

EFFECT OF ACUFIRST® BRACELET ON APPETITE REDUCTION

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1 Study Rationale and Experimental Device

Acupuncture, Chinese medical science existing for many centuries, is recognized and well known by the western medical world.

This medicine is based on the evolution of the energy circulating in the human body, conveyed by called ways meridian on the surface of the skin communicating with the internal organs by intermediate ways.

These meridians contain energy points or acupuncture points, the stimulation of which, by needles, by massage or by electric impulsions acts on the behavioural problems of the individual.

These fluctuations in energy represent the evolution of the Yang or the Yin, the Chinese concept of the medicine based on the modifications of these two energies, either in excess, or in deficiency.

There are 14 meridians going through the skin. The channels go from thorax to arms, then from arms to head, then from head to feet, and from feet to thorax following precise schedules according to the solar hour.

The frontside of the wrist is crossed by three meridians, the lung meridian (L), the heart meridian (H) and the master meridian of the heart MH or HS; among these, some points are used to treat specific disorders such as the meridian lung points L7 and L9, the meridian heart points H5, H6, H7 and the master heart meridian points MH6 (HS6), MH7 (HS7).

Heart points H5 (behavioural disorders connected to excesses), H6 + H7 (emotionalism and anxiety) and L7/L9 (respiratory rate and circulatory disorders) are used to treat the stress.

Heart points H5/H6 (rhythm disorders, vago-sympathetic imbalance) and MC7 or HS7 (behavioural disorders, tightness) have effect on the appetite excess

The points H5, MH7 (HS7) and L7/L9 are indicated in the abuse of tobacco consumption.

Their use, the whole set of points or individual point, is known to give noteworthy benefits.

As application of these data, the ACUFIRST® bracelet, using the technique of stimulation of acupuncture points by electric impulses, was conceived to have effect on the behavioural disorders, such as appetite excess. Endowed with program called *Diet*, the ACUFIRST® bracelet acts through electric impulses of weak voltage and weak intensity stimulating the specific acupuncture points for this program.

The RISE HEALTH and BEAUTY Ltd Company entrusted us with the realization of a study which objective is to demonstrate the effect of the ACUFIRST® bracelet on this disorder of the modern life.

2 Study Design and Investigators

Knowing the effects of stimulating acupuncture points by electric impulses and knowing the configuration of the micro-electrodes of the ACUFIRST® bracelet, we agreed to realize a study on the effect of the bracelet on the appetite reduction.

The ACUFIRST® bracelet has seven versions; within them, the *Diet* program.

The location of the bracelet on the right wrist allows the execution of this program.

The bracelet is pre-programmed to shoot an impulse on points having effect on appetite reduction.

The study had lasted two months and had been conducted by 10 therapists, physicians and physiotherapist masseurs, member of the Association for medicine, traumatology and re-education of football for District of Essonne.

Each therapist had to recruit 3 subjects. Finally, 30 subjects had participated in the study and followed the *Diet* program.

On Day 0 (D0), the therapist included the subject in one program, after having explained him/her the objectives and schedule of the study, in order to obtain his/her entire cooperation.

Then, the subject was given an ACUFIRST® bracelet and a case report form (CRF).

Every day during 30 days, the subjects were requested to run the bracelet each time he/she wanted to have a snack.

The subject reported on the CRF how many times he/she had run the ACUFIRST® bracelet and his/her opinion on its efficacy according to a 4-point scale:

- 0 = not effective,
- 1 = poorly effective,
- 2 = fairly effective
- 3 = very effective.

The subject had to bring the CRF back at the Day 15 (D15) visit (mid-study visit); during this visit the therapist controlled that the subject has used the bracelet as he/she was instructed to, and that the CRF was correctly filled in.

At the final visit Day 30 (D30), the subject brought back the CRF entirely filled in.

The recruitment had appeared to be more difficult than anticipated as a mutual confidence was compulsory to reach the study goals. Anyway, all subjects included in the study had complied with all instructions provided by the therapists:

- they had used the bracelet for the planned 30 days in the *Diet* program,
- they all filled in correctly and completely the CRF.

In addition, the subject motivation can be emphasized; it had permitted to collect data of good quality.

The statistical analysis was carried out by Michel Le Faou, MD, supported by a statistician.

