A NEW HARMLESS METHOD FOR THE DIAGNOSIS OF THE ERECTILE DYSFUNCTION: THE DIGITAL INFLECTION RIGIDOMETER

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**Introduction:** We have designed the Digital Inflection Rigidometer (DIR), a new electronic method for the diagnosis of the erectile dysfunction (fig. 1).

**Objectives:** We aim to demonstrate that the DIR, used by the patient himself either at the clinic or at home will provide accurately, in a noninvasive and fast way the penile axial rigiditiy (PAR) in grammes, the relative intracavernosal pressure (RICP), the glans temperature (GT) and the total time of useful erection.

**Method:** 15 impotent patients were evaluated. We used DIR, Rigiscan and Eco-Doppler in the diagnosis process. Patients where divided into two groups A, of 8 patients and B, of 7 patients. Minutes before evaluation, we injected both groups with 15 mg. PGE1. Patients from group A were monitored with the Rigiscan. Eco-Doppler evaluation was performed to group B. Axial rigidometry test was applied to both groups, instructing how to use the DIR and, that in case erection was achieved, they should take measurements with a frequency of 5 minutes.

**Results:** From group A, in three cases the Rigiscan showed a circumferential rigidity between 60 and 80% which did not correlate to the axial rigidity achieved between 300 and 400 grs. The Eco-Doppler evaluation showed normal vascular anatomic parameters but did not correspond to a normal axial rigidity, above 500 grs.

**Conclusions:** The DIR has proved to be the only equipment able to measure reliably the axial rigidity, the relative intracavernosal pressure and the glans temperature in a noninvasive way, and it offers the possibility of being used by the patient himself either at the clinic or at home. It provides too information about the total time of erection.

**KEY WORDS:** impotence, diagnosis, penile axial rigidity, relative intracavernosal pressure.

INTRODUCTION

When we read in literature about the diagnosis of the erectile dysfunction about the quality of the erection, we may find the following expressions: unstable, suitable erection, short erection, bad and good quality of the erection, sufficient or insufficient erection.

Don’t you think these appreciation lack precision?
How can we know the grade of erection and how can we value it in a more precise way?

Up to date, there was no available equipment with which to measure the PAR, the penile force for penetration and the moment of inflection.

It was necessary to have an equipment to measure the penile rigidity in an accurate way and given in grammes. And more important, an equipment that enables the patient to take the measurements in the privacy of home.

At the Clinic it is impossible to achieve a sufficient stimulating atmosphere, in an erotic-sexual aspect, since there is a psychological inhibition to stimulus, due to the environment in which the test is performed.

There are many other examples in the recent literature that show the need pointed out by Dr. Goldstein for an accurate device able to provide the PAR, as the Rigiscan can only provide the circumferential rigidity.

What is the penile axial rigidity (PAR)?

"The methodology to record the quality of penial erection is based on the determination of penile blood pressure, blood flow, temperature, circumference and rigidity. The latter characteristic, penile rigidity, has proven to be the most elusive yet most informative parameter of erectile quality."

The rigidity of the penis is the pressure capacity in its longitudinal axial measured in grammes.

In other words, the rigidity of the penis is its capacity to penetrate during sexual intercourse without the help of the hands. Karacan demonstrated that the average penile axial rigidity needed for penetration in a well lubricated vagina is 500 grs.

What is the intracavernosal relative pressure (ICRP)?

The intracavernosal relative pressure is a new concept in Andrology. The DIR provides such pressure based on the patient's arterial maximum pressure.

The DIR registers the PAR when the patient makes pressure with the glans against the sensor. The device registers 50 measurements per second, for a period of 5 seconds. After this 5 seconds or at the moment of inflection, should the penis bend, the DIR shows on its display the force exerted by the glans against the measuring sensor. (fig. 2)

That force is due to the blood pressure inside the corpora cavernosa. The DIR provides through a mathematic calculation

\[ \text{Pressure} = \text{force (grs)} + \frac{908}{109} \]

the pressure of liquid necessary inside the corpora cavernosa expressed in mmHg,
therefore, the relative intracavernosal pressure is the pressure needed in order to achieve a determined rigidity, given in grammes.

