

Clinical Trials Confirm LightSheer Duet as Game Changer in Hair Removal

By Kevin A. Wilson, Contributing Editor

Lumenis, Ltd. (Yokneam, Israel) reasserted its leadership in the aesthetic market with the release of the versatile LightSheer Duet platform for laser hair removal. Featuring two handpieces, the smaller spot size ET delivers higher fluences with contact cooling and the larger spot size HS (high speed) provides lower fluences with vacuum-assist. The

ability to perform single pass treatments and no need for external cooling make laser hair removal with LightSheer Duet easier on clinicians, as well as patients. Furthermore, the HS handpiece's safety, efficacy and treatment speed have been supported by recent clinical trials.



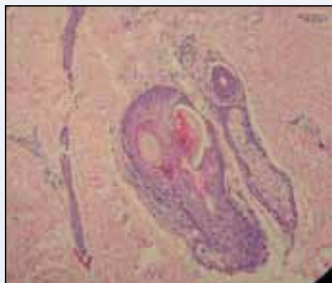
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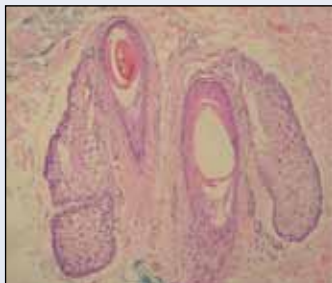
Built around the popular and effective 800 nm diode laser, the original LightSheer has arguably been the gold standard in laser hair removal, noted dermatologist Shlomit Halachmi, M.D., Ph.D., of the Rabin Medical Center (Petach Tikva, Israel). “The fact that new technologies often choose LightSheer as the basis for comparison emphasizes that it’s such a trusted and popular device.”



Shlomit Halachmi, M.D., Ph.D.
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Hair follicle treated with sapphire-cooled (ET) handpiece showing significant thermal damage



Hair follicle treated with vacuum-assisted (HS) handpiece, showing significant thermal damage
Photos courtesy of E. Victor Ross, M.D.



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The platform itself, according to E. Victor Ross, M.D., director of the laser and cosmetic dermatology unit at Scripps Clinic in San Diego, Calif., has always been very user-friendly. “The interface is very intuitive and the device guides you through treatment, so the learning curve is very shallow.” LightSheer Duet also runs on a standard power outlet for hassle-free installation and use.

“Harnessing the principle of selective photothermolysis for hair removal is very effective,” Dr. Halachmi stated, “but it can be somewhat difficult for patients to tolerate due to long treatment times, and some discomfort. There is also an inherent risk in some treatments because higher fluences translate into greater discomfort and an increased risk of adverse events. Laser manufacturers have begun to address this problem by developing creative technologies that deliver the laser energy in different ways, so that the hair follicle absorbs a therapeutic level of energy but the temperature of the epidermis remains low and safe.”

While the LightSheer Duet ET handpiece provides the traditional laser hair removal modality in a small 9 mm x 9 mm spot size, with higher fluences (10 – 100 J/cm²), the HS handpiece offers lower fluences (4.5 to 12 J/cm²), but a much larger 22 mm x 35 mm spot size which is the largest of any currently-available hair removal diode laser. This makes hair removal with LightSheer Duet a faster, more comfortable procedure, which is more attractive to patients. “This significantly larger spot, among other things, is what makes the HS handpiece stand out,” said Dr. Ross. “This translates into a reduction in treatment time of up to 75%, which has numerous, obvious benefits as long as the safety and efficacy are there.”

Dr. Halachmi also pointed out that the vacuum-assist technology incorporated into the HS handpiece brings with it additional benefits, led by one in particular: “by inducing pressure at the periphery of the treatment area at each pulse, pain is further reduced via neural gating. This makes treatment even more comfortable.”

In addition to laser hair removal, LightSheer Duet ET is also FDA cleared for the treatment of benign vascular lesions and leg veins, pseudofolliculitis barbae (PFB) and benign pigmented lesions.

Editor’s Note: In the following clinical roundtable, five dermatologists share their knowledge, clinical expertise and experience with LightSheer Duet ET and HS. Collectively they bring decades of clinical and research experience with laser hair removal.

“There are three major characteristics differentiating the HS handpiece from everything else. The first is the spot size. Second is the vacuum-assist. Thirdly, the gold plating inside the handpiece increases the efficiency of energy delivery.”

