

イヤシドーム  
IYASHI DÔME®

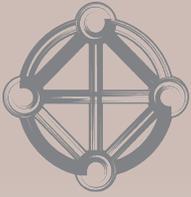
— Detox —

— Anti-aging —

— Slimming —

# CLINICAL TRIALS AND MEDICAL PUBLICATION





イヤシドーム  
IYASHI DÔME®

## SLIMMING PROGRAMME

Individual clinical trial

Global results are analysed by the summation of before and after scores. Evaluation protocol for Iyashi Dôme weight loss.

18 volunteers aged 25 to 57.

No change whatsoever in nutrition or physical activity was prescribed during the protocol.

The results obtained with the device indicate that the Iyashi Dôme is efficient for weight loss, skin quality enhancement, relaxation and reduction in the appearance of fine lines. The results reveal a 100% satisfaction rate among volunteers who participated in the treatment programme.

Over 2 months, at a rate of 2 sessions a week lasting 30 minutes each (i.e.: 16 sessions), the average weight loss was 4kgs - weight loss of up to 6kgs was observed.

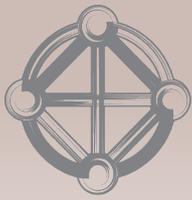
1 to 2 dress size reduction.

Loss of 2 to 3% body fat.

Dr JOACKIM VALERO

Trial performed with Class 3 medical measuring device TANITA





## RESULTS AND ANALYSIS

At the end and during the course of the study, the variation of weight over a total of 8 sessions, with 2 sessions per week during 1 month (dd/mm/yy):

	13/09/2007	17/09/2007	20/09/2007	24/09/2007	27/09/2007	01/10/2007	04/10/2007	08/10/2007	bois en gramme
Mme N	56,8 kg / 56,3 kg	56,6 kg / 56,4 kg	56,4 kg / 56,2 kg	56,3 kg / 55,9 kg	56,5 kg / 56,3 kg	56,2 kg / 56,1 Kg	56,5 kg / 56,2 kg	55,5 kg / 55,2 kg	- 1600
Mr R	99,5 kg / 99 kg	99,6 kg / 99,1 kg	98,9 kg / 98,3 kg	99,6 kg / 99 kg	98,7 kg / 98,2 kg	99,4 kg / 98,7 kg	100,3 kg / 99,5 kg	100 kg / 99,3 kg	-200
Mme V	52,8 kg / 52,6 kg	52,4 kg / 52,2 kg	52,4 kg / 52,2 kg	52,4 kg / 52,2 kg	52,9 kg / 52,7 kg	52,7 kg / 52,5 kg	52,2 kg / 51,9 kg		( - 900 g )
Mr J	99,3 kg / 98,7 kg	99,2 kg / 98,7 kg	99,4 kg / 98,6 kg	98,2 kg / 97,8 kg	98,4 kg / 97,7 kg	97,9 kg / 97 kg	98,1 kg / 97,2 kg	97,4 kg / 96,8 kg	-2500
Mlle A	57,7 kg / 57,6 kg	56,5 kg / 56,2 kg	56,7 kg / 56,4 kg	56,5 kg / 56,2 kg	56,5 kg / 56,2 kg	56,5 kg / 56,1 kg	56,9 kg / 56,5 kg	55,3 kg / 54,9 kg	-2800
Mr S	85,3 kg / 84,8 kg	85 kg / 84,5 kg	84,7 kg / 83,9 kg	84,7 kg / 84,3 kg	84,6 kg / 84,2 kg	84,2 kg / 83,8 kg	84 kg / 83,5 kg	83,4 kg / 82,9 kg	-2400
Mme F	63,7 kg / 63,3 kg	64,4 kg / 64 kg	64,3 kg / 63,9 kg	64 kg / 63,2 kg	63,1 kg / 62,6 kg	62,1 kg / 61,6 kg	63,6 kg / 63 kg	62,4 kg / 61,9 kg	-1800
Mme S	50,5 kg / 50,4 kg	51,3 kg / 51 kg	50,6 kg / 50,4 kg	52 kg / 51,8 kg	51,1 kg / 50,9 kg	51,2 kg / 50,9 kg	50,9 kg / 50,6 kg	51,3 kg / 51,1 kg	PLUS 200

Over 1 month, with 2 sessions per week for a total of 8 sessions, the average weight loss is 1.5 kg. (On condition that individuals did not change their habits in terms of nutrition or physical activity).