Consequently, the relativity of that pressure is based on the grammes achieved and will vary according to the arterial maximum pressure and the penile anatomy of the patient.

The glans temperature (GT)

Very often when patients explained their impotence symptoms, they mentioned that the glans remained flaccid and sometimes cold. For that reason we thought it was interesting to know the glans temperature as an additional diagnosis parameter.

Usually the temperature of the glans in its flaccid state ranges from 34'5º to 35'0º C., in a room temperature of 20º and 30º C.

When penis has reached erection of an axial rigidity higher than 500 grs, the glans temperature increases by 1º-1'5º C, if there is no pathology.

This new parameter allows the physician to verify a good blood circulation inside the spongy corpora.

In case of a fibrosis of corpora cavernosa, with an axial rigidity lower than 400 grs. due to the penis bending, the glans temperature will be between 34'5 and 34'8º C, therefore will not increase as it should, and nor will it increase in case of a fibrosis of the spongy corpora. Up to date, there was no device to measure and record the temperature of the glans. 4

Erection duration

It is one of the most important parameters given by the DIR. The device can measure the total time of erection maintained by the patient during the course of the rigidometry test at various points during the erotic stimulus.

As a result, we are able to know if there is a sufficient/insufficient arterial blood flow as well as the efficiency of the corpore-o-veno-occlusive mechanism.

MATERIAL AND METHODS

How does the Digital Inflection Rigidometer work?

A. PHYSICAL PRINCIPLE

The Digital Inflection Rigidometer is designed to determine if the applied force has been total and lineal, or if, on the contrary, that force has suffered a moment of inflection during its time of application, although the pressure of the penis against the DIR's sensor continues.

This is the D.I.R.’s work basic principle:
When two forces are confronted in the same way but in opposite directions, a resultant is produced in the direction of the greatest.

When two forces are confronted in the same way but in opposite directions and one of them presents a vectorial variable, the vectorial value is reflected in the D.I.R. The result given from the measurement is the value of the force from the sum of the diverse vectors in the angular value. Therefore, the real force of use can be determined. (figs. 4-5) 5

B. HOW TO USE THE DIGITAL INFLECTION RIGIDOMETER?

At the clinic, we do the D.I.R. test after video-sex-stimulation or/and an injection of vasoactive drugs. Before instructing the patient how to use the DIR, we load the patient's personal data in the device through the software as it gradually requests the information on each screen. Then we handle the device to the patient, who will make the measurements either in the privacy of a separate room at the clinic or at home. In order to take the measurements, the patient will turn on the device and press START to begin the session. Afterwards, he will press the glans against the sensor along the longitudinal penile axis. The D.I.R. can register up to 8 measurements; after that the display will show the message "NO MEMORY". The maximum pressure that the device can register is 3500 grs.; above which the pressure against the glans can be painful. We ask the patient to take the measurements in case he has an erection every 4 or 5 minutes by introducing the penis inside the sensor and pressing with the glans against the measuring membrane for a minimum of 5 seconds. If the physician wants to know the glans temperature also, the patient must keep the glans in contact with the membrane during 10 more seconds, but without exerting any pressure. When the patient uses the D.I.R. at home, he can measure too in 5 seconds the PAR before penetration during the sexual intercourse with his partner at the moment in which he believes that he has achieved maximum erection.
After the patient has taken the measurements, either at the clinic or at home, we will be able to have access to the data registered by connecting the D.I.R. to our computer system, and we obtain a graph with all the parameters that have been registered. (fig 6).

To make it easier to detect an erectile dysfunction, the bars of the graphs are into three colours:

Red represents measurements below 400 grs of axial rigidity.
Yellow represents measurements between 400 and 500 grs.
Green represents measurements above 500 grs. The intensity of the colour will be darker as the rigidity measured in grs. is above 1000 grs.

The GT appears on the upper part of the bars, in green numbers that indicate centigrades. The ICRP is indicated in red given in mmHg. On the right hand side of the graph you can see the maximum, average and minimum PARs registered. The DIR shows the total number of measurements performed and on each session it registers the date, time of start and moment when the maximum rigidity is recorded or inflection occurs.

