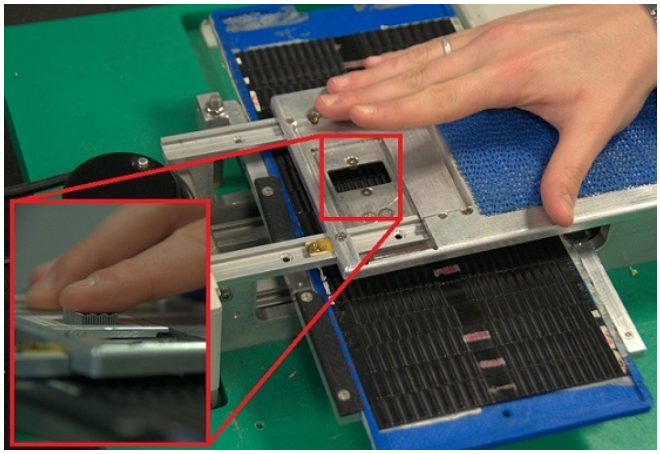

Fig. 1. Dynamic Investigation Test-rig on hAptics: DITA

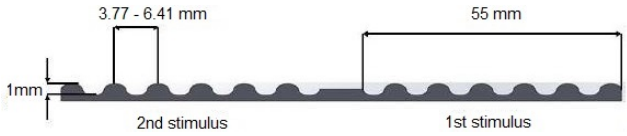

Fig. 2. Grating geometrical properties

A. Test Rig

The metallic support, covered with a blue non-slip surface, is used to support the right arm of the subject during every test; in fact to improving the subject's comfort, the Test-rig has been optimized. All the structure on which the arm is posed, can be moved both by arm itself and motor in a single direction, to allow the exploration of the gratings. In this work, the gratings are 17; each of them has two elements (stimuli) divided by a flat part, as shown in Fig. 2. One of the stimuli is called "reference stimuli", its wavelength is 5.09 mm and it is the same for all the gratings, the other one is called "main stimuli" and the wavelength changes depending on the grating. Using also 6.41, 6.08, 5.75, 5.42, 4.76, 4.43, 4.10, 3.77 mm as wavelengths, and considering there are two positions, 17 different trials are obtained. The subjects moved the arm backward in the direction of that called first stimulus and explored it two times, as the red dashed line shown in Fig. 3. While to investigate second stimulus, the subject moved forward and finally stops on the center. In order to obtain a scale for determining the levels of the peripheral neuropathy, 5 pins-arrays are used in the experimental tests as an artificial tactile handicap. These tactile penalizing device are metallic supports with the following distribution: 7x7, 9x9, 11x11, 13x13, 17x17 as shown in the Fig. 4. In the Table I, are numbered from 01 to 05 and the bare finger is 06. Higher number of pins means that touch sensitivity is closer to the bare fingertip, while a lower number of pins means few contact points between skin and stimulus; so the sensitivity is more penalized. The arrow demonstrates that the tactile sensitivity decreases when the number of pins decreases, as shown in the Fig. 4. The tests carried out with these devices are named pins-array tests.

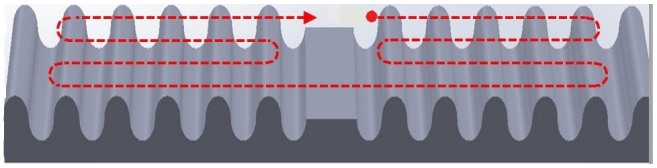

Fig. 3. Path followed by the fingertip during a complete exploration

TABLE I

FROM LEFT: PINS-ARRAY IDENTIFICATION NUMBER; RESOLUTION, INTER-AXIS DISTANCE PINS

Number	Resolution	Pin distance [mm]
01	7x7	2.00
02	9x9	1.50
03	11x11	1.20
04	13x13	1.00
05	17x17	0.75
06	Bare Finger	No pins

B. System Friction Feedback

A friction compensation system has been introduced for two main reasons:

- Some patients may not be strong enough to push and pull a lot of time the slider;
- even if pushing and pulling is possible, it requires focus, so that the patients will be distracted from the test.

iGUS DryLin guide systems with a feedback control was used during the tests. The low friction slider set a position X1(H) depending to the applied force F. This is confronted with system position X2 (G) to find a ΔX. According to it, a Δv is obtained as the scheme in Fig. 5 shows. This Δv is added to the actual velocity of the system that determines the position X2. The algorithm to compute the difference in velocity, is showed in the same Fig.5 and X1 and X2 are confronted in the following ways:

- If the light slider is forward with respect to the system, an acceleration is detected and the system speed must be increased;
- If there is a synchronization between the two sliders, the speed is correct and must be kept constant;
- If the light slider is backward with respect to the system, a deceleration is detected and the system speed must be decreased.