Name	Weight (kg)					Fat Mass (% Kg)			BMI			Waist measurement			Hips measurement			TOTAL difference		
	1	4	8	12	16	1	8	16	1	8	16	1	8	16	1	8	16	(Kg)	SIZE	F.mass %
Stéphane G	85,3	84,3	82,9	81,7	79,4	24,6	23,1	21	29,2	28,4	27,2	101	97	93	98	97	92	-5,9	50/46	-3,8
Johan M	99,3	97,8	96,8	95	93,7	25,1	24,1	24	32,4	31,6	30,6	111	110	109	113	111	109	-5,6	52-54/50	-1,5
Flore M	63,7	63,2	61,9	61,7	61,6	28,2	26,7	25	22,6	21,9	21,6	84	82	78	103	102	102	-2,2	40/38-36	-3,2
Mr Roch	99,5	99,6	100	98,8	98,7	26,4	26,5	24,8	33,6	33,8	33,4	105	102	102	110	108	106	-1,8	56/52	-1,6
Annabelle R	57,7	56,2	54,9	55	55,9	26,6	24,2	20,9	21,2	20,2	20,5	88	87	86	94	92	92	-1,8	40/38	-5,7
Violette F	52,8	52,2	50,5			23,4	21,1		21,3	20,5		73	72		93	91		-2,3	38/36	-2,3
Claudia N	56,3	56,3	55,2			30,1	28,6		22,8	22,4		81	79		101	98		-1,1	38/38	-1,5
Hervé L	64,9	63,7	63,2			14,5	11,4		22,5	21,9		91	89		91	90		-1,7	40/40	-3,1
Laetitia L	63,4	62,6	62,7			30,1	24		26,4	25,1		88	85		103	102		-0,7	40/40	-5,9
Judith O	85,4	84,4	83,7			36,9	35		35,5	34,8		99	97		110	110		-1,7	44/42	-1,9
Chritel S	69,1	69,1	69,4			32	33		25,1	25,2		82	83,5		100	100		0,3	40/40	1
Nathalie B	64,9	65	64,3			27,5	28,4		23,2	23,1		90	90		98	97		-0,6	40/40	0,9
Maria M	86,6	87,4	86,1			39,8	39,7		33	32,8		106	106		120	118		-0,5	46/46	-0,1
Sonia B	50,5	51,8	51,1			14,6	15,7		19,7	20		74	73		93	91		0,6	36/36	1,1

## SIGNIFICANT FACTS

Over 1 month, with 2 sessions per week for a total of 8 sessions, the average weight loss is 1.24 kg with variations

- going from weight gain: +200 gr in the case of an individual with the lowest Body Mass Index (BMI 19) and the lowest body fat percentage
- to 2.8 kg. This individual is overweight (BMI 32.4)

Over 2 months with 2 sessions per week for a total of 16 sessions, progressive average weight loss is 3.4 kg. (On condition that individuals did not change their habits in terms of nutrition or physical activity).

Between each weighing there is a decrease in body fat in favor of body water, with the hypothesis of a "release" of water in the cells.

The weight loss was always well tolerated and accompanied by a feeling of wellbeing.



## STUDY CONCLUSION

This study highlights various points concerning the Iyashi Dome:

It appears, and this point will need to be dealt with in depth, that there is a definite rebalancing action that occurs in terms of slimming and the figure. Indeed, certain people will gain weight (especially thin individuals with a low body fat percentage), others will see their weight decrease or remain stable. One can therefore refer more to a weight rebalancing action that occurs according to the individual's physique and primary needs rather than of systematic and non-targeted weight loss. This rebalancing action also appears to occur on the body fat/lean body mass proportion of each participant.

The study shows results of up to 6 kg weight loss in the 2 months of Iyashi Dome sessions (on condition that the individuals did not change their habits in terms of nutrition or physical activity). The results with regards to slimming are very satisfying as the treatments are very well tolerated throughout the session, resulting in a more balanced figure and a 100% satisfaction rate. The feeling of comfort and wellbeing provided by the session support the prospect that the treatment program will be duly followed and will therefore deliver optimal effectiveness.

Over 2 months with 2 sessions per week for a total of 16 sessions in 2 months, average weight loss is 3.4 kg which is progressive, gentle and long-lasting.

Findings showed weight loss up to 6 kg in 2 months (16 sessions).

Loss of 1 to 2 dress sizes (16 sessions).

Loss of 2 to 3% body fat, and up to 20% (16 sessions).

By comparing the effects of 8 Iyashi Dome sessions with those of 16 sessions it is found that slimming continues with the number of sessions.

Body fat tends to decrease after one session. This decrease may be explained by the liberating mechanism of the intracellular / extracellular water exchange. This decrease of the extracellular mass is found throughout the sessions.

The results are in favor of progressive, balanced and well-tolerated slimming method. However, certain participants do not respond at all to these treatments and in other rare cases, participants can gain weight.



