

Combined Therapies for Medical / Aesthetic Procedures Using a Hybrid Laser and Pulsed-Light System

F. Urdiales, M.D. and C. Fajardo, M.D. Miramar Medical Institute, Malaga, Spain

ABSTRACT

The demand for light-based cosmetic therapy has increased over the past decade, along with clinical experience in evaluating the impact of light/tissue interaction. In our analysis we have compiled several axioms, including the limitation of single application wavelengths. In an attempt to develop new applications from single wavelength devices, manufacturers and users have adapted complex pulsing and multiple “low energy” passes to impact secondary targets while sparing surrounding structures. The end result was a less predictable outcome for the patient. The increased competition of the secondary market purchasers (who benefit from the experience of their peers as well as the ability to invest in newer technology) has created a demand on manufacturers for systems that are upgradeable. We have been using a multi-application product, the Harmony system, which has the ability to treat multiple levels/types of chromophores using separate or complimenting wavelengths, and provides significantly better and safer results. This report demonstrates the value of a new laser and light-based technology system which allows the user to add any of seven separate technologies. The treatments were performed using the Harmony™ system (Alma Lasers, Inc) through a variety of treatment heads that interchange with a single platform. The technology provides: Advanced Fluorescence Technology (AFT 420-980nm), Lasers (Q-Switched 532nm, Long-pulsed 1064nm, 1320nm and 2940nm ablative technology), UV, and Near Infrared. Our experience with the Harmony confirms that, in our hands, it is more effective than systems which provide only one technology and it has yielded a greater return on our investment. Our office now utilizes combined technologies based on 4 therapeutic categories: (i) Monotherapy (single handpiece - AFT or laser); (ii) Combined Therapy - the use of two or more different handpieces powered by different technologies (AFT and laser) interchangeably and progressively to treat a given skin irregularity (iii) Bimodal Therapy - the use of two handpieces powered by the same technology (AFT or laser) interchangeably and progressively to treat a given skin irregularity; and (iv) Light-activated Drug Therapy - the use of a light-based therapy along with aminolevulinic acid. Our office has found the Harmony to be our platform of choice, providing the greatest safety, efficacy and cost basis, with a significantly rapid return on our investment.

INTRODUCTION

Over the past decade, the aging population has been looking for minimally invasive procedures to treat a variety of medical and aesthetic imperfections. The demand varies by age and gender with our female patients easily 3 to 1. Based on a “non-scientific” three week sampling of our patient base, the average “non-surgical” requests are lentigines, sun damage dyschromia 32%, facial telangiectasia 27%, the treatment of wrinkles 22.5%, acne control 18%, other 5%, and a combination of indications 28%. This list was not divided into specific groupings, it simply reflected those indications most requested over a 3 week period. Most telling was the combination section where patients requested multiple cosmetic corrections.

Light-based therapy manufacturers have slowly recognized opportunity in patient demand, although

there has been an increase in multi-technology systems over the past 3 years. As the technology became safer, more effective and subsequently more widely used, the demand for technology with greater predictability and lower costs appears to lead the list of preferences. Multi-application systems have been introduced by some manufacturers to meet the demands of patients and the needs of practitioners to maximize results and the number of applications that can be treated by each platform.

We have referred to treatments at our office as “Combination Therapy”. These grouped applications create a better result for the patient and the practice. Since most applications require multiple treatments, the addition of grouped applications (along with the revenue they bring) is easier to recommend when the patient desires a full cosmetic change.

THE HYBRID EVOLUTION

While laser and light-based systems are widely considered to be the gold standard for the treatment of many cosmetic imperfections and medical indications, these systems also have their limitations. Warranty fees, disposables and consumables can create patient fees that quickly become cost prohibitive. Systems may have significant downtime (require high maintenance) precipitating higher than normal cancellations. If downtime occurs frequently, the provider may find that patients will turn elsewhere for treatment.

Our office was also concerned about technology obsolescence. How long could we maintain an edge on the market and our competition? Harmony utilizes 7 distinct technologies, each equivalent to or ahead of technology on the market today. For our office to be competitive, we needed to have the best return on our investment without compromising expected results and safety.

Combined therapies also includes the combination of Harmony with photodynamic therapy (ALA, 5-20% concentration) for the elimination of actinic keratosis, textural skin structure support, reduction of acne vulgaris and reduction of dyschromia and microvasculature. The results from combination therapy provide significant improvement in fewer treatments. Multiple systems require greater financial commitment as well as more office space. In every office, it is important to properly evaluate and select the right system based upon the goals of the practice. For our office, monotherapy systems would not work to meet the needs of our patients or the return on investment.

