

Lustre Pure Light Classic Home Use Device Study

European LED Academy

Investigators

Dr. Michèle Pelletier (MD) Dermatologist. Toulon. President of the European LED Academy. Lead investigator.

Dr. Linda Fouque (MD) Dermatologist. Nice. Vice President of the European LED Academy.

Dr. Yannick Saussaye (MD) Dermatologist. Montpellier. Vice President of the European LED Academy

Study Purpose, Protocol and Results

The clinical effectiveness of Lustre Pure Light Classic in mild to moderate acne vulgaris following the standard IFU (instructions for use) was assessed by 3 independent Dermatologists from the European LED Academy following a standardised assessment protocol and Acne scoring system.

All patients were washed out of all other treatments 4 weeks before the study commenced and only used the Lustre Pure Light Classic devices during the period of the study.

After the initial scoring and consenting process the clinical results were assessed by each investigator on days 30, 60, 90 with a further observational assessment carried out on day 120 to assess maintenance and persistence of results based on the standard IFU (instructions for use) protocol for maintenance treatment.

Standard Acne assessment score used

1 = skin is almost clear: rare no inflammatory lesions present, with rare non-inflamed Papules (papules must be resolving and may be hyper pigmented, though not pink red)

2 = some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only; no nodular-cystic lesions)

3 = non-inflammatory lesions predominate, with multiple inflammatory lesions evident: several to many comedones and papules/pustules, and there may or may not be one small nodular-cystic lesion

4 = inflammatory lesions are more apparent: many comedones and papules/pustules, there may or may not be a few nodular-cystic lesions

5 = highly inflammatory lesions predominate: variable number of comedones, many papules/pustules nodular-cystic lesions

Clinical assessment parameters studied

5 clinical parameters were studied:

- a) The reduction in sebaceous secretion levels
- b) The increase in pore tightening
- c) The percentage reduction of inflammatory lesions
- d) Overall improvement in acne using an acne assessment score
- e) Overall patient satisfaction: Quality of life improvement

Summary Results

We noted the following overall results:

- a) A 75 % reduction at day 30 in inflammatory lesions in all patients
- b) An 80% reduction overall in seborrhoea at day 90
- c) An 80% tightening of pores at day 90
- d) Overall a 90 % good overall result experienced
- e) Overall a 90% continuing good result from days 90 to 120 days in the maintenance phase

Conclusions:

Lustre Pure Light Classic was seen to be an effective treatment which was easily integrated into the everyday lifestyle of patients participating in the study.

Lustre Pure Light Classic was seen as an attractive alternative to oral contraceptives (3rd generation pill with vascular risk) and systemic and topical antibiotics.

Lustre Pure Light Classic in the treatment of mild to moderate acne vulgaris

Background:

Acne is a common skin disease found in adolescents but it is increasingly found to be persistent in the adult population. It has been shown to have a negative effect on self-image and can lead to depression. Several evolutionary aspects are commonly seen over time. Hyperkeratosis infra-fundibulum is a classic characteristic as is the presence of cysts, blackheads or whiteheads, pustules, inflammation and nodules with deeper inflammation resulting in the risk of scar formation

The *P. acnes* bacterium is responsible for: Specific and nonspecific immunity as a super antigen, non-specific immunity and neutrophil attraction, production of interleukins 1A4, with the presence of interferon - T receptors TLR2 and is mainly responsible for the inflammatory phase and persistence of the acne vulgaris condition.

The effects of blue light in the visible spectrum

We know the effect of the solar spectrum on drying lesions and especially the increase of the keratinization cap horn responsible for the occurrence of acne delayed after sun exposure in susceptible individuals. Blue light at a wavelength of between 405 and 420 nm has several effects: An antibacterial action by the effect of blue light on corprophyrin 3 which promotes a natural photodynamic therapy that results in the reduction of *P. acnes* bacterium.

The stimulation of the production of peptide LL37 acts as an anti-infective and an anti-inflammatory effect is seen by the reduction in production by keratinocytes of IL-1 and ICAM-1.

Limitations of current treatments and controversies

The published literature over the last 20 years has reported the occurrence of acquired resistance to oral and local topical antibiotics along with an increased risk of thromboembolism using 3rd and 4th generation oral contraceptives.

The withdrawal of the Dianette 35 in France further limits the treatment options available to acne patients.

Finally, the incidence of cases of adolescent suicide after taking oral retinoid preparations has led to them being avoided routinely in any adolescent at risk.

This is why it has become necessary to seek alternative therapies and phototherapy should be part of any modern acne management programme.

Study Protocol:

The number of Patients enrolled was 15 aged between 15-44 years of age with a history of mild to moderate acne vulgaris.

Patients were washed out from other therapies for a period of 4 weeks before the trial commenced to study the effect of Lustre Pure Light Classic as a mono therapy as a consequence no other oral or topical treatments were used. Patients were coached through the IFU (instructions for use).

Patient Profiles:

To date in the interim results reported 8 patients 5 female and 3 male have completed the study, 2 with mild acne, 4 with moderate acne and 2 with severe acne. 3 patients are awaiting final write ups of their results but show similar results to the 8 reported patients and 4 patients have been lost to follow up.

Study parameters:

Initial definition of clinical grade: acne mild, moderate & severe was assessed using a standard acne scoring system. An individual clinical assessment was undertaken before treatment, and then at 30, 60, 90 and 120 days: A visual count of blackheads, whiteheads, papules, nodules, pustules was performed for each patient.

An improvement grid of 25, 50, and 75,100 % improvement of the lesions in each category was scored at each patient visit by the investigator.

Device description

The Lustre Pure Light Classic pack contained all the elements required for the required 12 weeks of phototherapy, 1 hour of treatment per day for 12 weeks or 8 hours a week with a total weekly dose of 28.8 joules.

The therapy heads were applied directly by the patient to three areas: forehead, cheeks and chin following an initial coaching session and thereafter were using the companies' standard IFU (Instructions for use).

Overall Results

From the 30th day inflammatory lesions begin to fade until disappearing on the 90th day. Cysts were seen to subside on the 60th, 90th days. 8 patients are reported here in the interim results 3 male and 5 female ranging from 15 years of age to 44 years of age. 2 patients presented with mild acne, 4 with moderate acne and 2 with severe acne with 3 additional patients to be completed and 4 lost to follow up.