## DETOX CURE

For centuries, the Japanese have been burying themselves in the sand of various hot springs in order to purify their bodies and eliminate their toxins. The heat (far infrared radiation emitted by the sun) warms the sand and gives it specific properties that are precious to the body's wellbeing.

This tradition is carried on today with Iyashi Dôme thanks to its performance in far infrared technology.

### Clinical trial

A clinical trial was carried out in Switzerland on 22 patients. Samples of sweat were taken from each patient's body after a session of Iyashi Dôme lasting 25 minutes. The sweat was taken using a Pasteur pipette from the patient's chest and arms. No metal utensil was used when taking sweat samples. The Laboratory MGD in Geneva (Switzerland) analysed the sweat samples and then compared them with the analysis of urine samples of these same patients. "The analysis [...] shows that the Iyashi Dôme increases the amount of toxic heavy metals eliminated such as Strontium, Barium, Nickel, Lead, Molybdenum, Tellurium, Chromium, Cobalt, Arsenic, Cadmium, Aluminium and Copper. This chart shows that the quantities of heavy metals are higher than the average quantity of 514µg/l, with particular effectiveness with regards to Aluminium elimination. [...]"

## CONCLUSION

"Analysis of 2ml of sweat taken from patients who underwent Iyashi Dôme Far Infrared sessions lasting 25 minutes demonstrates that there is a real impact on the elimination of heavy metals from the body. The simultaneous analyses of urine samples show the heavy metals are essentially eliminated through sweat.

The action is particularly efficient with regards to the elimination of Aluminium."

Iyashi Dôme

\*P. Blanchemaison, F. Morillon, R. Clement, The Detox Cure.

Advantages of the far infrared device Iyashi Dôme in the removal of heavy metals. Genesis 2012, n°167, 20-23 (Medical Journal of Gynaecology, n°167 May 2012)

## Alternative therapies

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As “women’s doctors”, we are faced daily with patients’ questions about therapies that are unknown to us. From now on, Philippe Blanchemaison, one of the first to join the loyal and enthusiastic editorial board at *Genesis* 16 years ago, will regularly take stock of topics that are worthy of interest and about which we know nothing, or almost nothing. D.E.

## The “Detox” cure

My patient asked me about the advantages of an infrared “detox” treatment program. So what can a gynecologist think when a patient comes to his/her practice asking for an opinion about a “detox” treatment program using an infrared device in order to eliminate the buildup of heavy metals through a sweating process?

Women’s magazines depict “Detox” treatment programs as very fashionable trends. They are all about “cleansing the body from a potential excess of heavy metals”, thanks to nutritional supplements, capsules or herbal teas that contain specific plants with draining properties.

In view of the success of this concept of “body congestion” with our tired and stressed-out patients, it is interesting to consider a proven procedure for eliminating metabolic waste from the organism: Far Infrared therapy.

Heavy Metals feature among these “wastes”.

- The modern definition of heavy metals exists in European law

### The definition

Within the framework of the “directives on metabolic waste”, in European law the term heavy metal refers to any Arsenic, Cadmium, Aluminum, Chromium, Lead, Mercury, Nickel, Tellurium, Thallium, Cobalt, Titanium, Vanadium, Silver, Molybdenum, Antimony compound as well as these materials in metallic form, classified as dangerous substances if

they are absorbed over a certain threshold.” This new definition replaces the old one that described heavy metals as those metallic elements with a density over 4 000 kg/m<sup>3</sup>.

An even older definition considered “heavy metals” as all the metallic elements between Copper and Lead in the Mendeleev’s periodic classification.

Forty-one metals match this general definition, to which five metalloids must be added.

Heavy metal toxicity is acknowledged

These metals referred to as “heavy metals” are potentially toxic over a certain threshold and should be distinguished from trace elements (Zinc, Magnesium, Selenium, Silicon dioxide...) that the body uses daily as catalysts (in very small quantities they accelerate the enzymatic biochemical reactions without participating in them).

Nowadays, however, the definition of metallic trace elements or MTE tends to replace the definition of heavy metals. These MTE are more or less bio-assimilated and may also be concentrated within the food chain according to the elements and the context (acidity of the environment, MTE synergy between each other or their interactions with other pollutants).

This is the reason why some are subject to monitoring regulations in water, soil and air when they are associated with aerosols or dust as well as in food.

The AFSSA (Agence Française de Sécurité des Aliments - *French Food Safety Agency*) is on alert.

A report by the AFSSA (French Food Safety Agency) dated April 2005 on the “evaluation of the risks related to the use of filter systems for tap water covered with metal oxides” focuses on the use of selective adsorbent gratings composed of Aluminum Sulfate or Aluminum Chloride. The report states these gratings are “very efficient to begin with but become less and less efficient over time as the areas of adsorption become saturated”.