Below this box, we can observe the information regarding the patient: his clinical history number, personal data, age and maximum arterial pressure.

At the lower part of the graphs there is a space for typing medical observation and diagnosis.

This is how the D.I.R. works:

The sensor takes 50 measurements per seconds during 5 seconds. It registers the maximum pressure exerted by the glans against the sensor at the exact point at which inflection occurs corresponds with the PAR.

When the patient's data is entered, it is essential to include the maximum arterial pressure of the patient. The D.I.R. can determine through a complex algebraic calculation the ICRP, in relation to the PAR achieved.

The sensor of the D.I.R. has a very sensitive thermometer which can measure the GT in fifteen seconds.

Comparison of the DIR with the Rigiscan
During the 92nd AUA Meeting, held in New Orleans, Dr. Goldstein and col. in their communication spoke about the real need of the knowing the axila rigidity in the diagnosis process: "rigiscan radially-based rigidity has correlation to intracavernosal pressure, a major determinant of penile axial rigidity. Rigiscan rigidity, however,
incorrectly assesses the effect of penile diameter and cavernosal expandibility on axial rigidity and is insensitive to penile length. There is need for an improved clinical measure of penile axial rigidity."

As we explained, we use the Digital Inflection Rigidometer at our Clinic in order to know the following parameters: the PAR in grams, the ICRP (related to the systolic arterial pressure) and the GT in only 15 seconds.

The Rigiscan measures only the circumferential rigidity and the duration of an erection, because tumescence is not a useful diagnosis parameter, as it is only a step from flaccid state to erection. The measurements can last between 30-60 minutes in real time. 7-8

When diagnosing an erectile dysfunction, every andrologist aims to: 9

1. know the quality of the erection through its rigidity.
2. evaluate the effect on the erection of an erotic stimulus.
3. know the effect of the vasoactive drugs and other new drugs.
4. know the rigidity of the penis as result of a stimulus.
5. be able to measure the duration of an erection
6. measure the variations in the erection due to positions, movements or other circumstances.
7. obtain this data with the fastest, most reliable, painless way.

All the above parameters can be provided by the Digital Inflection Rigidometer.

With the use of the DIR we are able to establish the resistance to penetration of the vaginal introitus, which in 16% of the studied couples was superior to her partner's PAR, sometimes greater than 600 grs., unabling any possible penetration. Such resistance can be due to the sclerosis of the vaginal introitus which may be the real cause of the penetration incapacity.
RESULTS

Rigiscan versus Digital Inflection Rigidometer

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<tr>
<th>Rigiscan</th>
<th>Digital Inflection Rigidometer</th>
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<tr>
<td>1  The Rigiscan only measures the circumferential rigidity at the base and at the tip of the penis and in only 55-60% of the cases they are correlated to PAR.</td>
<td>The DIR measures the real PAR and provides in the 100% of cases its real value and the ability of penetration.</td>
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<td>2  In order to use the Rigiscan in real-time, we need a monitor and VSS or injection of vasoactive drugs.</td>
<td>The DIR measures accurately the axial rigidity in only 5 seconds, with the collaboration of the patient, with no need of a monitor.</td>
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<tr>
<td>3  Rigiscan: The patient must wear the sensors at least for a period of 20 minutes.</td>
<td>With the DIR there is no circular sensor. The patient uses the sensor when he wishes and only during 15 seconds.</td>
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<td>4  The Rigiscan does not inform of the penile curvature or inflection.</td>
<td>The DIR informs of the moment of inflection which corresponds to the patient's maximum rigidity.</td>
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<td>5  The Rigiscan needs maintenance of the sensor rings.</td>
<td>The DIR does not need any maintenance.</td>
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<td>6  The Rigiscan may indicate in a 60% of cases an optimum circumferential rigidity both at base and tip of penis, although in all the pathologies of penile curvature, fibrosis of corpora cavernosa, Peyronie's disease, etc... it will provide a false positive.</td>
<td>The DIR provides accurately in all cases the axial rigidity of penis, the necessary rigidity for the sexual intercourse and at which pressure the penis bends.</td>
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<td>7  The Rigiscan can be used by the patient at home only when the patient sleeps, therefore with no help of the sensorial stimulus.</td>
<td>The DIR can be used by the patient at home in the erotic ambience that he creates with his couple and when he thinks the penis has achieved its maximum erection. The measurement only takes 5 seconds and he can take up to 8 measurements. The Rigiscan does not present all these advantages.</td>
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<tr>
<td>8  The Rigiscan can not inform of a venous leakage, while the DIR can confirm its existence.</td>
<td>When from the clinical history a venous leakage is suspected, we indicate the patient to measure the PAR with the DIR and, if pressures obtained are greater than 600 grs., he should walk 4 or 5 steps along the floor and take the measurement again. If there is a venous leakage, the axial rigidity will immediately drop to 300-400 grs.</td>
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After comparison of the two devices, we consider that the Digital Inflection Rigidometer is the most reliable device to know the quality of an erection, and thus, to come to an accurate diagnosis of an erectile dysfunction. It provides in a fast and painless way reliable information about: penile axial rigidity, given in grams; relative intracavernosal pressure and glans temperature, offering the advantage that the measurement can be taken by the patient himself, either at the clinic or at home, increasing his self-confidence and avoiding this way the psychological inhibition at the clinic.