All 8 patients saw a significant reduction in inflammatory lesions, blackheads and pustules over the course of their treatment from the 4 week period onwards. We reported a 75% reduction in inflammatory lesions and day 30 an 80% reduction in Seborrhoea at day 90 as a results of the reduction in P.acnes bacterium. We report an 80% effect on the tightening of pores as a result of the healing process and overall a 90% improvement in patient self-assessment on the quality of life scores at 90 days.

Psychological & Quality of Life Observations

Given the well published social and psychological impacts suffered by many persistent acne sufferers we were keen also to observe and assess the impact on improvements in a)levels of anxiety reduction b)patients own self assessed scoring of perceived acne improvement as well as c)the reduction in skin irritation that lead patients to scratch at their lesions.

We assessed each patient and asked each patient to assess their feelings across these parameters at the start of the study and we observed marked improvements across all of these parameters throughout the study period in general terms with 1 exception.

Our belief is that this effect is critical to patient compliance. When patients begin to see the impact of the treatment their compliance and wellbeing begins to increase. We recorded other positive benefits in addition to the main observations including increased desire to improve their overall appearance and their ability and desire to socialise.

These positive effects suggest that the Lustre Pure Light Classic can provide not only clinical benefits which can be measured but important secondary effects which although subjective in nature are the patient's own record of how they feel which is an equally important factor when treating these persistent acne sufferers.

Sample Results



RESULTS



D30 : Start of improvement of inflammatory lesions and complete resolution at D90

D60: improvement of whiteheads

D90: improvement of seborrhoea

D120: later result: persistence of results after the treatment is stopped one case with a positive effect after a more long time : 3 months



Patient 7: 15 years old



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After 2 months without treatment
Inflammatory lesions and less
blackheads





Discussion and observations:

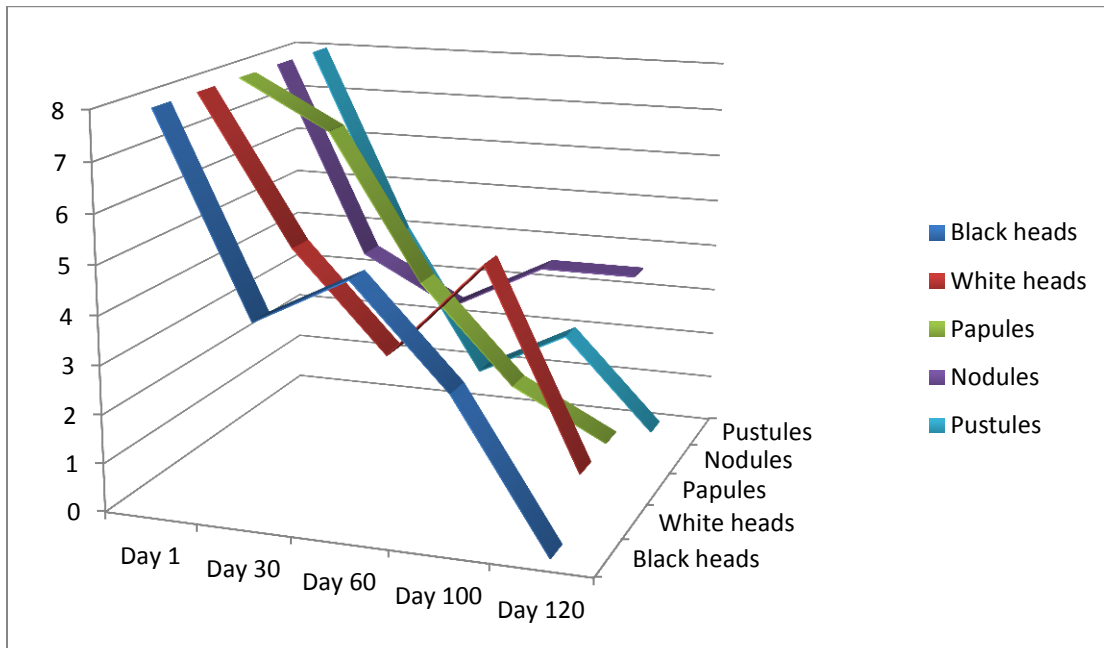
15 patients were enrolled into the study. 11 patients completed the study (8 are reported in the interim results) 3 are in the process of being written up but show similar outcomes to the 8 reported and 4 patients were lost to follow up.

Some parameters were significantly improved such as papules and pustules and fluent seborrhoea which is often poorly managed and neglected. The delayed effect on the cosmetic appearance of skin texture was seen as very positive and a phenomenon of photo bio- modulation.

The Lustre Pure Light Classic device is seen as a very modern expression of new therapy for the treatment of Acne Vulgaris.

The patient takes control of their own condition which promotes a sense of being in control of their condition. The pore tightening effect is the result of a skin rejuvenation effect of photo-bio modulation. The scar-prevention effect seen by removing the inflammatory lesions is an excellent preventive effect which reduces the need for future and potentially expensive cosmetic management. This important improvement can be seen as creating an improved healing environment for the tissue and thus preventing secondary scarring.

Summary:



Overall assessment:

8 patients are reported here in the interim results 3 male and 5 females ranging from 15 years of age to 44 years of age. 2 patients presented with mild acne, 4 with moderate acne and 2 with severe acne with 3 additional patients to be completed and 4 lost to follow up. All 8 patients saw a significant reduction in inflammatory lesions, blackheads and pustules over the course of their treatment from the 4 week period onwards. We reported a 75% reduction in inflammatory lesions and day 30 an 80% reduction in Seborrhoea at day 90 as a result of the reduction in P.acnes bacterium. We report an 80% effect on the tightening of pores as a result of the healing process and overall a 90% improvement in patient self-assessment on the quality of life scores at 90 days with a 90% continuing good result at 120 days in the maintenance phase.