Another report by the AFSSA, dated March 17<sup>th</sup> 2005, declares that “treatments based on sand covered with activated Iron or Aluminum oxides can present the following inconvenience: these filters act like biological reactors that can lead to the formation of Nitrates and/or Nitrites linked to the presence of Ammonium ions”.

However, the report concludes that treatment processes covered with activated alumina, or Aluminum hydroxide, eliminate a certain number of heavy metals from drinking waters: Arsenic, Cadmium, Chromium, Nickel, Lead, without causing the formation of residues that are sometimes carcinogenic.

The potential dangers are very real.

The UFC “*Que choisir*” (French Federal Union of Consumers) questioned the AFSSA on the dangers related to consumers’ exposure to Aluminum, and more specifically on the presence of Aluminum in the water supply and food.

These questions follow the publication by the 330 Unit at INSERM (French Institute of Health and Medical Research) in the American Journal of Epidemiology (1) of the results from the 8-year monitoring of the “Paquid” cohort, finding an increased risk of dementia, in particular Alzheimer’s disease, in subjects exposed to Aluminum concentrations higher than 100 µg/l in the water supply, reopened the debate, begun in the 70’s, on Aluminum’s possible role in Alzheimer’s disease. In order to answer this question, a report written by the AFSSA and the INVS (French Institute for Public Health Surveillance), published November 1<sup>st</sup> 2003, concluded “although some effects related to chronic exposure to Aluminum can currently be considered as proven (encephalopathy, psychomotor disorders, disorders of the bone tissue and of the hematopoietic system under the form of hypochromic anemia), it appears that no causal relationship can be reasonably considered for other initially-suspected effects (Alzheimer’s disease), given the current level of knowledge”.

However, studies evoking too high a level of heavy metals in human blood and tissue cells are regularly published.

Very recently, new concerns have arisen concerning the presence of Aluminum particles in food.

On the one hand, we are exposed to Aluminum that is naturally present in water and food, and on the other hand to Aluminum used in medicine and cosmetics, food additives, cooking utensils and in water treatment. After Iron, it is the most widely used metal for industrial applications.

In France, the average consumption is around 5 mg per day. However, these relatively low figures do not take into account the other sources of Aluminum (medicine, cosmetics and cooking utensils)!

Non-processed foods contain just a small amount of Aluminum. On the other hand, its use as a coloring agent inevitably implies the ingestion of high doses of this metal. It is allowed for coloring the surface of cooked meats, sweets, candy, tablet-making and cake decorations. It is therefore used as a food additive: acidifiers, colorants, emulsifiers and raising agents. They are the E 520, 521, 522, 523 that can be found in the egg white used in cooking preparations, preserved, crystallized and iced fruit and vegetables; and the E 541 used in pastries.

The E 554, 555, 556, 559 in dried foods in the form of powder (soups, purees), salt, nutritional supplements and sliced or grated industrial cheeses.

Aluminum salts (inorganic salts) are also used in deodorants and certain vaccines.

- What is an infrared device's mode of action?

It is at the beginning of the 19<sup>th</sup> century that British astronomer William Herschel discovered infrared radiation. He held a mercury thermometer in the spectrum obtained with a glass prism in order to measure the temperature of each color. He found that the temperature was the highest towards the red end of the spectrum, including beyond the red end of the visible spectrum. For the first time, it was concluded that heat could be transmitted by an invisible form of light, that is to say neither by convection (hot air transfer) nor by conduction (propagation between solid bodies).

#### A touch of biotechnology

It wasn't until 1947 that the positive action of infrared radiation on human tissues was understood, when the Japanese government invested in research to find systems that would enable cells to regenerate from side-effects suffered by the Japanese population after the release of the two atomic bombs.

While this research was being carried out during the 50's, NASA took up research on infrared radiation because it discovered waves in the visible spectrum that are vital to the metabolism and growth of human tissues. This radiation, called "growth radiation", corresponds to far infrared waves, that is to say the region between 8 and 14  $\mu\text{m}$ . In Japan, during the 80's, the first far infrared emitting devices were made using ceramic. This period marked the beginning of the development of infrared domes in Japan. The Iyashi Dome was then created, with the particularity of replacing the ceramic, a mineral, by organic plant material: "B-carbon" technology was born, delivering improved vibratory resonance with an emission wavelength between 5 and 20  $\mu\text{m}$ .

In 1998, the Shimazu Laboratory discovered, for the first time, Dioxin in the sweat of a subject who had just spent 30 minutes in an Iyashi Dome. One Iyashi Dome session can cause the whole body to lose up to 600 ml of sweat.

There is a centuries-old tradition in Japan for people to bury themselves in the warm sand of various hot springs in order to purify their bodies and eliminate the toxins from their bodies. The heat (far infrared radiation emitted by the sun) is diffused by the earth and heats the sand which has specific properties.

