

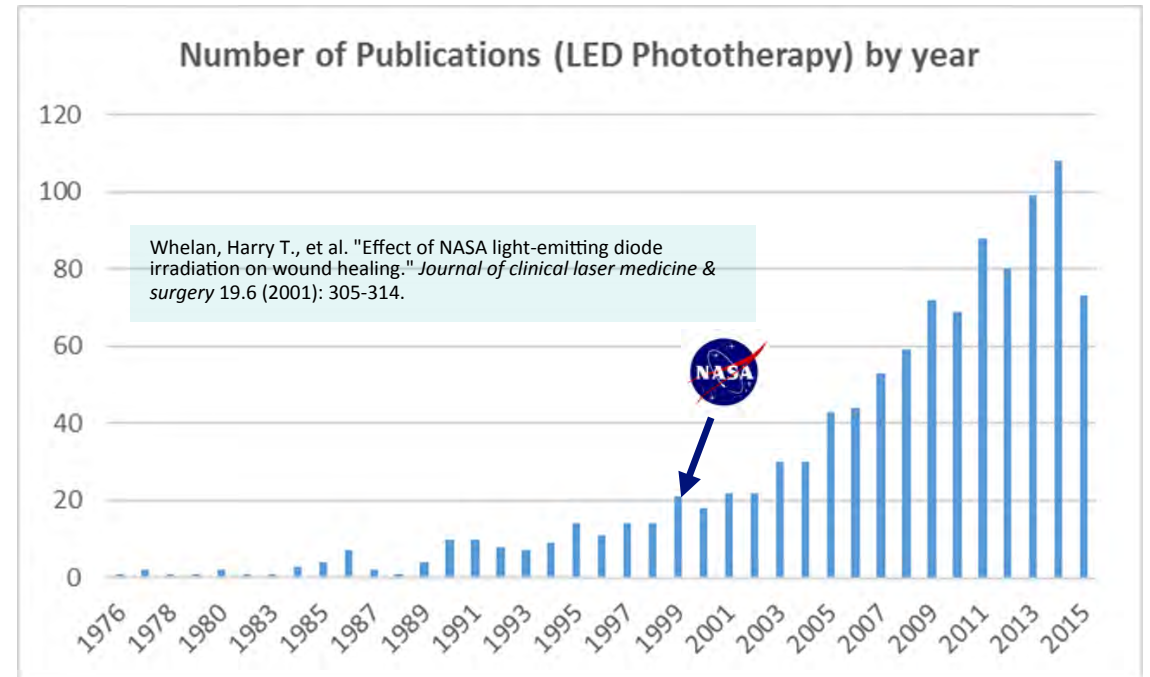
Lightfusion interim results

September 2016

lightfusion™
ADVANCED LIGHT THERAPY

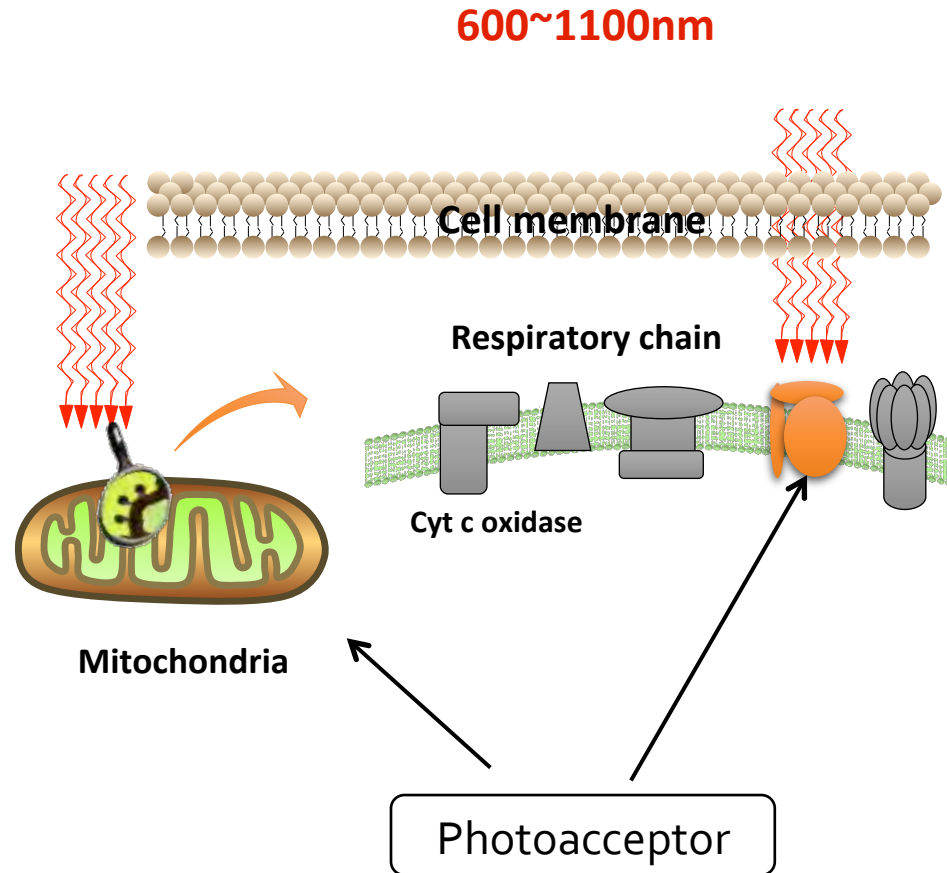
Heritage of Phototherapy

- As early as 1967 Endre Mester demonstrated that low level light stimulated hair growth in Mice.
- 3 years later Mester used red light (HeNe) 633nm to treat skin ulcers
- In 1980s Dr Tiina Karu, conducted studies on how low powered light stimulated cells and discovered that cells within the body contained specific photoreceptors that absorbed light.
- Until the late 1990's most low level light studies used laser diodes, however in 1998 this changed. Professor Harry Whelan at the NASA Space Medicine Laboratory