Since 1995, we have used the DIR with more than 150 patients affected of erectile dysfunction and the results showed to be on a level when compared with the diagnosis obtained through the Rigiscan, but in fact more precise and accurate since the Rigiscan only provides the circumferential rigidity and does not give information about axial rigidity which is essential for a satisfactory penetration. The Rigiscan cannot determine the inflection data and therefore could give false parameters.

The 150 patients were divided into the following pathologies:

- Diabetics ........................................ 41
- Vascular disease .............................. 31
- Peyronie disease .............................. 24
- Venous leakage ............................... 14
- Psychological ................................... 11
- Congenital curvature ....................... 10
- Alcoholism ..................................... 6
- Tobacco and drugs ...........................  5
- Primary erectile dysfunction .............. 5
- Rectal surgery ................................. 2
- Spinal chord tumor ........................... 1

As part of the protocol, all 150 patients were injected 20 mg. of PGE1 before taking the measurements with the DIR. The results were as follows:

The DIR registered in 29 of the 41 diabetic patients a PAR between 200 and 300 grs., while the PAR of the rest of diabetic patients was greater than 500 grs.

Of 31 patients that presented a vascular disease, 25 showed a PAR of between 300 and 500 grs. The PAR of the 6 other patients was above 500 grs.

In the 24 patients with Peyronie's disease, 18 presented a positive Rigiscan with a circumferential rigidity of 70 per cent. The DIR proved that the PAR was below 300 grs.

In the 14 cases in which venous leakage was suspected, patients used the DIR at home when in its privacy the erections reaches its peak, the PAR was more than 600 grs. Patients were instructed to pace around the room and retake the pressure with DIR in all cases where there was a real penis leakage. PAR dropped to 300 grs.

In the 10 patients with congenital curvature, the Rigiscan presented circumferential rigidities around 60/70%, while the DIR informed of PAR below 400 grs.

All patients with psychological erectile dysfunction presented PAR between 600 and 1200 grs.

The rest of studied patients did not reach 200 grs. of PAR.
The D.I.R. provides us with a very valuable information in regard to the PAR in the following cases:

- Erectile Disfunction (E.D.) with an arterial background.
- E.D. with a venous background.
- E.D. with a psychological background.
- E.D. of a mixed origin.
- Control of the effect of vasoactive substances.
- Control of the effect of video-sex-stimulation
- Measurement of morning erections.
- Control of practical results of Vacuum Plus Treatment.
- Control of practical results of venous surgery
- Control of practical results of arterial surgery.
- Control of rigidity after implantation of the prosthesis
- Control of failings of hydraulic prosthesis.

**CONCLUSIONS**

We are persuaded of the advantages that this new device represents for the diagnosis of the erectile dysfunction, as for the first time it is possible to measure the **penile axial rigidity**, the **relative intracavernous pressure** and the **temperature of the glans**. All these measurements are taken accurately, in a maximum of fifteen seconds, with no pain and at a reasonable cost.

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