How to measure gait improvement

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One of the most challenging tasks for physicians dealing with movement disorders is correctly measuring the improvement achieved by intervention. In particular, we have noticed that Gait performance in patients with Parkinson's disease is significantly affected by the patient's awareness of being tested, or even just being observed. The effect of this condition alone can be so strong, that it causes a transition from "off" to "on" and from freezing of gait (FOG) to non-freezing. The effect is magnified by the clinical environment and by the presence of a physician - the patient feels that he/she is expected to perform better - and he/she does! In some patients, this “clinical effect" can raise the level of the baseline performance without intentional intervention) to the performance level that might) be achieved by any other stimulation. This may be viewed a positive effect in itself. It should not really matter how the stimulation, or the clinical effect, is created, and, in this context, the device may be viewed as a means for bringing on the "clinical effect". However, if the clinical effect is present from the start (that is, the baseline condition is "on"), only a part of the effect of the device can be measured. This is the additional "cuing" effect, consisting of visual cuing by the virtual tiles, and auditory cuing by the audio channel. The question is how to separately measure these two effects, the "clinical effect" and the "cuing effect", and how to measure the combined effect of the device.

To this end, let us assume that the natural gait performance of a PD patient called "N" can roughly exist on two different levels: OFF(N) and ON(N). The normal performance of N may be either OFF(N) or ON(N), or it may fluctuate between OFF(N) and ON(N). The gait performance of N can be brought from level OFF(N) to level ON(N) by medication or by some trigger. The "clinical effect", or just putting the device on the patient without turning it on, may each serve as such a trigger. Turning the device on creates a "cuing effect". Let CB(N) denote the clinical baseline condition of N, that is, the initial performance level of N as N comes to the clinic. Depending on the level of arousal ("OFF(N)" or "ON(N)) at the clinical baseline condition, we may have

(1) CB(N) = OFF(N)

or

(2) CB(N) = ON(N)

Let BE(N) denote the burdening effect of the device. The clinical

performance of N, with the
device on the patient, but turned off, CPOFF(N), may be either

(3) CPOFF(N) = OFF(N) - BE(N)

Or

(4) CPOFF(N) = ON(N) - BE(N)

Let CP(N) denote the clinical performance of (N), with the device turned on, and let CE(N) denote the cuing effect. Turning the device on, the clinical performance of N may be either

(5) CP(N) = CPON(N) = OFF(N) - BE(N) + CE(N)

or

(6) CP(N) = CPON(N) = ON(N) - BE(N) + CE(N)

The on-line improvement in performance of N due to the device, I(N), is measured as

(7) I(N) = CP(N) - CB(N)

In a fluctuating patient, a combination of (1) and (6) yields

(8) I_(N)= (ON(N) - OFF(N)) + CE(N) - BE(N)

With training, the burdening effect BE(N) will be reduced or even eliminated, yielding the maximal improvement that can be obtained due to the device

(9) Imax(N)= (ON(N) - OFF(N)) + CE(N)

For a non-fluctuating patient, we shall obtain, in both the case of (1) + (5) (patient OFF) and the case (2) + (6) (patient ON), the improvement