What distinguishes the new HS handpiece from the ET handpiece, and competing technologies in general? What do you think is the most significant benefit, and why?

Dr. Ross – There are three major characteristics differentiating the HS handpiece from everything else. The first is the spot size, which is significantly larger. This allows for a much faster treatment. Second is the vacuum-assist, which draws tissue up into the treatment tip before the laser is fired. This theoretically reduces the concentration of competing chromophores such as epidermal melanin and hemoglobin, but also reduces treatment pain, so there’s no need for topical anesthetic or epidermal cooling. Thirdly, the gold plating inside the handpiece increases the efficiency of energy delivery.

Omar A. Ibrahim, M.D., Ph.D. – The limitations of currently available hair removal devices include small treatment spot size, treatment-associated pain, and the need for epidermal cooling. In my opinion, the HS handpiece is a game changer in laser hair removal treatments for a few reasons. It has the largest spot size of any commercially available hair removal laser so treatments of larger body areas, such as the back or legs, can be performed more rapidly, which may lead to improved affordability. Also, the science behind the HS handpiece allows for successful treatment at a lower fluence, thereby conferring hair removal efficacy similar to that of other lasers, but with much lower levels of discomfort during treatment.



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Girish Munavalli, M.D. – The spot size of the HS handpiece and subsequent increase in treatment speed make it ideal for the larger areas of the body like the back or legs. These areas take forever with smaller handpieces, but with the HS it takes practically no time at all. Plus, the fluence is so low and it’s so well tolerated that you don’t need



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topical anesthesia or similar pre-treatment protocols which would increase the overall treatment time. The ET is still great for smaller areas such as the chin; it’s perfectly fine with the active sapphire cooling, and the pulse width is adjustable so you can modulate the energy delivery as well, making the platform very ver-

satile. You can easily switch between the two handpieces, simply by putting one back and taking the other one out. The device knows which one you’re using and changes the user interface automatically, so the time it takes to switch is minimal.

Dr. Halachmi – Although traditional laser hair removal is effective and generally well tolerated, there are three aspects which can be improved: treatment speed, discomfort and risk of adverse events. The large spot size of the HS handpiece has significant advantages in all three areas. First and most simply, you can cover more area more quickly with a larger spot size. Secondly, the larger spot size allows better penetration of the laser energy – meaning that less energy needs to be applied at the surface to achieve therapeutic heating at the depth of the hair follicles. Lower fluence at the epidermis translates into less pain and lower risk of adverse events.



LightSheer Duet ET handpiece



LightSheer Duet HS handpiece
Photos courtesy of E. Victor Ross, M.D.

“The 800 nm diode laser is well-absorbed by melanin, and it will penetrate to the hair bulb, but the epidermis is still largely spared; those qualities are essential to effective hair removal treatment.”

Caucasian, skin type: IV, brown hair
 Fluence: 11 J/cm²
 Pulse time: 50 – 100 ms
 Vacuum: Medium



Axilla before Tx, baseline



Axilla six months after three LightSheer Duet HS treatments



Axilla 15 months after three LightSheer Duet HS treatments
 Photos courtesy of Suzanne L. Kilmer, M.D.

Are there other devices that use the same basic reduced-fluence principle?

Dr. Halachmi – For reduced discomfort, one competing device is designed to heat the deep follicles effectively while reducing epidermal heating, but it does so from a different approach. The handpiece is moved repeatedly and quickly over the treatment area to allow slow heat build-up in the follicles, while the epidermis cools between the repeated passes. For improved treatment speed, a different device scans laser light over a large area. In comparison, the HS handpiece addresses both treatment speed and comfort for patients and clinicians with its larger spot and vacuum-assist technology.

What is the benefit of having the ET handpiece on the device as well?

Dr. Halachmi – Certain areas will require a small tip, while others are suitable for the larger spot, so it’s convenient to have both the small spot ET and the large spot HS handpieces attached to the same platform. We switch on the fly between the large and the small tips, simply by lifting one or the other from its holster when needed.

What determines whether you choose the ET or HS handpiece for treatment?

Suzanne L. Kilmer, M.D. – For a larger area, or one that’s more sensitive and large enough to accommodate the spot size, the HS handpiece would be the way to go because of the speed and relative comfort. The ET handpiece would be better for smaller or curved areas where the HS handpiece is not suitable for use.