Clinical Evaluation report Lustre Pure Light Classic

Patient: BRE

Age: 22

Sex: F

Type of acne:

mild

moderate

severe

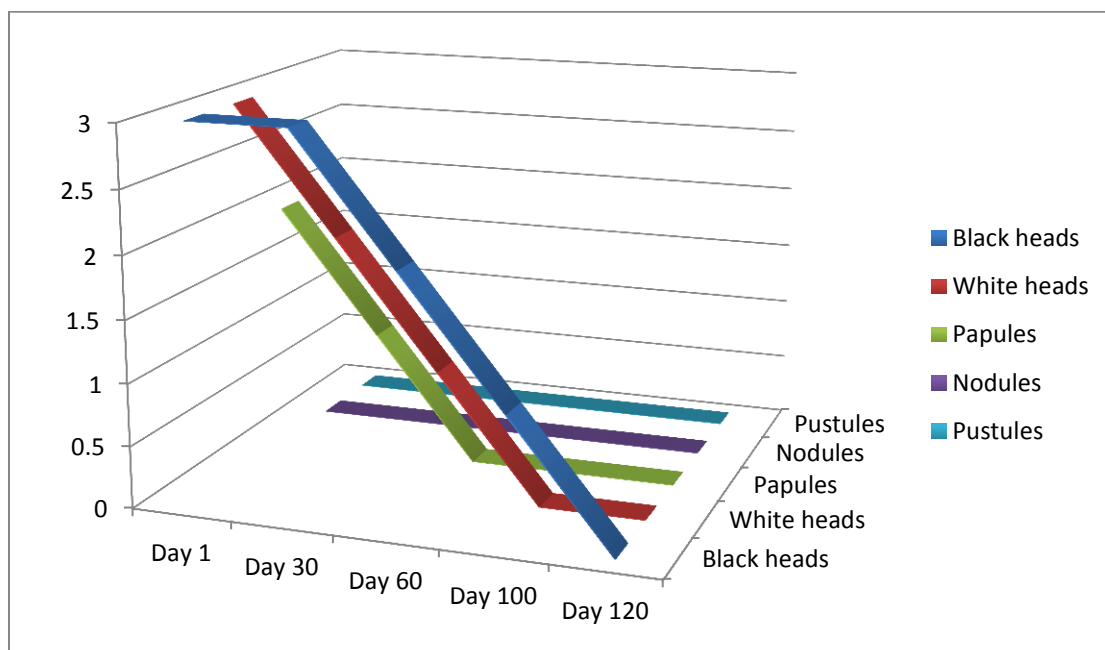
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	+++	+++	++	0	0
Day 30	+++	++	+	0	0
Day 60	++	+	0	0	0
Day 90	+	0	0	0	0
Day 120	0	0	0	0	0

+: 25%

++: 50%

+++: 75%

++++: 100%



Overall Patient assessment: 4: Good

Clinical Evaluation report Lustre Pure Light Classic

Patient: LAU

Age: 17

Sex: F

Type of acne:

mild

moderate

severe

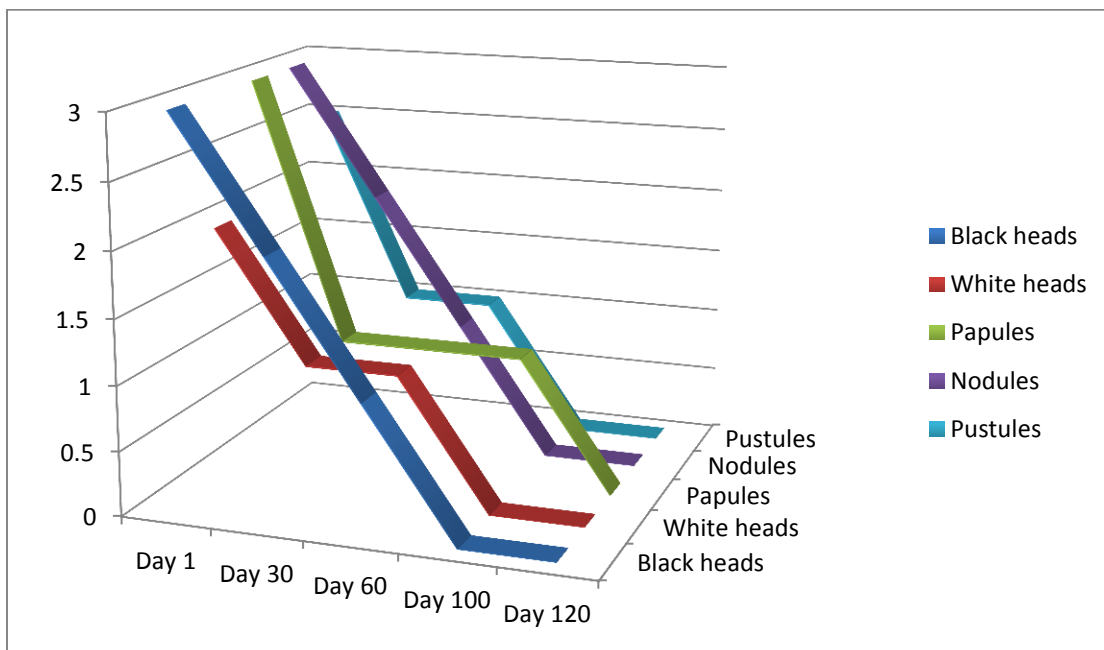
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	+++	++	+++	+++	+++
Day 30	++	+	+	++	+
Day 60	+	+	+	+	+
Day 90	0	0	+	0	0
Day 120	0	0	0	0	0