demonstrated that low level light delivered from quasi-monochromatic LEDS speeded up the healing of wounds.
- Since then there has been over 1700 randomised clinical studies and many in vitro studies demonstrating the effects of low level light therapy on a range of indications.



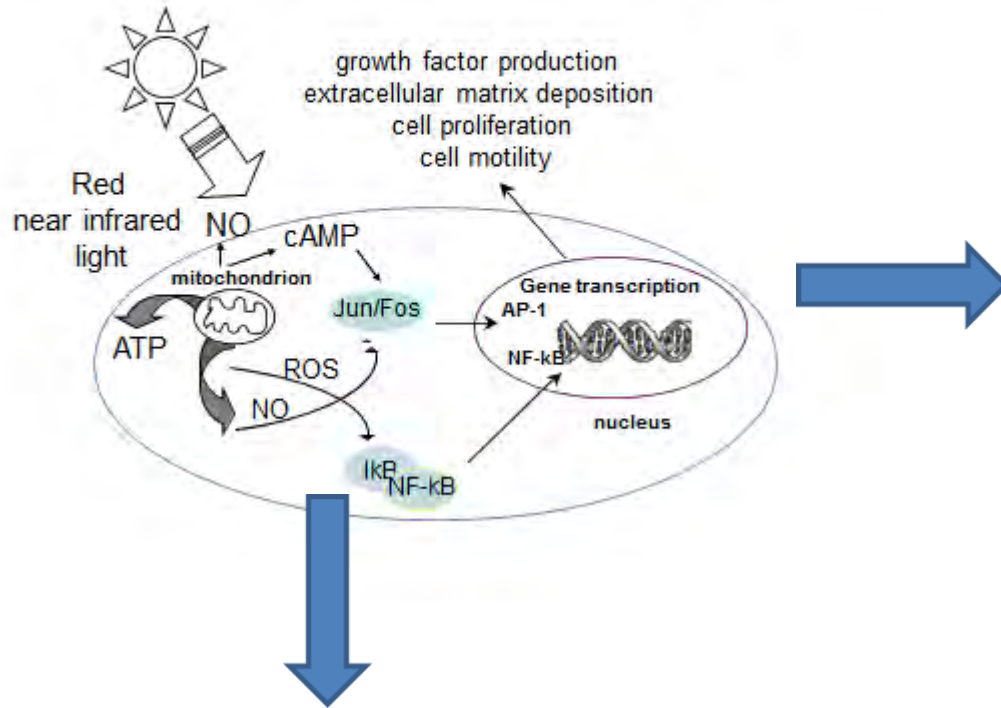
Photobiomodulation

- Photobiomodulation (PBM) is the process where incident photons of light are absorbed by chromophores of living tissue.
- Most common is cytochrome c oxidase in the respiratory electron transport chain of mitochondria.
- In vitro studies demonstrate that PBM through low level light therapy (LLLT) can significantly stimulate a variety of cell lines.