Suzanne L. Kilmer, M.D.
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What is the function of the gold plating inside the HS handpiece?

Dr. Ross – During laser hair removal with an 800 nm diode laser, 50% to 60% of the energy is simply remitted off the skin. The gold plating inside the vacuum tip reflects many remitted photons back to the skin, optimizing the use of the energies employed for low-fluence hair reduction.

Is there any special quality to the 800 nm wavelength that makes it ideal for hair reduction?

Dr. Kilmer – The 800 nm diode laser has a relatively established history of efficacy for long-term hair reduction. As a community we have so much experience with this wavelength that there are relatively few unknowns at this point. The wavelength is well-absorbed by melanin, and it will penetrate to the hair bulb, but the epidermis is still largely spared; those qualities are essential to effective hair removal treatment.

What are the benefits of vacuum-assist technology?

Dr. Halachmi – There is a recession in the tip, into which the skin is drawn by vacuum. This theoretically and temporarily reduces the density of competing melanin and hemoglobin, which theoretically reduces the loss of laser energy to competing chromophores, but the benefit of that is minimal compared to what the larger spot size does to facilitate ease of treatment. The best benefit of the vacuum-assist technology is the reduction of

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pain by the neural gate theory; the suction sensation triggers the large sensory nerve fibers before the application of energy which inhibits the transmission of pain signals to the brain. The patient feels the vacuum pressure rather than the laser pulse.

[What is the role of compliance in hair removal treatment? How does LightSheer Duet help improve compliance?](#)

Dr. Ibrahim – Compliance is critical to achieving long-term hair reduction with any laser treatment. Even the best hair removal lasers require a series of five to ten treatments or more for near-total hair reduction. Often patients will also need occasional maintenance treatments thereafter. The vacuum-assist technology and larger spot size of the HS handpiece facilitate energy delivery allowing for lower levels of treatment discomfort. This makes it much easier for patients to tolerate treatment, in comparison to other hair removal lasers, so patients are more willing to adhere to a full treatment course and thus achieve the desired clinical outcomes.

Dr. Munavalli – It's accepted that patients will need quite a few treatments to achieve the clearance they expect, and that hair removal treatment is uncomfortable. If patients come in and struggle to tolerate treatment after a few tries, you simply won't see them again, and they will undoubtedly be unhappy with the experience. This is understandable, but we want to avoid this if at all possible because our success rides on patient satisfaction and confidence in us. With the HS handpiece this issue is all but eliminated because treatment discomfort and treatment time are dramatically reduced. If it doesn't take too long and doesn't hurt much, patients are much more likely to get what they came for.

[Please describe your recent clinical trials with the HS handpiece.](#)

Dr. Halachmi – We conducted a side-by-side comparison study of the LightSheer Duet HS handpiece versus the traditional ET handpiece for axillary hair removal in 14 healthy women aged 18 to 59. Once per month, all participants underwent ET treatments on one side and HS on the other, using parameters that were matched to their skin type and hair. We performed a course of five treatments in this pilot study. Follow-up was conducted one and three months after the fifth treatment. Evaluations were conducted by photography, as well as participant feedback. Of the 14 participants, 11 completed the study; three left for reasons unrelated to treatment. All 11 subjects who completed the study experienced comparable hair reduction on both sides. When we compared the ET and HS sides after five treatments and three months follow-up, we saw no discernable difference between the ET and HS treated sites.

We saw significant hair reduction after five treatments. For complete hair reduction in the axilla, about twice the numbers of treatments is needed in my experience. The study participants were offered to continue the treatments outside of the study, at their own cost. Nine of the eleven indicated that they would like to continue treatment using the HS handpiece.

Dr. Munavalli – We did a remarkably similar informal trial independent of Dr. Halachmi's study, treating eight patients, using each handpiece on both sides – but not limiting ourselves to just one area – and compared efficacy. We had some long-term follow-up of up to nine months after five treatments. What we basically found was that

Asian, skin type: III, brown hair
Fluence: 11 J/cm²
60 ms
Vacuum: Medium



Axilla before Tx, baseline



Axilla six months after three LightSheer Duet HS treatments



Axilla 15 months after three LightSheer Duet HS treatments
Photos courtesy of Suzanne L. Kilmer, M.D.