III. EXPERIMENTS DESCRIPTION

A. Procedure

The experiments procedure can be summarized in the following way:

1) the subject must place his/her arm upon the light slider;
2) the subject's fingertip is moved along the grating beginning from the 1st stimulus and then on the 2nd stimulus with or without penalization systems (pins-array);
3) the operator starts each trials directly from the computer and have to ask at the subject the following

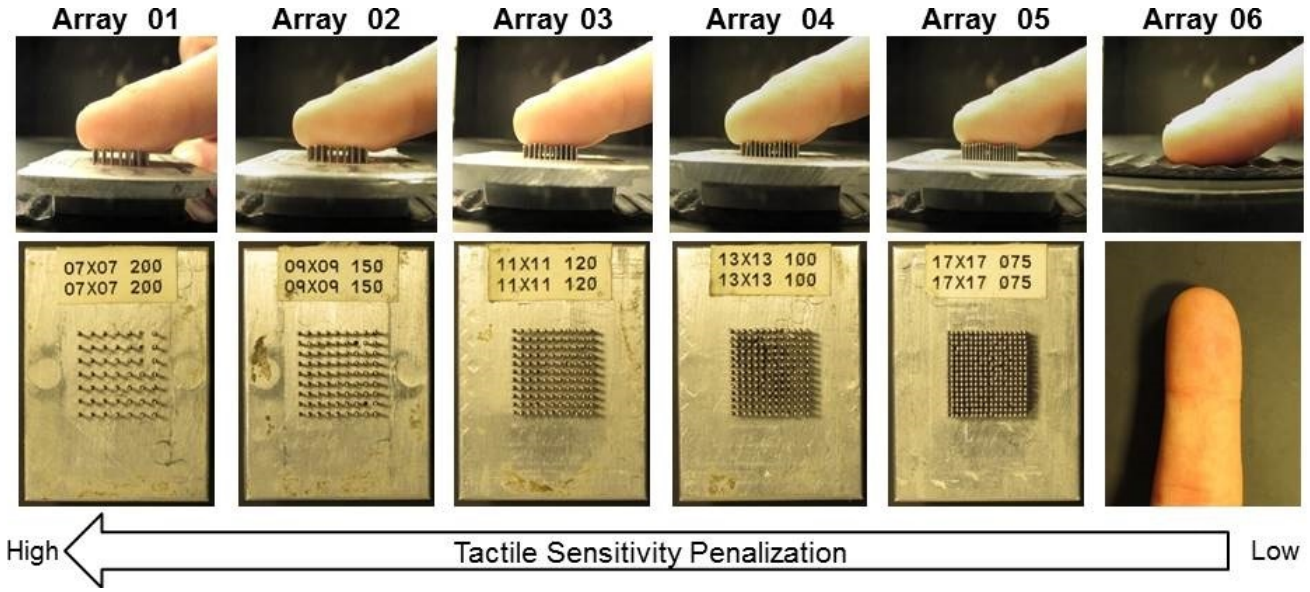

Fig. 4. Pins-array tactile penalization

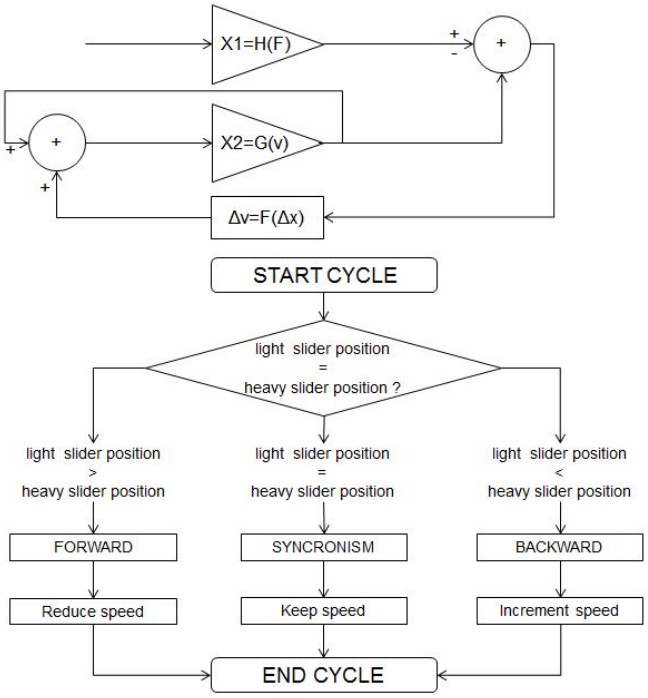

Fig. 5. Friction System Feedback

question: "Has the second stimulus a spatial frequency higher than the first one?";

4) the subject's answer can be only "YES" or "NO" depending on which stimulus is perceived as the one with the higher spatial frequency.

To make sure that touch is the only sense involved in the tests, subjects had worn headphone and black glasses.

