

Study VQD-42-012

**Assessment of the capacity of giving up tobacco
of an electronic patch, O² patch**

*Study 10-page report submitted by
Mr VQ DANG, MD on March 9th 2004*

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of an electronic patch, O² patch**

Study promoter : IDT France
Impasse en Marcie
F-66600 Salses le Château - France
www.idt-France.fr
www.slim-patch.net
email : idt@idt-France.fr
Phone : +33 -4 68386233
Fax : +33 -468386143

Study conducted by : MEDI-ESPACE private hospital
Avenue Catalogne
F-66600 Salses le Château - France
Phone : +33 -468386774

Study Director : Mr VQ DANG, MD
Pain treatment
Cancer metastasis research & treatment
vqdang@aol.com
Phone : +33-4 68386774

AIMS

The aims of this study are :

- to explore the capacity of the total relief of tobacco dependency by O² patch, a chemical substance free electronic patch against smoking
- to confirm the success of giving up tobacco without anguish and compensatory side effects (nervous irritability, over-eating and insomnia)

The programmed aid to giving up tobacco of O² patch concerns two phases :

1. Phase 1 : Eliminating of the automatic smoking gestures in 2 weeks
2. Phase 2 : Total relief from tobacco dependency in a further 2 weeks

The total duration of test is one month.

INTRODUCTION

Tobacco addiction and cigarette dependence are serious in western countries :

- Smokers are getting younger and younger (55% of 18 –25 year old)
- 30% of women smoke

They are exposed to a significant increase in the risk of cardio-vascular pathologies (heart attacks, strokes,...) and cancers (lungs,...). Women who smoke suffer particular illnesses as low fertility, premature ageing, early menopause and breast cancer that is still a grave cancer by its frequency and its difficulty in treatment.

The last years have seen an awareness of the risks incurred along with a choice of life that causes smokers to giving up smoking. French studies confirmed more than 70% of smokers in France wish stopping smoking in 2004; they are 15 millions.

The pharmaceutical laboratories have put into markets a full range of Nicotine patches with various degrees of the chemical substance to help the relief from tobacco dependency. The main Nicotine protocols of treatment are at least 3 months with an average cost at 120€per month .

Various clinical tests have clearly showed the limits of the treatment by Nicotine : out of the side effects of the Nicotine chemical substance that are serious for cardio-vascular patients, pregnant women and women who take pills, only 10% of smokers who have tried them can totally giving up..

In two medical publications on 2004, INSERM –the French National Research Institute of Health and Medicine- clearly suggests that :

- the tobacco dependency would be due to other chemical substances and factors out of Nicotine
- smokers, especially pregnant women who smoke, have to stop smoking and to use the chemical substance free alternative means to stop smoking

OPERATING METHOD

1. *Smokers recruited*

10 confirmed smokers have been recruited in the clinical trial.

Any men has replied to our recruitment; the same regarding to young smokers under 20 year-old.

All of testers are female; the oldest is 61 year-old and the youngest 22.

The details of age, levels of tobacco dependency,... as shown in the picture below :

	age	Cigarettes/day	Years of smoking	Profession
1*	43	30	25	Professor
2*	42	25	6	Director of company
3	52	10	32	No profession
4*	54	15	15	Financial expert
5*	22	20	7	Barwoman
6*	34	20	20	No profession
7*	37	15	17	Hospital nurse
8*	40	20	20	Hospital nurse
9*	61	15	30	Retired
10	47	20	20	Private nurse
average	43.2	20	18.7	

* *Testers already have tried to giving up without success. Various methods have been tried and some testers have tried two or three distinct methods.*

1. *acupuncture (x1)*
2. *by themselves (x2)*
3. *Nicotine patches (x7)*

They have stopped the test after a variable delay : from 1 to 2 months

The two main reasons of the failure are :

- a. *the strong anguish under Nicotine patches*
- b. *the compensatory over-eating with the growth of the body weight*

Notes :

Women who already have child are most being concerned by the serious risks of illnesses caused by tobacco. Their motivation for giving up tobacco is high.

Two of them have tried to stop smoking during the pregnancy period without treatment or support from physicians.

The French national campaign against smoking has much effect on child, *especially girls*; they constantly ask their parents who smoke to stop smoking. It is a real another motivation of the parents to relieve tobacco.

2. *Bioparameters control*

The below bioparameters have been recorded before and at weekly meetings during the whole month of test

These parameters have indirectly showed the level of :

1. the anguish or nervous irritability
2. the compensatory over-eating

Bioparameters	Before test	Every weeks
Blood pressure mmHg	1 time	4 times
Weight Kg	1 time	4 times

3. *Means*

O² patch is used for the relief of tobacco dependency.