This tradition is carried on today with the far infrared Iyashi Dome.

Eliminating heavy metals with far infrared rays.

A clinical trial was carried out and completed in 2010 on 22 patients living in the Swiss canton of Fribourg. Samples of sweat were taken from these patients and analyzed by the Laboratory MGD in Geneva (Switzerland). The possible exposure to heavy metals of each patient was recorded, according to their profession, where they lived, the nature of the water pipes in their apartment block, the number of cigarettes or cigars smoked per day, use of cosmetics, number of dental amalgam fillings and their eating habits.

As soon as the patient started sweating large drops, the sweat was taken using a Pasteur pipette from the patient's chest and arms. Particular attention was paid to not using any metal utensils when taking sweat samples.

In the control group, the analysis shows the presence of many heavy metals in particular Aluminum, Strontium, Copper and to a lesser extent Iron, Nickel, Mercury and Molybdenum. Titanium, Chromium, Thallium, Cobalt, Silver, Vanadium, Cadmium, Arsenic and Antimony are either found in very small concentrations or are totally absent. Certain people have substantial concentrations of Aluminum (1 420  $\mu\text{m/l}$ ), Strontium (560  $\mu\text{m/l}$ ), Barium (313  $\mu\text{m/l}$ ), Lead (84  $\mu\text{m/l}$ ), Titanium (1 911  $\mu\text{m/l}$ ) and Chromium (38  $\mu\text{m/l}$ ). The values obtained were compared with quantities of the same heavy metals eliminated through urine. It is often incorrectly assumed that the quantity of eliminated urine per day is much greater than the quantity of sweat; and yet the elimination of sweat that occurs passively can range from 200 up to 1 500 ml/day in the case of an individual carrying out a light task in temperatures of 28°C. Moreover, Aluminum is only slightly eliminated by the kidneys (less than 100  $\mu\text{m/l}$  compared to between 600 and 1,000  $\mu\text{m/l}$  through sweat. Also, Nickel, Copper and Barium are eliminated in higher concentrations through sweat than through urine.

The analytical method used on the samples by the laboratory (ICP method, inductive couple plasma) requires heating the sweat that is then analyzed by paper chromatography, which enables each heavy metal detected to be quantified. The detection limit is 1  $\mu\text{m/l}$ . The minimum volume of sweat for analysis is 1.5  $\mu\text{m/l}$ . Some patients had high levels of Cadmium. Yet it has been proven that certain brands of dark chocolate contain Cadmium in greater concentrations than approved levels (under 1.5  $\mu\text{m/l}$ ).

- The analysis of the chart in figure 2 shows that the Iyashi Dome increases the amount of toxic heavy metals eliminated such as Strontium, Barium, Nickel, Lead, Molybdenum, Tellurium, Chromium, Cobalt, Arsenic, Cadmium, Aluminum and Copper. This chart shows that the total quantities of heavy metals are higher than the average quantity of 514  $\mu\text{m/l}$ , with particular effectiveness with regards to Aluminum elimination.

- The chart in figure 3 shows the total quantity of heavy metals in micrograms eliminated per liter of sweat for each analyzed individual, as well as the quantity and percentage of Zinc and Aluminum that is present, when these values are higher than the reference values. It can immediately be seen that all the total quantities of heavy metals higher than the average value of 5,014.4  $\mu\text{m/l}$ , have a large excess of Zinc, sometimes Aluminum.

One of the patients who was suffering from daily excessive perspiration, accentuated by stress, presented a very low overall heavy metal content, well below the reference values. On the other hand, this elimination rate significantly increased throughout the Iyashi Dome sessions.

## ▪ Conclusion

The analysis of 2ml of sweat taken from patients who underwent Iyashi Dome Far Infrared sessions lasting 25 minutes demonstrates that there is a real impact on the elimination of heavy metals from the body. The simultaneous analyses of urine samples show the heavy metals are essentially eliminated through sweat. The action is particularly efficient with regards to the elimination of Aluminum.

*Figure 2: Variation of analyzed metals in the sweat of 22 individuals.*

*Figure 3: Average metal contents excreted in sweat with mean deviation, extreme values excluded. Blue: average without value, deviation too great. Red: mean + standard deviation.*

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## ANTI-AGING CURE

Skin ageing is a natural and inevitable process that manifests itself through the appearance of wrinkles, fine lines and dark spots, a decrease in skin firmness and elasticity as well as a loss of radiance. Skin ageing involves both intrinsic factors (genetic and hormonal...) and extrinsic factors (stress, climate, pollution, smoking...). In addition to cosmetics, there are other non-invasive methods that fight against the effects of skin ageing.