TABLE II

ERRORS-ARRAY DEPENDING ON THE NUMBER OF TRIALS AS ABSOLUTE AND PERCENTAGE VALUES. T = TRIALS, A = ARRAY

Experimental Test - Errors							
T \ A	01	02	03		04	05	06
34	10	9	8		8	5	5
51	15	14	11		10	7	6
85	24	21	20		15	10	8
170	42	40	39		26	23	16

Experimental Test - Percentage							
T \ A	01	02	03	UNCER	04	05	06
34	30.0	28.3	24.2	16.0	24.2	14.2	14.2
51	30.0	28.9	22.2	15.0	20.6	13.9	11.7
85	28.0	24.7	24.0	12.0	18.0	12.0	9.0
170	24.7	23.7	23.2	8.0	15.0	13.5	9.67

B. Tactile Sensitivity Scale Development

Thirty subjects (23 males and 7 females, mean age: 24±2yr) participated in this study. Participants were without any previous experience in tactile psycho-physical experiments, right handed and university students. They were divided in 6 groups composed by 5 people. Each group experienced a different pins-array or bare finger (01-06). Each grating was tested 10 times per each subjects, that means the total number of trials was 170 per person. In order to relate the number of wrong answer (errors) with the number of trials, three subsets of 170 trials, each one consisting of 85, 51 and 34 trials, were extracted. These subsets were, respectively, the 5, 3 and 2 repetitions of the 17 gratings. Based on the well-defined procedure [13], for each test, were calculated the numbers of errors as shown in the Table II.

C. Pilot Study to validate the Tactile Sensitivity Scale

In order to validate the scale, authors have selected six subjects (mean age: 58±4yr). According to the current doctor's screening diagnosis, the first four were slightly ill, but not completely defined (between 0-1 level) and the other two almost in healthy (level 0). As already explained, the patient's task was to report the stimulus that has got higher spatial frequency, but, an important difference is about the number of trials: three subjects performed 85 trials, instead, the others ones only 51 trials. All the subjects performed the test with bare finger. The subject's errors were summed and converted in percentage in order to be compared with the Table II.

IV. RESULTS

A. Results of Tactile Sensitivity Scale

Analysis has been focused on subjects errors on each pins-array test with same penalizing device and summary statistic was calculated for each trial test (170, 85, 51 and 34 trials). Repeated measures with one-way ANOVA were conducted to check if there is a substantial effect of errors on pins-array test performance; when that happens, the difference between two pins-arrays performance is named "significativity". To detect the pairs of pin-arrays performance significantly different, in each trial test was calculated a post-hoc test. Significativities, obtained from the analysis, were used to define a high resolution standard pins-array scale, divided in three ranges: low (red), uncertain (light grey) and normal (green) tactile sensitivity, as shown in Table II. The uncertainty of the tactile sensitivity measurement is determined by the difference between two closest significant pins-arrays. These uncertainty values (UNCER) are 16%, 15%, 12% and 8% for 34, 51, 85 and 170 trials respectively, as shown in the Table II.

B. Results of Pilot Study

To validate the new scale, a pilot study was carried out with 6 patients divided in two groups who tested 51 and 85 trials each; the results are the following: first three subjects accomplished the test with 26, 22, and 8 errors (31%, 26% and 9%) respectively; the other three subjects with 22, 15, and 6 errors (43%, 29% and 12%) respectively. The highest error's percentages of the patients of two groups (43% and 31%) are higher than the worst performance and that means they are out the scale. While the 26% and 29% are positioned within the red range between the first (01) and second (02) pins-array level of the scale, as shown in the Table II. This result shows that these two subjects have a very low tactile sensitivity as a healthy subject with the worst penalization's device. Contrariwise, patients with only 9% and 12% of error's percentage, showed high precision during their tests, proving that they are completely healthy and positioning them-self in the green area between fifth (05) and sixth (06) pins-array. It is important to highlight as the result showed a percentage of false positives equal to 0, because all of the healthy subjects were completely healthy.

V. DISCUSSION AND CONCLUSION

From experimental tests conducted on healthy people, authors obtained a well-defined high resolution pins-array scale divided in six levels, as shown in the Table II. Thanks to ANOVA analysis these levels were grouped in three ranges: low (red), uncertain (light grey) and normal (green) tactile sensitivity. This scale was validated with pilot study results carried out on six subjects affected by peripheral neuropathy. The comparison between healthy and ill subjects showed the following results: despite they used their bare finger, two patients had performance worse than the first (01) level of pins-array scale; other two patients had performance similar to the first (01) and second (02) levels of pins-array scale; the last two patients result are similar to the sixth level (06). So the overall result is that this new scale defines three levels of tactile sensitivity within the first range (from 0 to 1) of the current neuropathy scale. The use of the pins-array scale permits, in clinical physical inspection, to evaluate the assessment of tactile sensitivity for supporting the peripheral neuropathies screening. It is important to notice that thanks to DITA device, the uncertain range of neuropathy scale (between 0 and 1 level) is reduced from 50% to only 8%. This finding opens up the possibility that the DITA, a non-invasive device, might be useful in clinical and pre-clinical diagnosis of peripheral neuropathies. Actually, authors tested the DITA device on only 6 subjects, but the future goal is to carry out more tests, in order to have the validation's scale on a largest sample group.

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