+: 25%

++: 50%

+++: 75%

++++: 100%



Overall Patient assessment: 4: Good

Clinical Evaluation report Lustre Pure Light Classic

Patient: BOU

Age: 35

Sex: F

Type of acne:

mild

moderate

severe

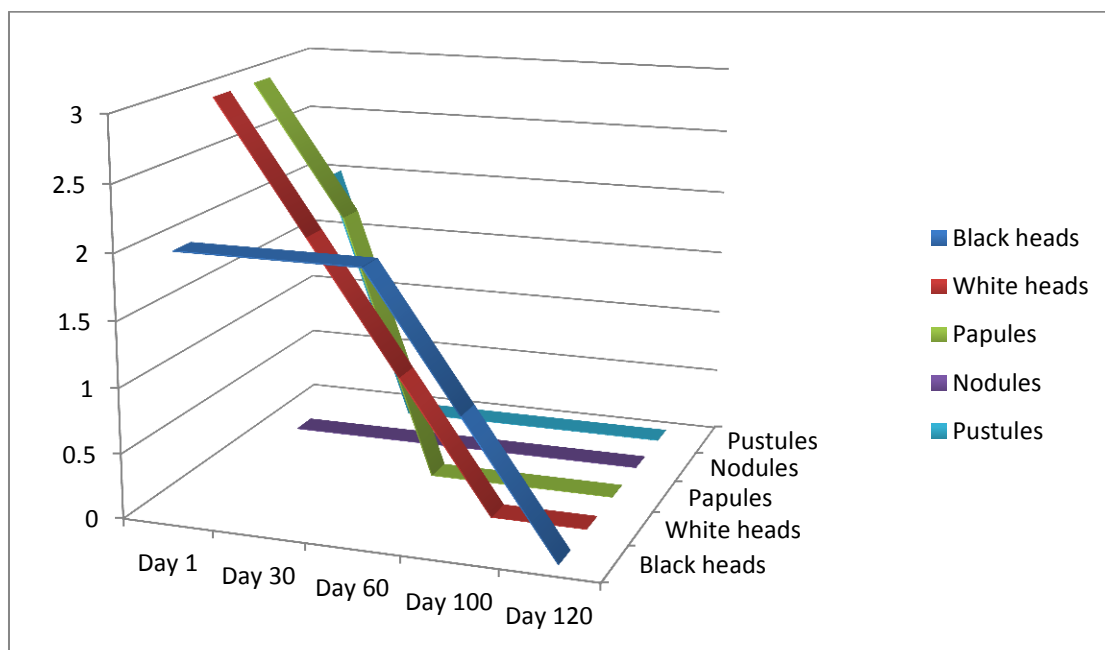
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	++	+++	+++	0	++
Day 30	++	++	++	0	0
Day 60	++	+	0	0	0
Day 90	+	0	0	0	0
Day 120	0	0	0	0	0

+: 25%

++: 50%

+++: 75%

++++: 100%



Overall Patient assessment: 4: Good

Clinical Evaluation report Lustre Pure Light Classic

Patient: LEB

Age: 35

Sex: F

Type of acne:

mild

moderate

severe

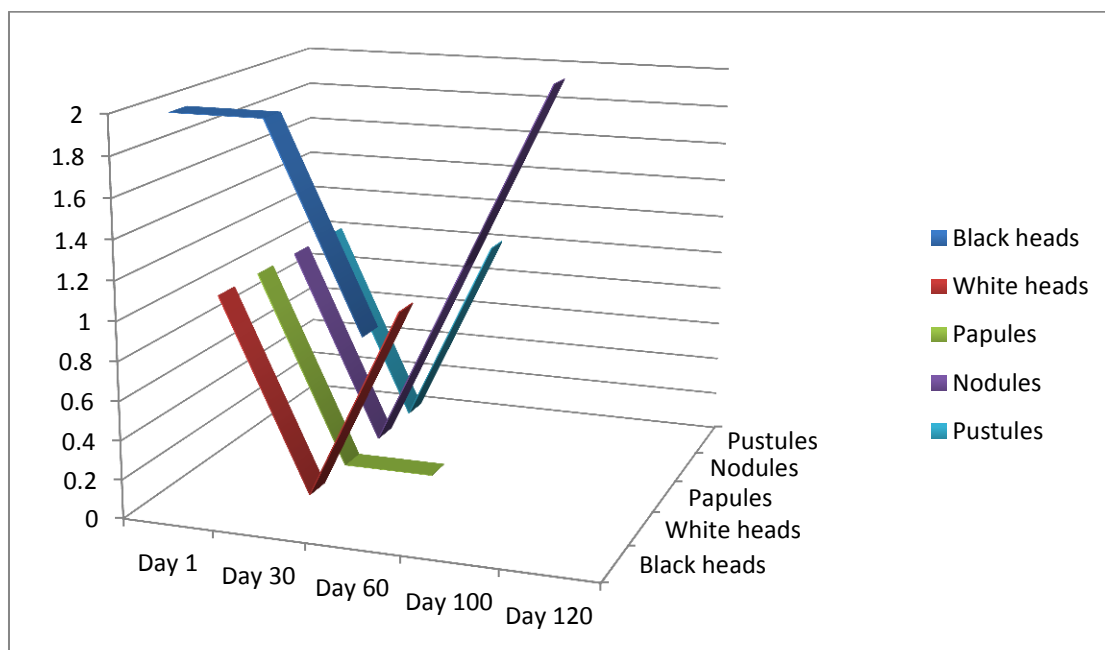
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	++	+	+	+	+
Day 30	++	0	0	0	0
Day 60	+	+	0	++	+
Day 90	0	0	0	+	+
Day 120	0	0	0	+	+

+: 25%

++: 50%

+++: 75%

++++: 100%



Overall Patient assessment: 2: Fair

Clinical Evaluation report Lustre Pure Light Classic

Patient: PET

Age: 30

Sex: F

Type of acne:

mild

moderate

severe

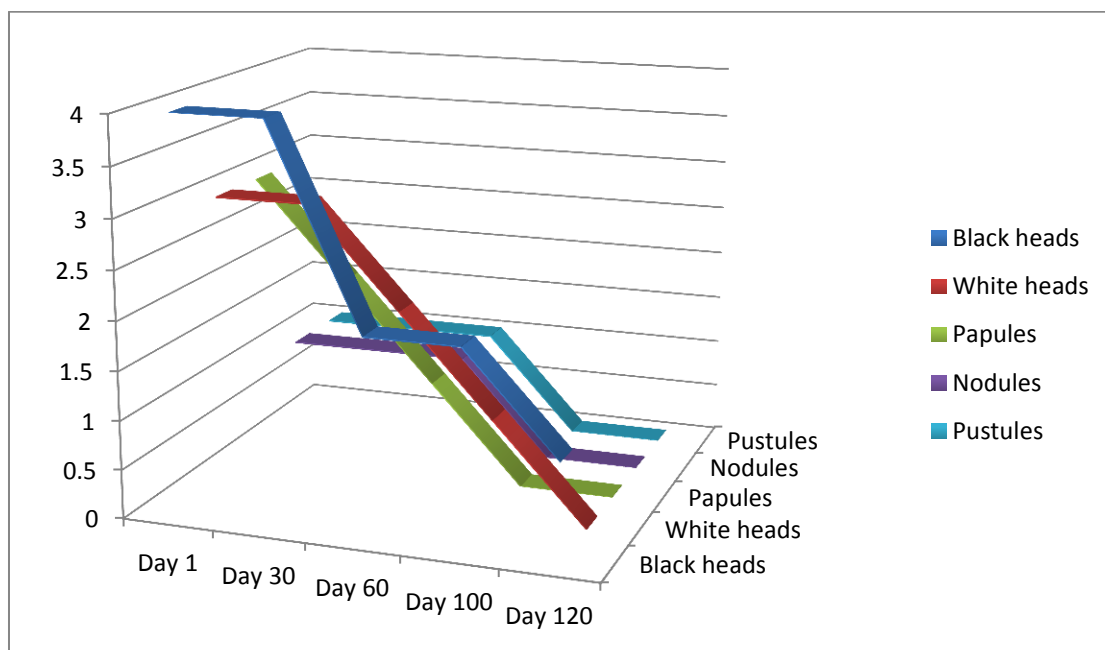
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	++++	+++	+++	+	+
Day 30	++++	+++	++	+	+
Day 60	++	++	+	+	+
Day 90	++	+	0	0	0
Day 120	+	0	0	0	0

+: 25%

++: 50%

+++: 75%

++++: 100%



Overall Patient assessment: 5: Very Good

Clinical Evaluation report Lustre Pure Light Classic

Patient: SAU

Age: 17

Sex: F

Type of acne:

mild

moderate

severe

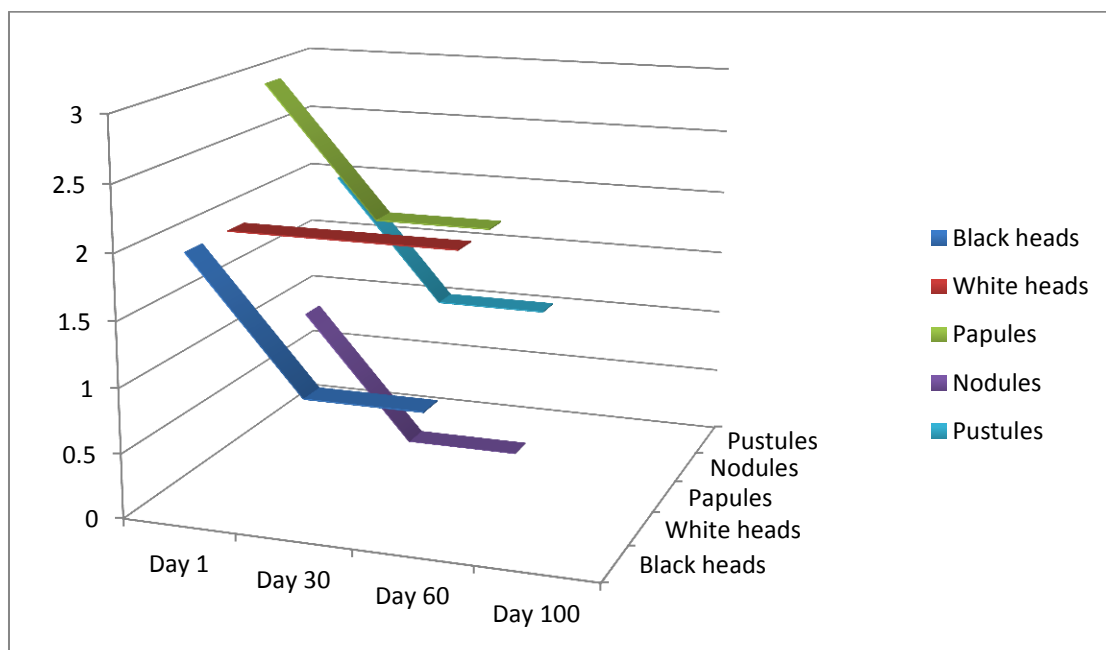
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	++	++	+++	+	+++
Day 30	+	++	++	0	++
Day 60	+	++	++	0	++
Day 90	0	+	++	0	++
Day 120	0	+	+	0	++

+: 25%

++: 50%

+++ 75%

++++: 100%



Overall Patient assessment: 2: Fair

Clinical Evaluation report Lustre Pure Light Classic

Patient: OLL

Age: 15

Sex: M

Type of acne:

mild

moderate

severe

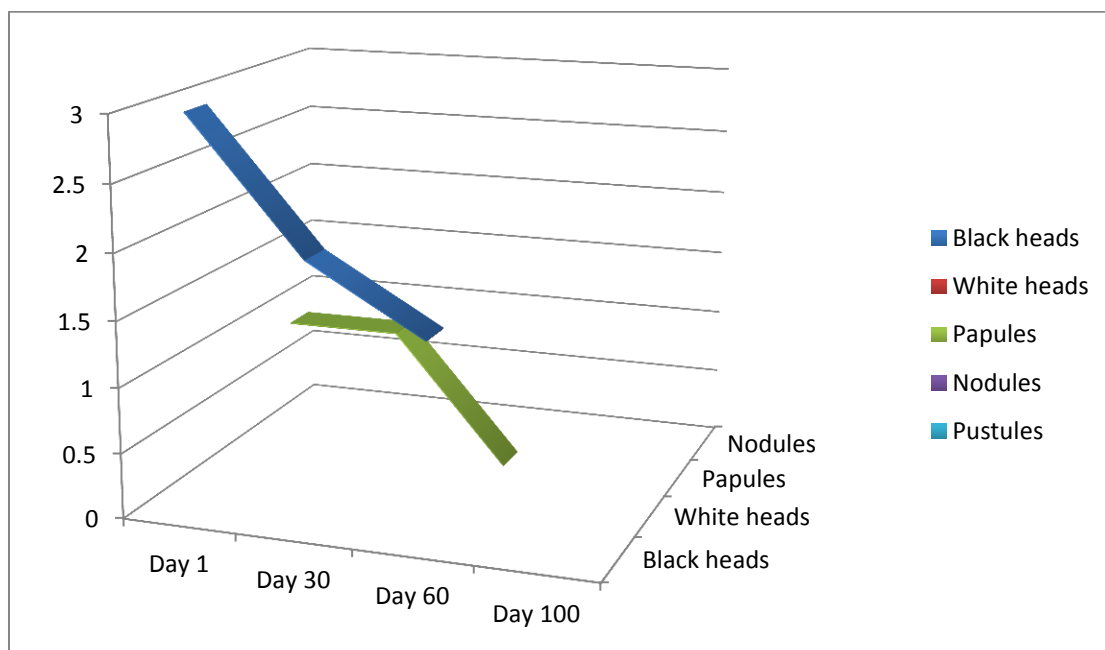
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	+++		+		
Day 30	++		+		
Day 60	+		0		
Day 90	+		0		
Day 120	+		0		