### Clinical trial

[...] The study was carried out on 13 patients, from 31 to 63 years-old, with skin phototype between II and IV according to the Fitzpatrick

Classification Scale. The 8 Iyashi Dôme sessions each lasted 30 minutes and were carried out twice a week over four weeks.

In order to take the research further, biometric measurements were carried out on both the face and body, using the Cutometer® to measure skin elasticity [...], the Corneometer® to measure skin hydration and the Mexameter® to verify the level of haemoglobin and melanin concentrations in the skin [...]. Finally, the Iyashi Dôme's actions on dermal thickness of face and body were visualized and measured using High Frequency Doppler Echography. These measurements define the increase or decrease in thickness of the dermis and, therefore, of the collagen and elastin fibres that compose the skin's connective tissue.

Dr Philippe BLANCHEMAISON

## CONCLUSION

The far infrared rays emitted by the Iyashi Dôme® are effective in improving the skin's quality and physiological properties [...]. More specifically, after 4 weeks' use the product improves skin density with an increase in the thickness of the dermis of both face and body, improves skin radiance on the face, decreases skin roughness on the face, decreases wrinkle volume on the face, improves skin hydration on the face and body, improves the complexion (evenness and luminosity of facial skin), improves skin elasticity and firmness on the body and face, stimulates skin microcirculation and reduces the signs of skin ageing. The product was judged to be effective on all skin phototypes and considered as being pleasant to use.

### ► The PHLEBOLOGIST'S LETTER

## A new aesthetic treatment to improve the skin's appearance: far infrared rays



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In Japan, hot volcanic baths (« Onsen therapy ») are well known for their rejuvenating effects on the skin. Can claims to deliver similar or better results be made by far infrared equipment used in Spas and medical practices?

Skin ageing is a natural and inevitable process that manifests itself through the appearance of wrinkles, fine lines and dark spots, a decrease in skin firmness and elasticity as well as a loss of radiance. Skin ageing involves both intrinsic factors (genetic and hormonal...) and extrinsic factors (stress, climate, pollution, smoking...). In addition to cosmetics, there are other non-invasive methods that fight against the effects of skin ageing.

Japan is a country of volcanoes where hot springs, called Onsen, are not hard to find (over 27,000 throughout the country as a whole). The water in these Onsens is famous for a variety of therapeutic effects thanks to the presence of microcrystalline silicates, such as Tourmaline, which have the property of emitting far infrared rays. The Japanese believe this water not only relieves pain and heals skin disorders but also provides a rejuvenating effect that, today, has been confirmed by clinical studies<sup>1</sup>. A treatment



Figure 1

called «Onsen therapy» (onsen-ryōhō) is based upon these properties. A Japanese company decided to reproduce and amplify them by developing far infrared ray equipment made out of organic black carbon associated with PIP Titanium technology that triggers a vibratory resonance specific to the Iyashi Dome equipment. This clinical trial shows that the Iyashi Dome improves the quality and physiological properties of the skin in 28 days, without using injections or chemical products.

#### ■ Material and trial method

This observational study evaluated the efficiency of far infrared ray equipment, the Iyashi Dome (Figure 1), on the skin's physiological and biomechanical properties using instrumental and biometric measurements and non-invasive imaging. The study was carried out on 13 patients, from 31 to 63 years-old, with skin phototype between II and IV according to the Fitzpatrick Classification Scale. The 8 Iyashi Dome sessions each lasted for 30 minutes and were carried out twice a week over four weeks.

#### ■ Method

Three evaluation visits were necessary to carry out the trial: one inclusion visit on Day 0, one control visit after 2 weeks of using the equipment and one final visit after 4 weeks. The visits on Day 14 and Day 28 evaluated the skin's physiological and biomechanical properties. The results were evaluated based on instrumental<sup>2</sup> measurements such as the High Frequency Doppler Echography, VisioFace®, Cutometer®, Corneometer® and

Mexameter®, along with a self-assessment questionnaire composed of 27 questions in order to collect and measure each participant's satisfaction. Any negative effects and possible complications were also recorded.

#### ■ Equipment

##### Instrumental and biometric evaluations

VisioFace® is a high-technology device that takes and analyses standardized pictures of the face<sup>3</sup>. All the parameters under evaluation remain the same and the colour pictures obtained can be reproduced and compared over time, providing the opportunity to measure a treatment's effectiveness on the skin's properties (dark spots, wrinkles, complexion colour and evenness). The following measurements were carried out using frontal images of the face.

-**Wrinkle analysis** is a complex mathematical calculation that measures the wrinkle's volume, surface area, depth and visibility index.