3 Subject Characteristics

In the « Diet » program, the majority of subjects were female (28, i.e. 93%), against only 2 men (7%). Women were in mean 5 years younger (mean age: 38 year-old) than the men (mean age: 42.5 year-old).

4 Study Results

4.1 Study Data and Statistical Analysis

All 30 subjects filled in and brought back their CRF; so there are no missing data (see section 8: data listings).

We considered as more interesting to analyse the data in term of total number of days of use of ACUFIRST® bracelet for all subjects (i.e. 900 days for each program), and to present the distribution of the subject opinion on efficacy during these 900 days.

The day-by-day summary of the subject opinion on efficacy is presented as well; it gives a rough idea on its evolution over time.

4.2 Efficacy on Appetite Reduction

The results show a clear trend in favour of the efficacy on the appetite reduction because during 900 days of use of the ACUFIRST® bracelet, the subjects considered the bracelet as fairly effective during 489 days (53.7%), very effective during 89 days (9.9%) and poorly effective during 290 days (32.2%) (Table 1 and Figure 1).

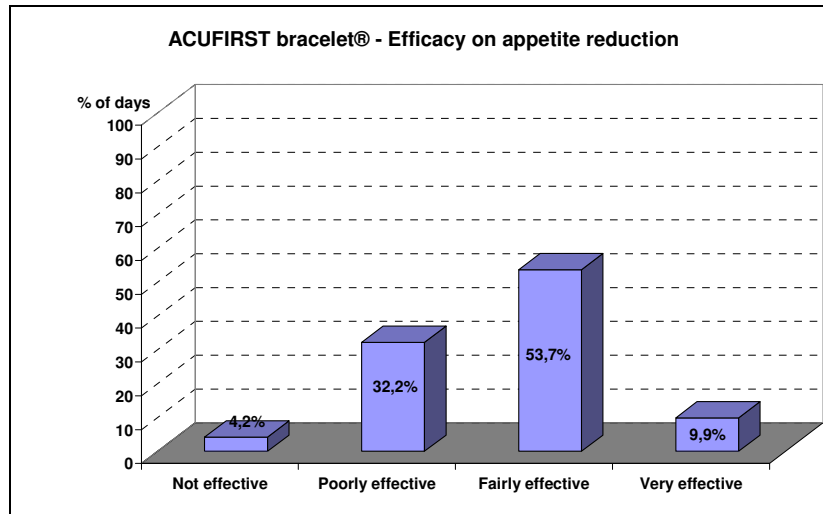
In summary, the effect of the ACUFIRST® bracelet was noted as effective (fairly or very) during 572 days (63.6%), and poorly or not effective during 328 days (36.4%).

Table 1: Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Appetite Reduction

	<i>n</i> *	%
Not effective	38	4.2
Poorly effective	290	32.2
Fairly effective	483	53.7
Very effective	89	9.9
Total	900	100