In our experience in the field of combined therapy, the Harmony is the world's first multi-application non-ablative and ablative system that incorporates laser, UV, Near Infrared, and proprietary AFT (Advanced Fluorescence Technology) pulsed-light source technologies all on a single platform. Harmony demonstrates the broadest range of treatment possibilities inherent in any single platform currently on the market (see Fig.1). Its ten interchangeable handpieces provide over 60 clinical indications – far more than any other system we reviewed. Each handpiece can be added or removed from the system in a simple “connect and go” procedure. The system automatically identifies and configures the software to match the handpiece in use, eliminating the possibility of human error. The various handpieces were comfortable to use and to connect to the system's console via a 3 meter umbilical connector. The pulse widths and repetition rates are preprogrammed according to the module's intended application.

PHOTOBIOLOGY AND LIGHT-SKIN INTERACTION

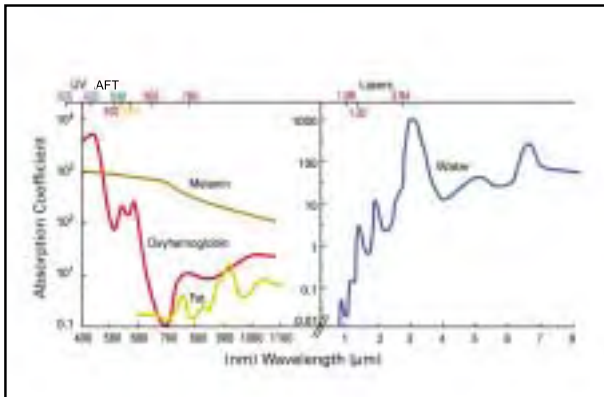
In order to skillfully use a single application system one must assume excellent diagnostic skills and a broad understanding of photobiology and light-skin interaction. This understanding is important for each of the application handpieces used with the Harmony system. The Harmony's spectral wavelengths for each application/handpiece and its endogenous chromophore are shown in Fig. 2.

Fig. 1: Harmony Technologies and Applications

| | Handpiece (wavelength) | Applications |
|--------|--------------------------------|--|
| AFT | AC 420-950 nm | Acne |
| | VP 540-950 nm | Vascular & Pigmented Lesions |
| | SR 570-950 nm | Skin Rejuvenation |
| | HR 650-950 nm | Hair Removal |
| NIR | Near Infrared | Deep Dermal Heating |
| UV | UV 300-380 nm | Psoriasis & Vitiligo |
| LASERS | LP 1064nm Nd:YAG Laser | Enlarged and Deep Leg Veins; Fine Wrinkles |
| | QSW 1064/532nm Nd:YAG Laser | Dark / Light Ink Tattoos; Pigmented Lesions |
| | LP 1320nm Nd:YAG Laser | Wrinkles, Acne Scars |
| | Er:YAG 2940nm Laser | Skin Resurfacing |

AC=acne; AFT=Advanced Fluorescence Technology; Er:YAG=Erbium Yttrium Aluminum Garnett; HR=hair removal; LP=long pulse; Nd:YAG=Neodinium Yttrium Aluminum Garnett; NIR=Near Infrared; QSW=quality switched; SR=skin rejuvenation; UV=ultra violet; VP=vascular pigmented.

Fig. 2: Absorption of Endogenous Chromophores



The wide spectrum of the Harmony visible light (420-950nm) and laser (532, 1064, 1320, 2940nm) handpieces allow treatment of non-ablative and superficial ablative cosmetic conditions. Use of the different handpieces should be matched with an understanding of the penetration of light or laser energy based on the scattering and absorption of the epidermis and dermis, as well as competitive chromophores for the selected wavelength. Melanin has a wide absorption spectrum, which slowly decreases from ultraviolet to near infrared wavelengths (300-1000nm). Melanin is particularly concentrated in the 10- μ m thick basal layer located typically 50-100 μ m below the skin surface. However, melanin absorption is also significant in the visible and near infrared wavelengths. Subsequent heat conduction to subjacent dermal collagen has been shown to participate in the desired remodeling for nonablative skin rejuvenation.

Hemoglobin and oxyhemoglobin strongly absorb light in the blue, green and yellow portion of the electromagnetic spectrum (400-600nm). There are relatively broad peaks at 410, 540, 570nm, with smaller peaks at 920-940nm. By taking advantage of longer wavelength hemoglobin absorption bands, where tissue penetration is increased and melanin absorption reduced, less heating of the epidermis should occur and more incident light energy is transmitted to dermal blood vessels.

Laser interaction depends largely on the optical properties of the skin, which are dynamic. In the near-mid infrared spectrum where water absorption is weak and relatively deep penetration is allowed, the epidermis and superficial dermis can be selectively damaged by two basic mechanisms:

- 1) Treating discrete chromophore in the dermis (melanin, oxyhemoglobin) or at the dermal-epidermal junction by using near infra-red lasers in the range of 1064 -1320nm.
- 2) Conversely, because of the very strong absorption band of water at 2940nm, it can be used for precise skin

ablation and remodeling.

Improvements in skin conditions (which resulted largely from sun damage, for example, erythema, telangiectasias, and pigmentary changes) can be achieved by targeting natural chromophores such as epidermal melanin and hemoglobin in blood vessels.