Photobiomodulation

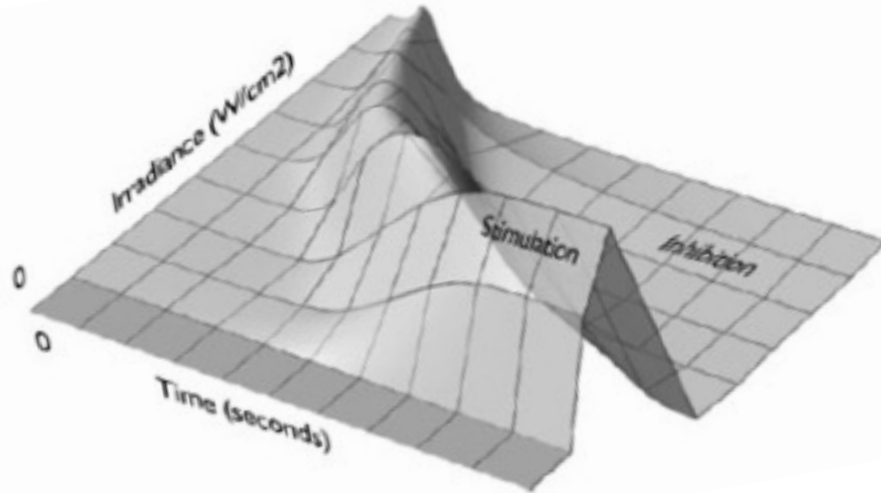
Mechanisms of Photobiomodulation



- Greater cellular energy
- Recovery of hypoxic tissue
- Protects against apoptosis

- Stimulates fibroblasts -new collagen
- Stimulation of mast and macrophage cells
- Effective removal of damaged collagen
- Increase in blood and lymph flow and removal of metabolic waste products
- VEGF synthesis resulting in angiogenesis
- Strengthens and repairs damaged capillaries
- Increases cell to cell communication
- Improved cellular adhesion
- Increases tissue tensile strength
- Improves skins supportive matrices
- Reduction in inflammatory markers

LLLT demonstrates classic Biphasic dose response



- If light is applied in insufficient irradiance or irradiation time is too short there will be little or no cellular response.
- As irradiance or irradiance time increases light becomes stimulatory promoting cellular response.
- At a given point if irradiance is too high or irradiance time is too long then the cellular response may be inhibited.

Important considerations for effective photobiomodulation;

- Correct wavelength
- Correct intensities
- Closely packed LED's
- Close proximity to the target

What is lightfusion? The next generation in phototherapy

- Uses two clinically proven wavelengths of light , 830 and 633nm, delivered from one diode, directly to the skin.
- Hydrogel mask specifically designed to allow light photons to penetrate.
- LEDS are closely packed and sit directly on the skin therefore leading to minimal diffraction of light allowing a lower intensity to be used.
- Low intensity of the LED's allows two wavelengths to be delivered simultaneously without causing cellular confusion



**An open label study to evaluate the efficacy of Lightfusion™
LED device and the hydrogel light fusion mask for
treating the signs of ageing**

**VITAGE LED Ltd,
The Pavilion, Josselin Road,
Basildon, Essex SS13 1QB.
United Kingdom**

Study objectives

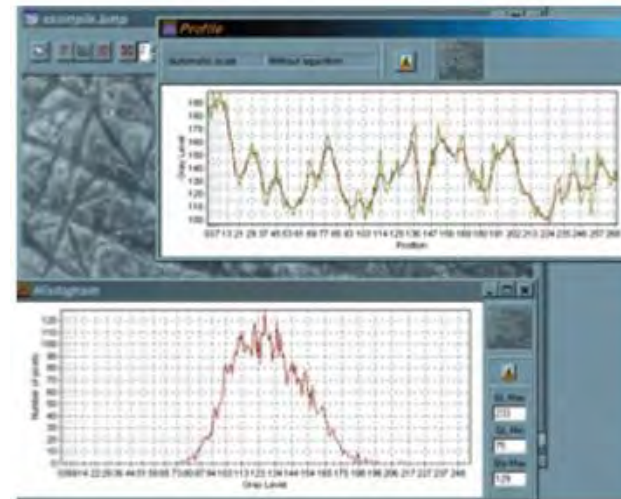
1. Evaluate the effect of one ten minute treatment on hydration and elasticity levels immediately after one treatment.
2. Evaluate the effects of one and two weekly treatments on wrinkle parameters
3. Primary endpoints... reduction in wrinkles by I grade (includes roughness parameters)
4. Secondary endpoints... improvements in secondary markers of photo ageing (texture and elasticity)
5. Safety endpoint... assess side effects

Study design – Assessment tools

- Two groups of 12 subjects, divided into 2 groups (1x4 weekly treatments and 2 x 4 weekly treatments)
- Age inclusion criteria 30-65, male or female, Fitzpatrick skintypes i-iv.
- Digital photography using the Visia system from Canfield. Baseline and follow ups
- Mechanical evaluation of elasticity, (cutometer), skin hydration (corneometer) and pigmentation (mexameter) measured using the MC 1000 - Courage and Khazada.
- Surface roughness and texture. SELS (surface evaluation of living skin) Visioscan - Courage and Khazada.