* *n* total number of days of use

Figure 1: Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Appetite Reduction

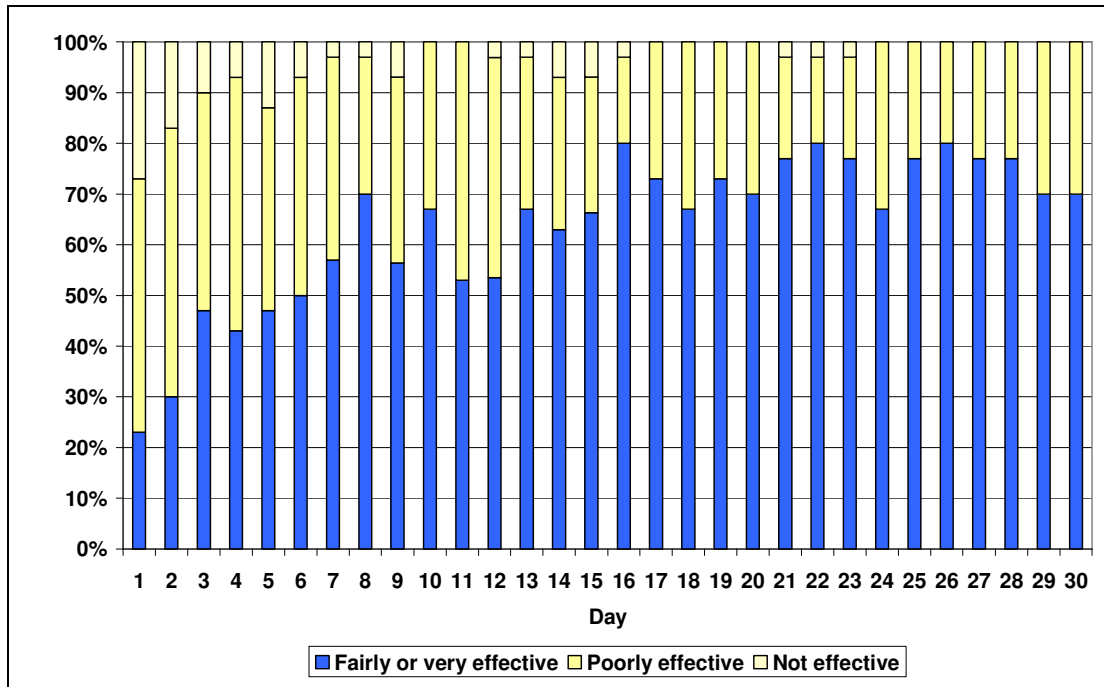


Over time, more than 60% of the subjects judged the bracelet fairly or very effective on the appetite reduction from the 13th day onward, with a peak of 80% on Day 16, Day 22 and Day 26 (Table 2 and Figure 2).

Table 2: Day-by-day distribution of the: Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Appetite Reduction

<i>Day</i>	<i>Not effective</i>	<i>Poorly effective</i>	<i>Fairly or very effective</i>
<i>01</i>	27%	50%	23%
<i>02</i>	17%	53%	30%
<i>03</i>	10%	43%	47%
<i>04</i>	7%	50%	43%
<i>05</i>	13%	40%	47%
<i>06</i>	7%	43%	50%
<i>07</i>	3%	40%	57%
<i>08</i>	3%	27%	70%
<i>09</i>	7%	37%	57%
<i>10</i>	0%	33%	67%
<i>11</i>	0%	47%	53%
<i>12</i>	3%	43%	53%
<i>13</i>	3%	30%	67%
<i>14</i>	7%	30%	63%
<i>15</i>	7%	27%	67%
<i>16</i>	3%	17%	80%
<i>17</i>	0%	27%	73%
<i>18</i>	0%	33%	67%
<i>19</i>	0%	27%	73%
<i>20</i>	0%	30%	70%
<i>21</i>	3%	20%	77%
<i>22</i>	3%	17%	80%
<i>23</i>	3%	20%	77%
<i>24</i>	0%	33%	67%
<i>25</i>	0%	23%	77%
<i>26</i>	0%	20%	80%
<i>27</i>	0%	23%	77%
<i>28</i>	0%	23%	77%
<i>29</i>	0%	30%	70%
<i>30</i>	0%	30%	70%

Figure 2: Day-by-day distribution of the Subject Opinion on Efficacy of the ACUFIRST® Bracelet on Appetite Reduction



5 Discussion

This open study had evaluated the effect of the bracelet ACUFIRST® on the appetite reduction and had shown a net trend in favour of the efficacy of the bracelet. The statistical analysis of each program data consisted in descriptive presentation of the distribution of the subject opinion on efficacy, expressed in days over the total of 900 days of use, thus 900 opinions of subjects. Moreover, the evolution in time of this opinion was presented by its day-by-day distribution.

However we are aware that the chosen criteria are essentially based on a subjective appreciation by the subject.

It would have been of great interest and more accurate to consider the evolution of the body weight, but but the study duration was too short to detect significant changes.

As a first pragmatic approach, we thus chose to consider the daily opinion of subject during thirty days; the high number of data allows valid statistical calculations.

The manipulation of the ACUFIRST® bracelet was made easier by the pre-programming of the bracelet.

The realization of the study required to target well the subjects and to give them a long and detailed explanation for the understanding of the protocol.

Two cutaneous reactions of allergy-type to metal were reported, but in both cases the study was completed without worsening.

6 Conclusion

The results obtained in the study reveal a real efficacy of the ACUFIRST® bracelet on the appetite disorders.