O² patch is a chemical substance free electronic patch.

By the compact and wireless design of the device, the testers have used it at home or anywhere they wish.

We advised testers to avoid any drugs or medicines against anguish or nervous irritability during the test

We advised testers to do not change their habits of diet and of life during the test



Product tested : O² patch, an electronic patch against tobacco dependency

4. Protocols of treatment

2 groups of 5 testers each have been formed.

We met them every weeks but at different moments to avoid any psychological or results influence of a group to another

Phase 1

The 2 groups have begun the treatment by the phase 1.

The aim of the phase 1 is both the eliminating of automatic smoking gestures and the control of inductive anguish

The area 1 of body (neck) has been treated

The testers used O² patch during (at least) 30mn a day

The total duration of this phase 1 was 2 weeks

At the weekly meeting, the Blood Pressure and the Weight have been recorded.

The daily cigarette consumption and the nervous irritability have been noted

We have noted also the simplicity of use and the consumption of accessories (battery, adhesive pad,...)



Phase 1

Treatment of the neck area

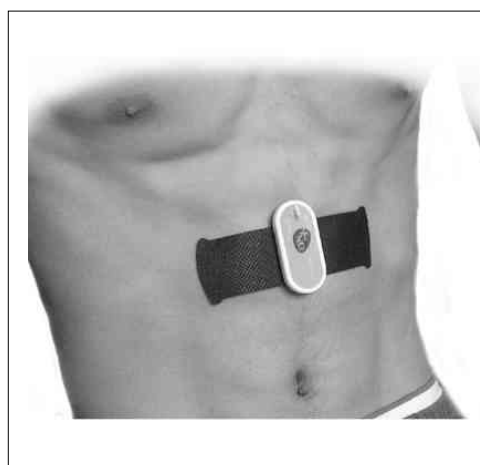
30 minutes of stimulation a day

Phase 2

The test has continued through the phase 2 of treatment in a further 2 weeks.
A total relief from tobacco dependency has been requested from the first day of the phase 2.

The testers have extended the use of O² patch to :

- the 2 body areas (neck and epigastrum)
- with at least 60 minutes of stimulation a day



Phase 2

Treatment of 2 body areas

30 minutes of stimulation each area a day

60 minutes of stimulation at all

RESULTS

1. Tester's Bioparameters

Tester	Age	Bioparameters	Before	Week 1	Week 2	Week 3	Week 4
1	43	Blood Pressure	102 - 66	110 - 75	109 - 67	104 - 69	104 - 75
		Weight kg	59.8	59.0	59.5	59.4	59.00
2	42	Blood Pressure	129 - 80	125 - 79	127 - 82	142 - 96	133 - 80
		Weight kg	81.2	80.7	80.8	81.6	81.3
3	52	Blood Pressure	123 - 80	120 - 85	119 - 79	160 - 94	144 - 94
		Weight kg	58.6	58.0	58.2	58.8	58.2
4	54	Blood Pressure	143 - 90	145 - 90	139 - 89	135 - 89	136 - 81
		Weight kg	80.2	79.0	79.0	79.2	80.0
5*	22	Blood Pressure	120 - 65	126 - 67	122 - 65	(120-65)	(120-65)
		Weight kg	54.0	53.1	53.6	(54)	
6	34	Blood Pressure	124 - 67	117 - 65	110 - 63	106 - 72	112 - 70
		Weight kg	80.9	79.4	80.2	79.6	79.8
7**	37	Blood Pressure	98 - 67	109 - 75	104 - 63	103 - 60	105 - 69
		Weight kg	64.0	63.0	63.6	60.8	59.2
8	40	Blood Pressure	106 - 68	105 - 65	107 - 68	106 - 70	105 - 69
		Weight kg	55.0	54.0	54.8	55.0	55.00
9	61	Blood Pressure	110 - 70	125 - 75	112 - 78	116 - 73	115 - 69
		Weight kg	54.0	53.8	53.0	52.4	52.1
10	47	Blood Pressure	125 - 70	120 - 70	125 - 80	123 - 76	126 - 67
		Weight kg	58.0	57.0	57.5	57.3	57.00
		Blood Pressure average	118 - 72.3	120 - 74.6	117 - 73.4	121 - 76.4	120 - 73.9
		Weight average	64.6	63.7	64.2	63.9	63.5

* Tester 5 did not come for the control of the phase 2

** Tester 7 has lost 4.8kg at the end of the clinical test by the success of diet along the test duration. The blood pressure measurement has showed at week 1 a problem of dysrhythmias with abnormal low blood pressure. It seems that the problem has been corrected at week 4 by the losing of weight or the controlled anguish (?)