+: 25%

++: 50%

+++: 75%

++++: 100%



Overall Patient assessment: 4: Good

Clinical Evaluation report Lustre Pure Light Classic

Patient: FOR

Age: 15

Sex:M

Type of acne:

mild

moderate

severe

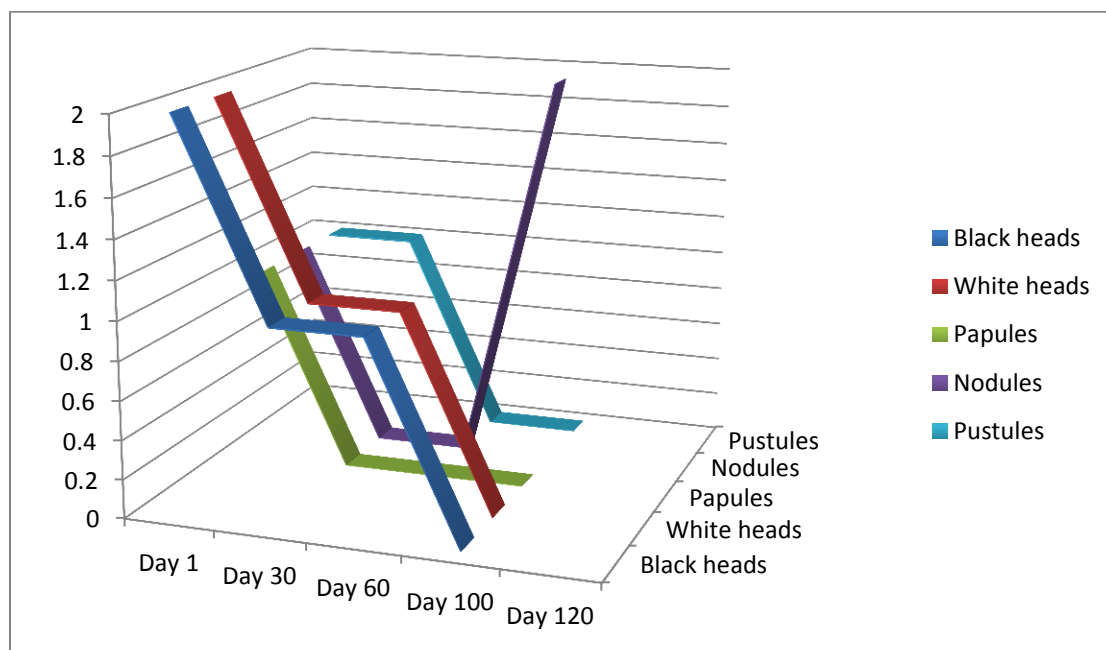
Lesions (+)	Black heads	White heads	Papules	Nodules	Pustules
Day 1	++	++	+	+	+
Day 30	+	+	0	0	+
Day 60	+	+	0	0	0
Day 90	0	0	0	++	0
Day 120	0	0	0	+	0