The spectrum of clinical possibilities when using the Harmony platform can be classified into four major categories:

- **Monotherapy** = the use of a single handpiece (AFT or laser) to treat a given skin irregularity.
- **Combined Therapy** = the use of two or more different handpieces powered by different technologies (AFT and laser) interchangeably and progressively to treat a given skin irregularity (Type I & II photorejuvenation indications).
- **Bimodal Therapy** = the use of two handpieces powered by the same technology (AFT or laser) interchangeably and progressively to treat a given skin irregularity.
- **Light-activated Drug Therapy** = the use of a light-based therapy (AFT) along with topical agents (e.g. Levulan/Metvix) to treat indications, such as actinic keratosis and (off-label) acne and photo-aged skin (skin rejuvenation).

A partial spectrum of some of the possible combined therapy procedures using more than a single handpiece are shown in Fig. 3. While the majority of combined therapy procedures involve dual applications (whether combined or bimodal therapy), in certain cases optimal results can be achieved through the use of 3 different handpieces, such as in the case of acne scars and traumatic tattoo, i.e., facial reconstruction post-trauma.

Fig. 3: Combination Therapy

| | | | |
|--------------------|-----------------|-----------------|------------------|
| Hair Removal | AFT 650 | AFT 570 | |
| Pigmented Lesions | AFT 570 | QSW KTP 532 | |
| Tattoo | AFT 570 | Er: Yag 2940 | QSW Nd: Yag 1064 |
| Port Wine Stain | AFT 540 | LP Nd: Yag 1064 | |
| Acne Scars | AFT 570 | Er: Yag 2940 | LP Nd: Yag 1064 |
| Acne Vulgaris | AFT 420 | LP Nd: Yag 1320 | |
| Hypertrophic Scars | AFT 540 | LP Nd: Yag 1064 | |
| Photoaging | LP Nd: Yag 1064 | LP Nd: Yag 1320 | |
| Photodamage | AFT 540 | AFT 570 | |

IMPROVED RESULTS

Using the Harmony system, we have had success in treating varying degrees of severity within each indication. Among the examples for the benefits of combined therapy using the Harmony are the following typical cases:

Hair Removal

AFT handpieces (650-950nm; 570-950nm)

Skin Rejuvenation + Remodeling

AFT Handpiece (570-950nm), Lasers (1064nm, 1320nm, 2940nm)

Telangiectasias

AFT (540nm) + laser (LP Nd:YAG 1064nm)

Acne & Acne Scars:

AFT (420nm) + laser (1320nm)

Keloid

AFT (540-950nm) + laser (LP Nd:YAG 1064nm)

Traumatic Tattoo

Laser (QSW 1064nm) + AFT (570-950nm)

Combined therapy and the use of different handpieces in various procedures help refine the quality of the final results. It is important to initially treat (based on the lesion diagnosis, color, depth and location) superficial lesions using the shorter wavelength handpieces, and continue to deeper epidermal-dermal lesions using the near infrared laser. Perhaps the most popular of these procedures today is the combination of nonablative photorejuvenation treatment (pulsed light and laser). Using the full potential of the Harmony, photorejuvenation is not just skin rejuvenation and wrinkle reduction. We compliment the treatment with the removal of unwanted facial hair, acne and soften or eliminate acne scars. Pigmented and vascular lesions and other cosmetic and aesthetic imperfections can now be treated easily and effectively, resulting in higher patient satisfaction. Examples of the various results achieved through combined therapy with the Harmony system are shown in Fig 4a - 4d.



Fig. 4a: Laser LP 1064nm Nd:YAG + AFT 540nm handpieces

Today, combined therapy modalities and procedures are being researched by numerous equipment providers and practitioners. Preliminary and ongoing clinical trials show improved outcomes in many cases vs.

monotherapy, both in safety and efficacy. As the results of these studies become available, a surge in the popularity of combined therapy is expected, with more practitioners offering combination treatments and increased consumer demand for such services.



Fig. 4b: AFT 540 + 570nm handpieces



Fig. 4c: AFT 540 + 570nm handpieces



Fig. 4d: Laser LP Nd:YAG 1064nm + AFT 540nm handpieces

SUMMARY

Based upon our experience, it is clear that combined therapy can produce results that surpass any single treatment modality in most cases. Combined therapy, whether relying solely on a combination of light-based devices or a synergetic combination of light-based therapy and the use of topical agents, is proving to be effective for an expanding list of clinical indications. The Harmony platform (Alma Lasers) offers the broadest range of laser and light-based technology available on a single platform and unique system features that reduce the potential for risks or complications. The system's hardware and software are user friendly and the learning curve is similar to that required for monotherapy experience.

Alma Lasers™
Wellbeing Through Technology

United States

6555 NW 9th Avenue
Suite 303
Fort Lauderdale, FL 33309
Tel: (954) 229-2240
Fax: (954) 229-8310

Headquarters

7 Haeshel St. P.O.B 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: +972-4-627-5357
Fax: +972-4-627-5368

www.almalasers.com Email: Info@almalasers.com