Visioscan

- Visioscan is a high resolution UVA camera that assesses the grey level distribution of the image. Data is quantitatively and qualitatively analysed and describes the skin surface as an index
- Roughness parameters are also measured that describe an irregular uneven surface



Surface Roughness parameters

Parameter	Description
R1	Maximum Height of the profile along a given line (Roughness)
R2	Average roughness estimated from several measurements
R3	Maximum roughness depth (Highest peak & depression difference)
R4	Average bare reference profile (Smoothness depth)
R5	Arithmetic average depth of roughness profile from the mean

	Mean Baseline R parameters		Mean Visit 5 R parameters		Difference in mean R parameters		Mean difference for L+R	Percentage change	
	L	R	L	R	L	R	L+R	L	R
R1	34.4	33.4	26.6	26.8	-7.8	-6.6	-7.2	-23%	-20%
R2	28	26.4	22.8	21.8	-5.2	-4.6	-4.9	-19%	-17%
R3	20.2	19.2	16.6	16.4	-3.6	-2.8	-3.2	-18%	-15%
R4	18.4	18.4	14.4	14.2	-4	-4.2	-4.1	-22%	-23%
R5	8.4	5.4	3.4	3.6	-5	-1.8	-3.4	-60%	-33%

Surface evaluation of living skin results (SELS Results)

Parameter	Description
Sesm	Smoothness in proportion to wrinkle number (SEW)
Sesc	Scaling calculated as a portion of light pixels (grey level higher than established threshold). Demonstrates improvements in surface moisture
Sew	Proportion of horizontal and vertical lines. Demonstrates improvement in wrinkle

	Mean Baseline Se parameters		Mean Visit 5 Se parameters		Difference in mean Se parameters		Mean difference for L+R	Percentage change	
	L	R	L	R	L	R	L+R	L	R
Sesm	161.3	196.1	107.9	114.4	-53.4	-81.6	-67.5	-33%	-42%
Sesc	0.6	0.41	0.5	0.47	-0.15	0.06	0.0	-23%	15%
Sew	125.6	184.9	72.6	98.3	-53.0	-86.6	-69.8	-42%	-47%

Explanation of Roughness Results

- A reduction in these values is expected if the treatment is demonstrating improvement in wrinkles and smoothness.
- In association with the SELS results designed specifically for skin analysis, it allows a more accurate overview of the treatments effectiveness than photographic assessment alone.
- The first microprofile obtained before treatment was irregular with numerous microbumps suggesting rough skin surface and visible wrinkling.
-
- The 1st profile was similar but after the 4th treatment, assessment week 5 it was visibly milder suggesting antiwrinkle properties after a series of treatments.
- Based on the same photos – the surface parameter was analysed which is the ratio of wavy to stretched plane. High values indicate uneven or irregular surface while decreasing surface value shows the area becoming smoother.

Elasticity – hydration -pigmentation

Parameter	Mean Baseline	Mean Post treatment (1)	Percentage change
Elasticity	52.4	63.3	20.8%
Hydration	66.9	74.9	17.6%
Pigmentation	196	193	-1.5% (tolerance)

Before & After Images



Before



After











Subjective analysis

The next morning after a Lightfusion™ treatment;

	Agree or Strongly agree	Neither agree or disagree
My skin feels softer and smoother;	9/10	1/10
My skin feels plumper and more hydrated	9/10	1/10
My skin looks brighter and more refreshed	9/10	1/10
My skin feels firmer or tighter	9/10	1/10
My fine lines appear less visible	9/10	1/10

Summary

- Objective mechanical tests clearly show improvements in surface roughness (wrinkles) one week after a four week course of Lightfusion.
- R values are supported by Surface evaluation results
 - A reduction in Sesm demonstrates smoother skin
 - A reduction in Sew demonstrates a global improvement in wrinkles
 - A reduction in Sesc demonstrates less scaliness of the skin, most probably due to increased hydration and improvements in cell turnover
- Objectively; skin post treatment is firmer and more hydrated
- Subjective analysis supports objective results
- No reported adverse events