+: 25%

++: 50%

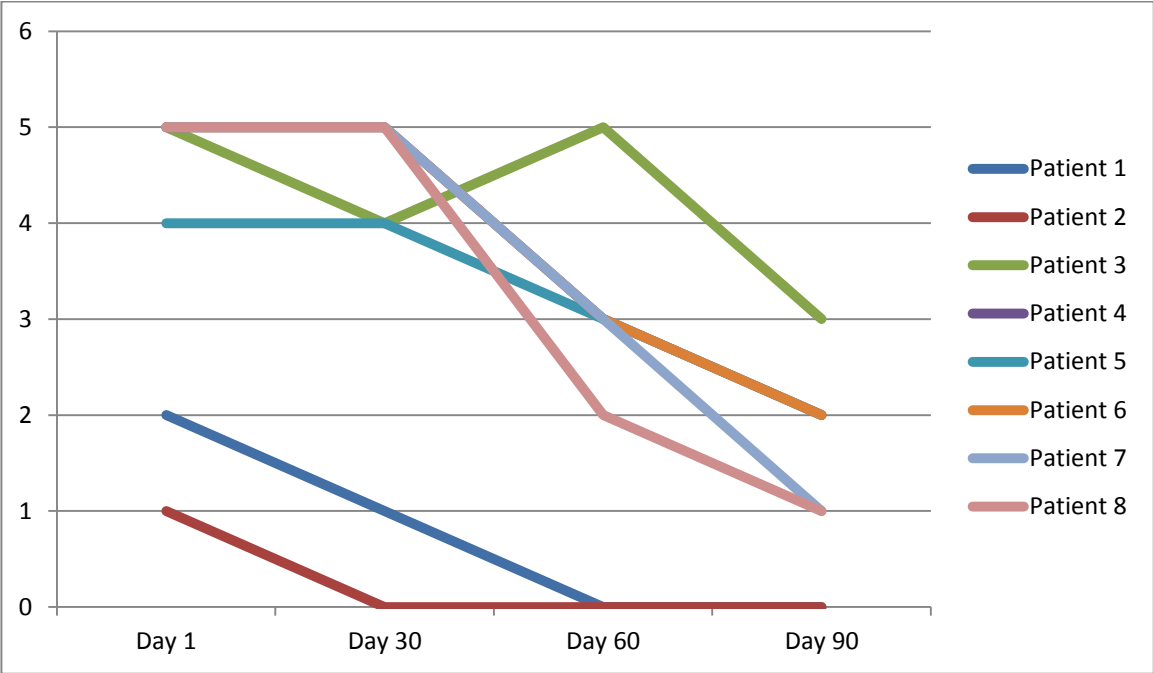
+++: 75%

++++: 100%



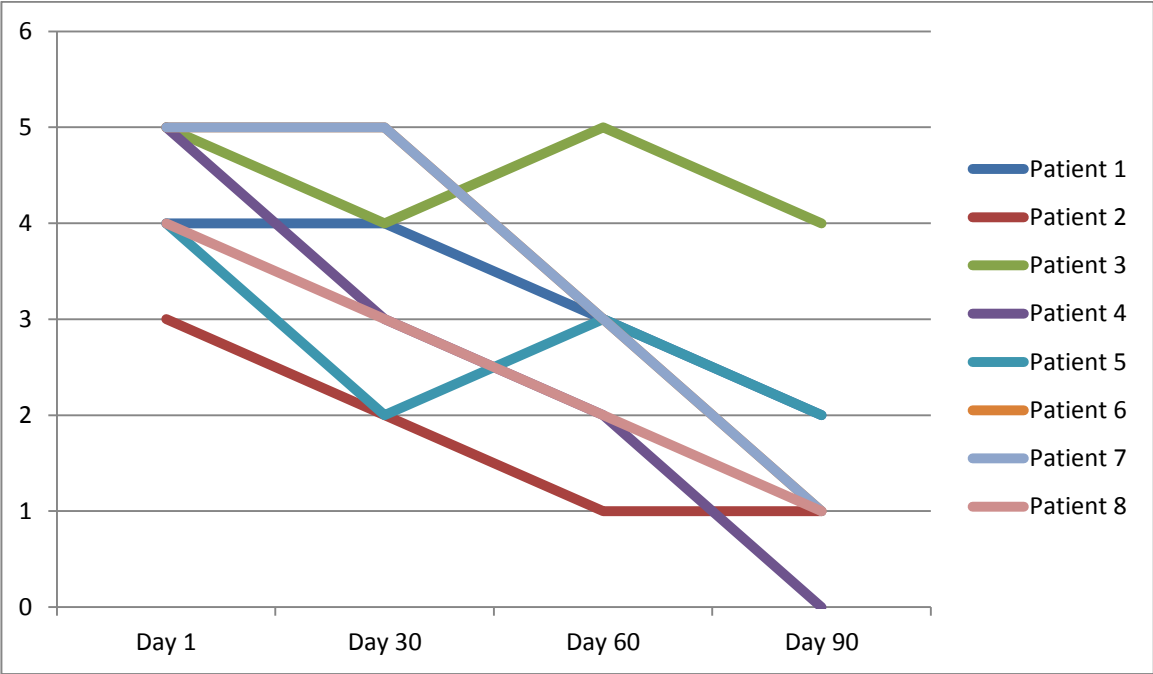
Overall Patient assessment: 5: Very Good

Level of Anxiety:



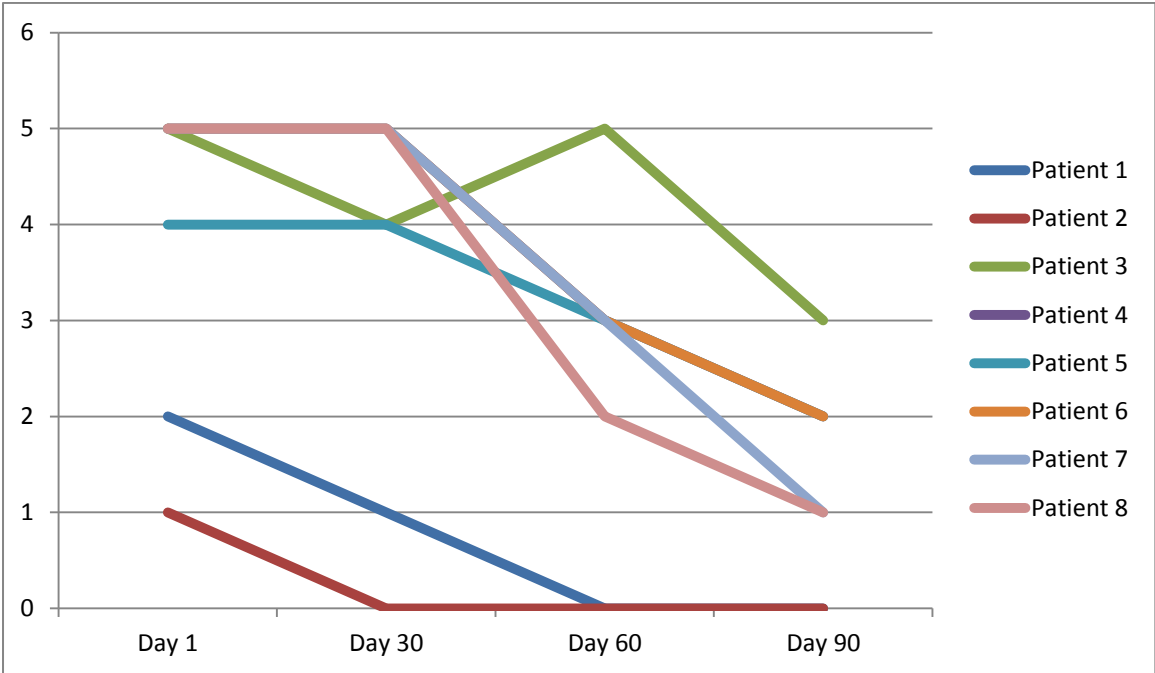
Patient 1:0 day :2/30 day : 1 / 60 day : 0 / 90 day : 0
 Patient 2 :0 day :1/30 day :0 / 60 day : 0 / 90 day : 0
 Patient 3:0 day :5/30 day : 4 / 60 day : 5 / 90 day : 3
 Patient 4:0 day :5/30 day : 5 / 60 day : 3 / 90 day : 2
 Patient 5:0 day :4/30 day : 4 / 60 day : 3 / 90 day : 2
 Patient 6:0 day :5/30 day : 5 / 60 day : 3 / 90 day : 2
 Patient 7:0 day :5/30 day : 5 / 60 day : 3 / 90 day : 1
 Patient 8 :0 day :5/30 day :5 / 60 day : 2 / 90 day : 1