The subjects having participated in the study considered that the ACUFIRST® bracelet helped efficiently on the disorders of the appetite reduction in 64% of cases.

This study relied essentially on subjective criteria and would require to be confirmed by a long-term study, including larger number of subjects.

The technique gives the advantage to make the subject sensitive and responsible of him/herself.

Switching on the bracelet each time a sudden urge to snack appears, implies to bring the subject out of its routine and to make him/her become aware of the perverse effect of his/her ritual gesture.

At least for that, the bracelet brings one more weapon in the fight against this disorder of the modern life.

7 Bibliography

André LEBARBIER, Acupuncture pratique, ed. Maisonneuve, 1975

J.A. LAVIER, Vademecum d'acupuncture symptomatique ed. Maloine, 1985

8 Efficacy Data Listings

Listing 1 : Individual Efficacy Data on the Appetite Reduction

SUBJECT INITIALS																														
Day	M.E.	S.K.	M.L.	M.H.	C.M.	N.V.	N.S.	V.D.	P.S.	S.T.	C.F.	J.Z.	I.R.	G.D.	E.T.	B.M.	V.D.	C.T.	S.L.	S.S.	C.N.	M.A.	J.L.	J.L.	R.E.	M.T.	T.V.	S.T.	S.G.	S.K.
01	1	2	2	1	1	1	0	0	1	1	0	0	0	2	1	2	2	1	0	0	2	1	2	1	1	1	1	1	1	0
02	2	1	1	0	2	1	1	0	1	1	1	0	1	2	2	2	1	1	1	0	2	1	2	1	1	2	1	1	2	0
03	2	2	1	0	2	1	1	0	1	1	2	0	1	2	2	2	1	1	1	1	2	2	2	1	1	2	2	2	2	1
04	2	2	1	1	2	1	1	1	1	1	2	0	1	2	2	2	1	1	1	1	2	2	2	1	0	2	2	1	2	1
05	2	2	1	1	1	2	2	0	0	1	2	0	1	2	2	3	2	1	1	1	2	1	3	1	0	2	2	2	1	1
06	2	1	2	1	2	1	2	1	1	1	2	0	2	2	2	3	2	1	1	1	2	1	3	2	0	2	1	2	1	1
07	1	2	2	2	2	1	2	1	1	1	2	0	2	2	2	3	2	1	1	1	2	1	3	2	1	2	1	2	2	1
08	2	2	2	2	2	2	1	1	2	1	2	0	2	2	2	3	2	1	1	1	2	2	2	1	1	2	2	2	2	2
09	2	2	3	2	2	1	2	0	2	1	1	0	1	2	2	3	2	1	1	1	2	2	2	1	1	1	2	2	2	1
10	3	2	3	2	2	2	2	1	2	1	1	1	2	2	2	3	2	1	1	1	2	2	3	1	1	2	2	2	2	1
11	3	1	3	2	2	2	1	1	1	1	1	1	1	2	2	3	2	1	2	1	2	1	3	2	1	2	2	2	1	1
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19	3	2	2	2	2	1	1	1	1	2	2	1	2	2	3	3	2	1	2	1	2	2	3	2	1	2	2	2	2	2
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25	2	2	2	2	2	1	2	1	1	2	2	1	1	2	2	3	2	2	2	1	2	2	3	2	1	2	2	2	2	2

SUBJECT INITIALS																														
Day	M.E.	S.K.	M.L.	M.H.	C.M.	N.V.	N.S.	V.D.	P.S.	S.T.	C.F.	J.Z.	I.R.	G.D.	E.T.	B.M.	V.D.	C.T.	S.L.	S.S.	C.N.	M.A.	J.L.	J.L.	R.E.	M.T.	T.V.	S.T.	S.G.	S.K.
26	3	2	2	2	2	2	2	1	1	2	2	1	2	2	2	3	2	1	2	1	2	2	3	2	1	2	2	2	2	2
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02	17	25	19	20	21	13	17	5	8	12	20	0	18	27	16	4	25	4	14	6	30	23	14	16	0	23	26	26	20	14
03	11	0	6	3	7	0	0	0	0	0	3	0	0	2	9	26	2	0	0	0	0	1	16	0	0	3	0	0	0	0