Notes :

- The blood pressure has been measured by the same arm blood pressure automatic monitor for accuracy and reliability
- The weight by the same electronic scale
- The 2 parameters have been measured by the same medical expert to avoid any modification by extra-influences (white coat phenomenon essentially)

2. The table of the variation of consumption of cigarettes is as below

Tester	Age	Cigarettes/ before	Cigarettes/ Week 1	Cigarettes/ Week 2	Cigarettes/ Week 3	Cigarettes/ Week 4
1	43	30	10	5	3	3
2	42	35	7	6	0	1
3	52	10	5	5	5	5
4	54	15	4	5	0	0
5**	22	20	7	4	**	**
6	34	20	4	3	0	0
7	37	15	7	5	3	4
8	40	20	9	8	4	0
9	61	15	5	4	4	0
10	47	20	7	5	0	2
average	43.2	20	6.5	5	2.1	1.6

**Absence of tester 5 to meetings at week 3 and week 4

3. The easy of use and the consumption of accessories

- The testers confirmed the easy-of-use of O²patch : *just stick and power on*
- About adhesive pad, some type of neck as short neck would be a temporary cause of non-adhesivity of pad in the beginning of treatment. Testers have resolved the problems by offering a better local moisture of skin.
- Some low hair line would be also a cause of problem of pad's adhesivity; testers have to stick O² patch completely under the hair line
- The consumption of battery was as indicated in the instruction guides : a battery for the whole phase 1. It can cover easily the whole 1-month treatment
- The consumption of pad is correct :
8 testers always used the same pad for the whole 1-month test.
1 of them needed a second pad for the phase 2

4. The inductive anguish and the compensatory side effects

All testers confirm that they stayed relaxed.

They constantly confirmed that they felt more relaxed as before the treatment by O² patch. They did not feel any anguish or any compensatory side effects as nervous irritability, over-eating or insomnia.

This was a constant status we have recorded with much attention during the phase 1 and the phase 2 that concerned the total relief of tobacco dependency.

At end of phase 1, there was a residual quantity of cigarettes smoked a day –about 5-6 units-. These cigarettes were described by smokers as the “*cigarettes of pleasure*”; nothing common with the tobacco or nicotine dependency.

8/10 smokers have totally relieved tobacco –*the cigarettes of pleasure*- at the end of the test when they are aware of the risks of health and when they are relaxed.

DISCUSSION

The fundamental parameters observed in this study are at 2 levels :

1. The variation of daily cigarettes consumption before and during the treatment
 2. The variation of the Blood Pressure and of the Weight.
- They are the objective indications of the absence of anguish or nervous irritability, and of the compensatory over-eating.
- They are the most important parameters in the efforts of giving up tobacco. Their failure automatically means the one of the treatment.

In other words, the absence of the inductive anguish or of the nervous irritability and the absence of the compensatory over-eating are two fundamental conditions for the success of the total relief from tobacco dependency.

In terms of the test, the various recorded data show the following observations :

1. The inductive anguish and the ill-living that cause the tobacco dependency are real. Almost of testers confirmed in the past their difficulties to cover the treatment by the simple reason of the impossibility of control of the anguish.
2. The notion of the “*cigarettes of pleasure*” is real. They usually concern about 5-6 cigarettes a day. After eating, smokers take the pleasure of smoking a cigarette. It seems that they are no thing common with tobacco or nicotine dependency!. To be efficient, the tobacco treatment has to include it in its strategy. The anxious smokers can only totally relieve tobacco when they aware of the health’s risks caused by the tobacco **and** when the inductive anguish has been well controlled. This observation would explain the relative weak number of young smokers (15 – 25 year old) who wish to stop smoking; it seems that at this age, “*smoking is pleasure!*” and the awareness of the risks still do not exist!
3. The action of O² patch against anguish, nervous irritability and compensatory over-eating or insomnia is strong and sure. Constantly, during the test, the smokers confirmed that they feel better, sleep better and are totally relaxed. This was the most important point that has strongly encouraged them to relieve the “*cigarettes of pleasure*”.
4. The failure of nicotine patches is not an obstacle for the treatment and the success by O² patch, a chemical substance free electronic patch.
5. It seems that O² patch would be also helpful as adjuvant treatment of Nicotine patch as this one does not control anguish or compensatory over-eating

CONCLUSION

In the above description operating conditions, after the whole 4 weeks of treatment against tobacco dependency, the O² patch, a chemical substance free electronic patch, demonstrated its efficacy of giving up tobacco without anguish or compensatory side effects, that are the fundamental conditions for the success of the treatment.