Patient Perception in overall Acne Improvement:



Patient 1 : 0 day :4/30 day :4/60 day :3/90 day :2
 Patient 2 : 0 day :3/30 day :2/60 day :1/90 day :1
 Patient 3 : 0 day :5/30 day :4/60 day :5/90 day :4
 Patient 4: 0 day :5/30 day :3/60 day :2/90 day :0
 Patient 5: 0 day :4/30 day :2/60 day :3/90 day :2
 Patient 6: 0 day :5/30 day :5/60 day :3/90 day: 1
 Patient 7: 0 day :5/30 day :5/60 day :3/90 day :1
 Patient 8 : 0 day :4/30 day :3/60 day :2/90 day :1

Reduction in skin irritation



Patient 1: 0 day: 2 /30 day: 1 /60 day: 0 /90 day: 0
 Patient 2: 0 day: 1 /30 day: 0 /60 day: 0 /90 day: 0
 Patient 3: 0 day: 5 /30 day: 4 /60 day: 5 /90 day: 3
 Patient 4: 0 day: 5 /30 day: 5 /60 day: 3 /90 day: 2
 Patient 5: 0 day: 4 /30 day: 4 /60 day: 3 /90 day: 2
 Patient 6: 0 day: 5 /30 day: 5 /60 day: 3 /90 day: 2
 Patient 7: 0 day: 5 /30 day: 5 /60 day: 3 /90 day: 1
 Patient 8: 0 day: 5 /30 day: 5 /60 day: 2 /90 day: 1

Appendices

1. Acne Assessment Score

1 = skin is almost clear: rare non-inflammatory lesions present, with rare non-inflamed papules (papules must be resolving and may be hyper pigmented, though not pink/red)

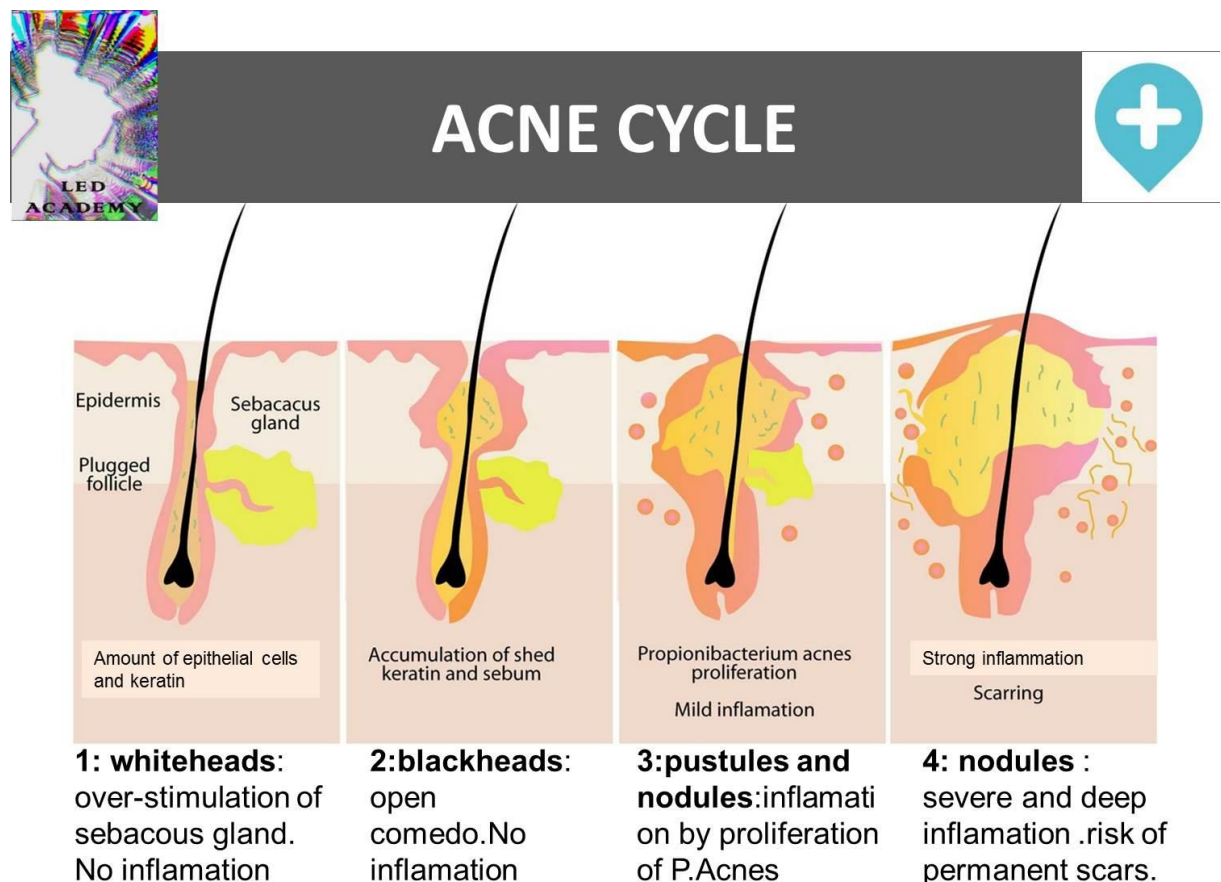
2 = some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only; no nodular-cystic lesions)

3 = non-inflammatory lesions predominate, with multiple inflammatory lesions evident: several to many comedones and papules/pustules, and there may or may not be one small nodular-cystic lesion

4 = inflammatory lesions are more apparent: many comedones and papules/pustules, there may or may not be a few nodular-cystic lesions

5 = highly inflammatory lesions predominate: variable number of comedones, many papules/pustules nodular-cystic lesions

2. The Acne Cycle



3. Bibliography :

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