“Compared to other commercially available long-pulsed diode devices, treatments may be faster to perform and less likely to be painful.”

Caucasian, skin type IV, brown hair
 Fluence: 9 – 10 J/cm²
 Pulse time: 47 – 100 ms
 Vacuum: Medium



Axilla before Tx, baseline



Axilla six months after three LightSheer Duet HS treatments



Axilla 15 months after three LightSheer Duet HS treatments
 Photos courtesy of Suzanne L. Kilmer, M.D.

efficacy between the ET and HS handpieces was very similar, but in terms of treatment speed and comfort, the HS handpiece was dramatically superior. This suggests that the HS handpiece has tremendous potential for success in the hair removal arena.

Dr. Ibrahim – In the prospective study we conducted, which is currently under peer-review for future publication, we sought to evaluate the long-term hair reduction capabilities of the LightSheer Duet HS handpiece. We enrolled 35 subjects (all women, predominantly Caucasian with some Asian and Hispanic, skin types II to IV) and treated their axillae with the HS handpiece for three treatments at intervals of four to six weeks, with follow-up visits at six and 15 months after the last treatment. Clearance was quantified using hair counts, with assessments performed by three different physicians independently, using photographs taken at baseline, at six month follow-up, and at 15 month follow-up.

Evaluation of the results showed statistically significant hair clearance, 54% and 42% at 6 and 15 month follow-up visits, respectively. For remaining hair, there was a mean decrease in thickness of 19% and a mean lightening of color by 10% at the 15 month follow-up visit compared to baseline. The majority of subjects reported feeling no more than mild-to-moderate pain during treatment without the use of pre-treatment anesthesia or skin cooling. Note that these numbers are after three treatments, and in a normal course one might perform five to ten treatments.

From the results we concluded that the LightSheer Duet HS handpiece is safe and effective for long-term hair removal. Compared to other commercially available long-pulsed diode devices, treatments may be faster to perform and less likely to be painful. This is the largest prospective study to evaluate long-term hair removal and the first to quantify decreases in hair thickness and darkness with treatment.

Dr. Kilmer – Another point Dr. Ibrahim and I would like to make about our study is that the hair count data, good as it is, understates the impact of the actual clinical result. While the more objective evaluation criteria of the study involved hard counts of individual hairs before and after the course of treatment, the true clinical outcome includes thinning and lightening of hair in the treatment area, which is admittedly more subjective but might better represent what one actually sees. When counting hairs, every one counts, whether it's fine and light or not. Even so, the hair count data for the study was very strong.

Dr. Ross – In our study¹, we treated five patients (male, skin types I to IV with relatively thick black hair) with three single pulse test spots on the right back with the lower fluence HS handpiece (10 – 12 J/cm², 61 ms pulse duration), and three single-pulse test spots on the left back with the higher fluence ET handpiece (30 – 34 J/cm², 14 – 16 ms pulse duration). Parameters with the ET handpiece were determined by patient pain tolerance and epidermal tolerance; this wasn't an issue with the HS handpiece. After treatment, punch biopsies were performed on each treatment area, sectioned transversely, as well as horizontally, and examined for thermal damage to the hair follicle. We chose to do this on males because the back is the area large enough to easily accommodate our test, and because any scarring from the punch biopsies would be less conspicuous.

We saw thermal damage in all sites tested. Overall, thermal damage with the ET handpiece was more severe, maybe 20% to 30% greater versus the HS handpiece. That makes sense because we used three times the fluence, but it's notable that we

“From a personal perspective, as a dermatologist and a person with skin of color, I’d like to see further study using the LightSheer Duet HS handpiece for darker skin types so that we might better establish and then optimize parameters.”

didn’t see three times the difference in damage. It didn’t scale as one might think at first, not even close. The actual difference in thermal damage was fairly subtle.

This study showed that even with relatively low fluence, one can achieve thermal damage sufficient enough to damage the follicle, possibly permanently. Specific to the HS handpiece, when you take the fluence alone and ignore the remitted-then-reflected photons (gold plating), large spot size and vacuum-assist, intuitively one would conclude that there shouldn’t be much therapeutic effect on hair follicles. Upon study, we believe it’s fair to conclude that these elements appear to contribute to the increased thermal damage seen.