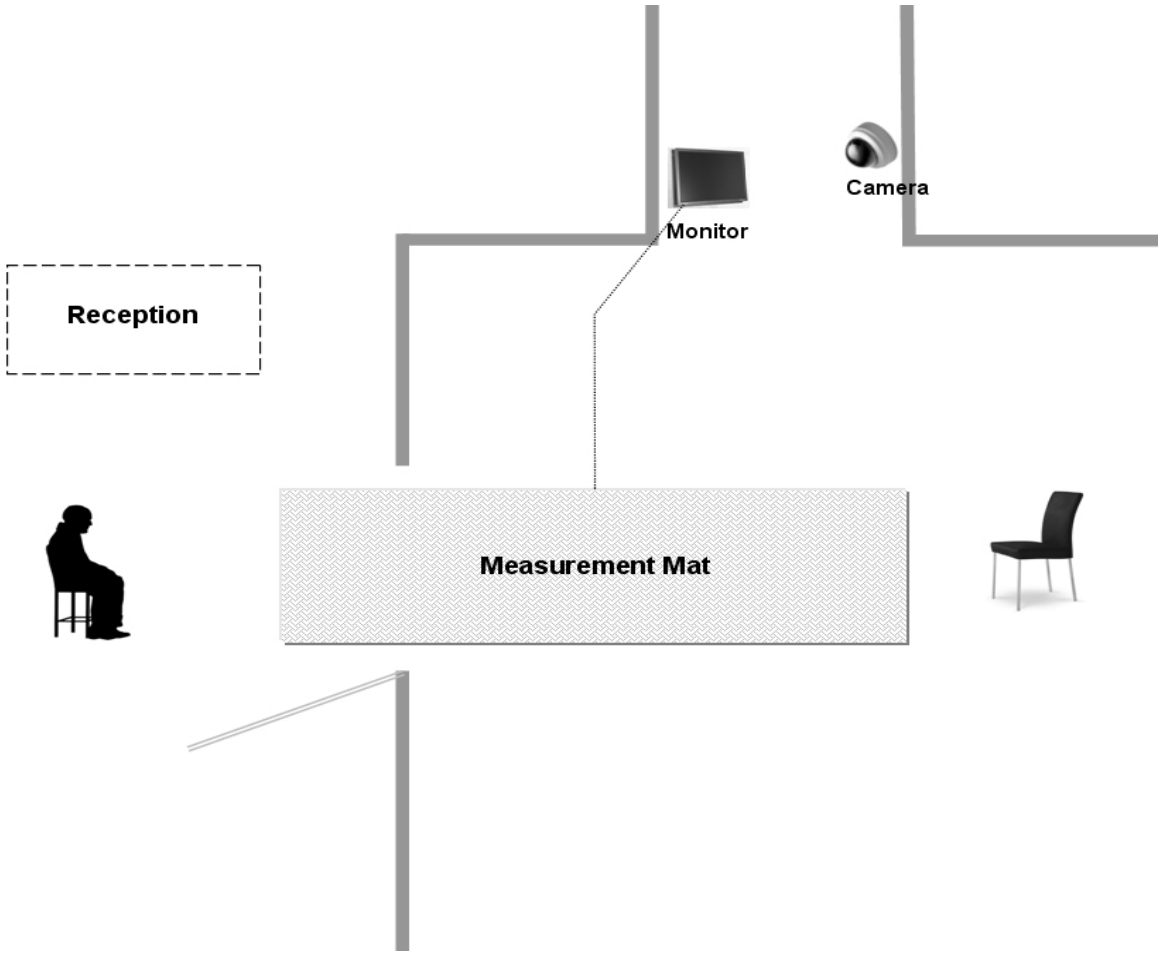
(I(N) = CE(N) - BE(N (9)

which may even be negative (as, without training, BE(N) may be greater than CE(N). With training, BE(N) will be reduced or even eliminated and the improvement will tend to be non-negative).

Clearly, in order to measure Imax(N) (or even I_(N)) in a fluctuating patient N, condition (1) must be satisfied, that is, the clinical baseline condition CB(N) must be OFF(N). In order to measure this condition, the patient, arriving at the clinic in OFF(N), must not be "switched" into ON(N) immediately by the clinical condition. This means that we must delay any such "switching" until after the baseline OFF(N) performance has been measured.

To achieve this, baseline performance shall be measured immediately upon arrival at the clinic, before any observation, description or explanation of the testing condition or equipment are made available to the patient. The patient should not become aware of the fact that he/she is being tested yet.

The scene has to be set up and the measuring equipment hidden before patient arrives. For instance, in a clinical scene using the GaitRigh mat system and a video camera, these are hidden and operated by remote control. The track includes a doorway to induce freezing of gait, as depicted in the figure below.



The following sequence of events takes place:

1) Patient arrives at reception desk.
2) Receptionist alerts test crew by a cell-phone.
3) Test crew starts equipment by remote control. Testing is conducted as follows:

a) Baseline (obscured):Patient is asked to approach a chair at the end of a given track and sit on it. Baseline performance is measured.

Nature of test is explained to patient. The following steps of test are conducted, measured and recorded:

b) Device off: Patient is asked to get up from chair and stand. Device is put on patient, turned off. Patient is asked to walk to end of track, turn around, walk back to the chair and sit on it.

c) Device on: Patient is asked to get up from chair and stand. Device is put on patient and turned on. Patient is asked to walk to end of track, turn around, walk back to the chair and sit on it.

d) Short-term residual: Device is taken off patient. Patient is asked to walk to end of track, turn around, walk back to the chair and sit on it.

Clinical performance analysis: Compare c) to b) to assess the on-line effect of the device without the burdening effect. Compare d) to a) to assess the short-term residual effect of the device.

At home training: Following initial clinical trials, as described above, patient may take the device home for a period of one to two weeks for training. It is recommended to train with the device twice a day for at least 30 min each time. In the words of one of the patients, "the trick is training with the device as much as possible".

Return visit to clinic: Following the at-home training period, patient returns to the clinic for a repeat of above clinical testing. Performance is compared to that achieved in initial clinical tests.