**-Skin colour analysis** is carried out using the CIE L\*a\*b\* colour space, as defined by the International Commission on Illumination in 1976 (CIELAB), the most commonly-used colour model in Dermatology. L\* provides information on lightness (ranging from black to white), a\* and b\* provide information on the colour (a\* ranges from green to red, b\* from blue to yellow): the parameter a\* appears under the name: erythema and b\*: pigmentation(4).

**-Skin roughness analysis** is measured thanks to numerous parameters of skin amplitude.

**-Complexion evenness analysis** is calculated thanks to the average and maximum deviation of dark spots compared to the rest of the skin. The following colour deviation parameter is used: E\* = as metric system(5).

In order to take the research further, biometric measurements were carried out on both the face and body, using the Cutometer® to measure skin elasticity, the Corneometer® to measure skin hydration and the Mexameter®(7,8,9) to verify the level of haemoglobin and melanin concentrations in the skin.

Finally, the Iyashi Dome's actions on dermis thickness of the face and body were visualized and measured using the High Frequency Doppler Echography. These measurements define the increase or decrease in thickness of the dermis and, therefore, of the collagen and elastin fibres that compose the skin's connective tissue.

#### End-of-trial self-assessment questionnaire

After 28 days of use and a treatment protocol composed of 8 sessions, the volunteers were asked to express their opinion by answering a self-assessment questionnaire at the end of the trial.

#### Statistical analysis

All the collected data were subjected to statistical analysis using standard deviation and the Student's t-test. For personal reasons that were not related to product use, three participants abandoned during the study and were therefore excluded from the statistical analysis. The analysis was carried out on 10 women, from 31 to 63 years-old (average age: 44).

#### Results

After 4 weeks, evaluation of the treatment protocol showed significant improvement in all measured parameters (p<0.05). The Corneometer® and Doppler Echography measured better scores for hydration (+39%) and dermis thickness (+33%), as well as an average 15% improvement in skin elasticity.

Results showed a **decrease in wrinkles** obtained by 100% of participants on at least one of the measured areas, up to -18% (average -10%). The Iyashi Dome® helps reduce and erase wrinkles

and/or fine lines (Figure 2).

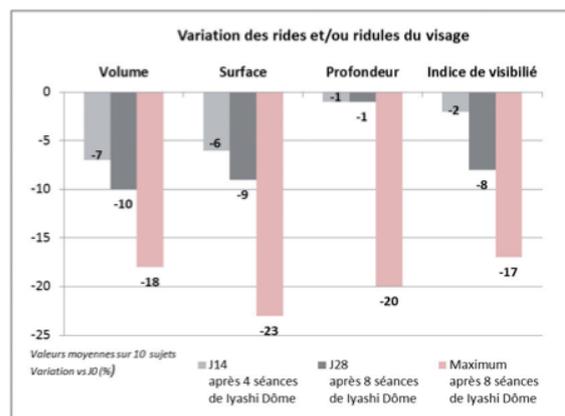


Figure 2

The study also shows that the Iyashi Dome improves **skin radiance**. The complexion became more luminous, up to +12% (average 4%) for 80% of participants. It also helps brighten the skin and reduce dark spots up to -24% (average -11%).

Analysis of **skin roughness** shows that the Iyashi Dome® helps reduce skin blemishes and rough patches up to -24% (average 13%) and promotes complexion evenness and uniformity. (Figure 3).

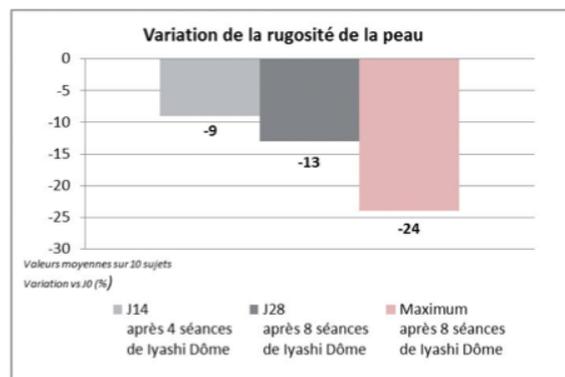


Figure 3

After 8 Iyashi Dome® sessions, the skin is found to be firmer with an **average 33%** increase in dermis density. Thanks to the stimulation and regeneration of collagen fibres, skin firmness is restored, leading to improved tissue support and a reduction in the appearance of skin ageing.

As for **skin hydration**, it was noted that the Iyashi Dome® improves skin **hydration** by an **average 39%** for 100% of participants, nourishes the epidermis and preserves the skin's natural moisture (Figure 4).