[Ideally, where would you like to go next with clinical study of LightSheer Duet?](#)

Dr. Ross – It would be great to see a nice, large, side-by-side study between the low fluence larger spot and the high fluence smaller spot, followed at 3, 6, 12 and 18 months out with hair counts. This would be an expensive and time consuming undertaking, which is why we probably won’t see it. The time and expense that comes with hair removal studies are common prohibitive factors. You need to do so many treatments, and patients – as well as the staff and physicians involved – must be willing to go through this. Most physicians and companies aren’t willing to do that for hair removal; maybe for a heart disease or cancer study, but not something like hair removal.

Dr. Ibrahim – In theory, the various features of the HS handpiece might make it better able to treat darker skin types. From a personal perspective, as a dermatologist and a person with skin of color, I’d like to see further study using the LightSheer Duet HS handpiece for darker skin types so that we might better establish and then optimize parameters.

[Do the features of the HS handpiece make it more suitable for treating darker skin types?](#)

Dr. Munavalli – The vacuum-assist technology with the HS handpiece artificially reduces the melanin concentration of the skin without affecting the hairs themselves, so theoretically this may improve treatment, but it’s difficult to pin that down. We have treated many darker skinned patients and they respond fairly well. You do have to be careful. There are tricks you can do like pre-cooling the skin. When considering patients with skin of color, the quality of the hair is a key factor in decision making. It’s important that patients with darker skin tones, who want to undergo laser hair removal, have dark, coarse hair at the treatment site.

[Do the features of the HS handpiece make it more suitable for treating men?](#)

Dr. Halachmi – The HS handpiece is excellent for men because it can cover a large area, like the back or chest, very quickly. We are cautious about choosing male candidates for chest and back treatment. Good candidates are those who have very dark and very coarse hair. Men with fine hair or light hair will not respond well to any laser hair removal treatment.



Lower abdomen before Tx, baseline



Lower abdomen six months after five LightSheer Duet HS treatments

Photos courtesy of Girish Munavalli, M.D., M.H.S., F.A.A.D.

“The safety of this device is well established. LightSheer has been around for so long, and the 800 nm wavelength is well known and has been thoroughly studied. It’s pretty much the gold standard for laser hair removal. Current studies are offering strong evidence that the new HS handpiece is a significant improvement over its predecessors.”

What are the business advantages of a faster, more comfortable treatment if safety and efficacy are equal?



Axilla before Tx, baseline



Axilla nine months after five LightSheer Duet HS treatments

Photos courtesy of Girish Munavalli, M.D., M.H.S., F.A.A.D.

Dr. Munavalli – The obvious benefit is the speed allowing you to successfully treat more patients in less time, with reduced pain increasing compliance, as well as the likelihood that patients will undergo the entire course of therapy and be satisfied with their results. If your competition cannot offer this then you have a competitive advantage, because patients historically want the best results with the least discomfort and hassle.

Dr. Halachmi – The major advantage is the reduced treatment time. This allows scheduling of more procedures in the same work hours, which increases revenue potential. An additional benefit is that no topical anesthetic is needed and no cooling gel need be applied to the treatment area, further reducing prep time and increasing the efficiency of the scheduling.

Dr. Ross – The HS handpiece is also easier on the user. The larger spot treats more rapidly in a single pass, and when you have larger areas you just want to cover a lot of ground fast. Treatment with older technologies takes longer; the patient gets tired and so does the clinician. Over the course of a day it builds up.

Would you like to share any treatment tips or final thoughts?

Dr. Ibrahim – The majority of patients in my experience prefer the vacuum-assist on the medium setting, to help minimize the level of treatment-associated discomfort. I also recommend that one always perform a thorough medical history, physical exam and have an honest discussion of the risks and benefits with any type of laser hair removal treatment in order to educate patients and optimize their experience.

Dr. Munavalli – The safety of this device is well established. LightSheer has been around for so long, and the 800 nm wavelength is well known and has been thoroughly studied. In terms of efficacy, that’s been proven over the years as well. It’s pretty much the gold standard for laser hair removal. Current studies are offering strong evidence that the new HS handpiece is a significant improvement over its predecessors. ■

Reference:

1. Xia Y, Moore M, Cho S, Ross EV. Evaluation of the vacuum-assisted handpiece compared with the sapphire-cooled handpiece of the 800-nm diode laser system for the use of hair removal and reduction. *J Cosmet Laser Ther* 2010 Dec; 12(6):264-268.