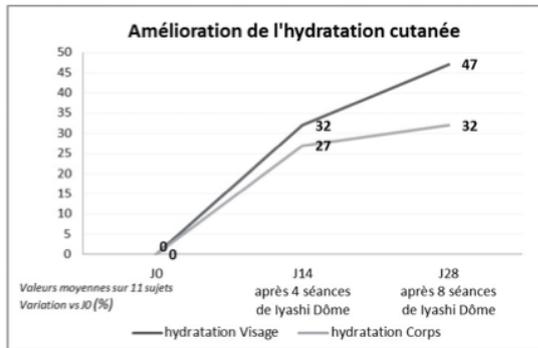


Figure 4

Analysis results for **skin elasticity** show that the **Iyashi Dome®** strengthens the skin by an average 12% and helps maintain and improve the skin's viscoelastic properties (Figure 5).

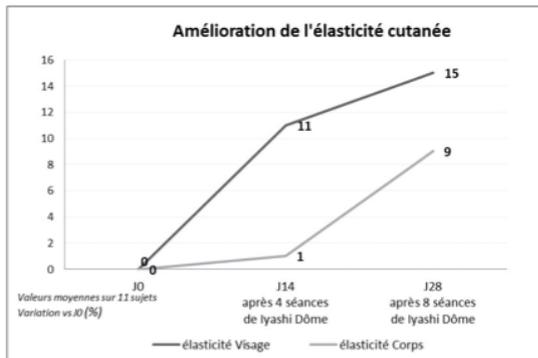


Figure 5

Analysis results for **haemoglobin concentrations** demonstrate that the **Iyashi Dome®** improves haemoglobin concentrations by an average +21%, showing that skin microcirculation is boosted, and, therefore, skin regeneration is improved.

Analysis results for **melanin concentrations** reveal that the **Iyashi Dome®** reduces melanin concentrations in the skin by -8%, with this effect being observed in 82% of participants, showing a decrease in melanosome production that fights against facial skin ageing (Figure 6).

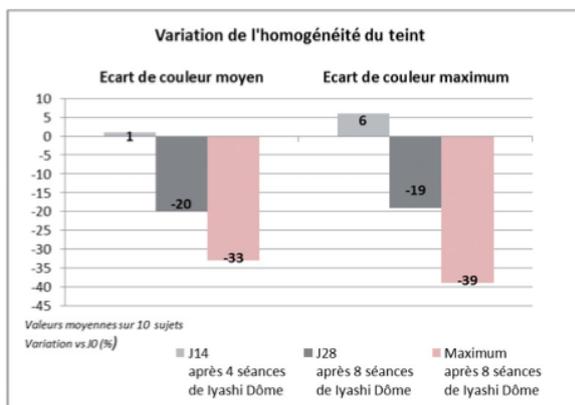


Figure 6

As for the satisfaction questionnaire, 91% of participants observed improved skin hydration, 82% smoother and softer skin, 73% reduced signs of skin ageing and 64% firmer and younger-looking skin, while 91% of women stated that their complexion is more luminous. The treatment was well tolerated and no unexpected negative effect was observed. The majority of participants (91%) declared they were satisfied or very satisfied with their results and the improvements of their skin's quality.

#### Discussion

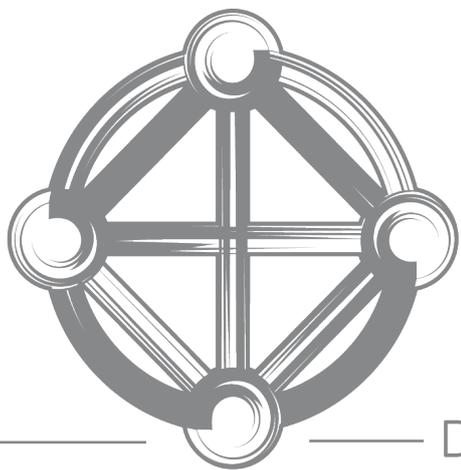
This *in vivo*, observational and non-randomised study was carried out under the control of the French Society of Health Accreditation (SFAS). It revealed the leading role of far infrared rays in correcting the signs of skin ageing and we have noted overall improvement of the skin's quality and physiological properties.

Results confirm the effectiveness of the **Iyashi Dome®** in reducing and repairing the multiple signs of skin ageing on the face and body thanks to the stimulation of cellular activity in the skin.

#### Conclusion

With regard to the parameters evaluated in participants, this study concludes that **the far infrared rays emitted by the Iyashi Dome® are effective in improving the skin's quality and physiological properties** during a 28-day period of use with a protocol comprising 8 sessions.

More specifically, after 4 weeks' use the product improves skin density with an increase in the thickness of the dermis of both face and body, improves skin radiance on the face, decreases skin roughness on the face, decreases wrinkle volume on the face, improves skin hydration on the face and body, improves the complexion (evenness and luminosity of facial skin), improves skin elasticity and firmness on the body and face, stimulates skin microcirculation and reduces the signs of skin ageing. The product was judged to be effective on all skin phototypes and considered as being pleasant to use.



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