Raydiance Report

Smart Light Applications in the Therapeutic Market

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Background

With a few notable exceptions, the use of lasers in surgical or other therapeutic applications has yet to reach its full potential. Clearly ophthalmic surgery, laser-enabled dermatological procedures, and a number of imaging techniques have provided significant patient benefit as well as dynamic commercial opportunities. And while the day of photons routinely displacing scalpels may still be before us, it would seem all but imminent.

There is a rapidly increasing demand for less invasive procedures, a growing reliance on and integration of software and real-time analysis in the operating room, and a premium put on precisely targeted therapies, whether chemical, radiological, or surgical. And as the scale of treatment moves from the macro to the micro, it seems evident that mechanical devices will be inadequate. The ability to operate with micron resolution—literally cell by cell—autonomously if desired, and without introducing heat to the target area is what will drive medical innovation in the coming years.

Raydiance's Smart Light™ platform is a commercial-grade ultrafast fiber laser that enables athermal ablation of virtually any material. To date Raydiance has deployed Smart Light in the high-value, medical device market. There is, however, no higher value venue than the human body. And the opportunities to advance the medical field with this enabling technology are varied and could have profound implications for the health care industry.

State of the Market

While there are certainly laser-based surgical procedures in which heat can play a beneficial role, the bulk of the potential for laser surgery lies with the ability to ablate extremely precise volumes without introducing heat damage to cells nearby. And true athermal ablation necessitates deploying lasers with pulses in the femtosecond regime. While technically feasible, this has traditionally been a very unreliable and commercially impractical technology. Perhaps the most notable commercial success story is that of the IntraLase™ flap cutting procedure for LASIK, a femtosecond pulse system that, years after introduction, is still difficult to both scale and keep in service. It has traditionally been the Achilles heel of the technology.

Raydiance's Efforts in the Therapeutic Market

Raydiance has brought to the table for the first time ultrafast technology that is reliable, practical and broadly deployable in venues ranging from manufacturing floors to surgical suites. Second, it has embedded software and computer control at every level of the laser operation, a fact that enables ready integration with external applications programs that can interact with the laser, or even facilitate the use of real-time feedback loops with techniques such as laser induced breakdown spectroscopy (LIBS). Researchers at New Mexico State University have demonstrated the ability to collect LIBS with the Raydiance platform, and there is every reason to believe this could be coupled with an "ablative mode" in real time.

Similarly, Adela Ben-Yakar's group at U.T. Austin is deploying the Raydiance system in an endoscope to both image with two-photon fluorescence and ablate tissue for potential laryngeal surgical applications. Other work has been done at U.T., Southwestern in burn debridement, and at the Musculoskeletal Transplant Foundation and Rutgers to advance tissue harvesting and decontamination.

Raydiance itself has done some in-house surgical proofs of concept with a variety of tissues, both hard and soft. Some of the salient work concerns corneal flap cutting at 1.5 µm, thought not possible by some—pig aortic tissue, pig skin, calf liver, human skin and tooth enamel. Some representative images are shown below.

A last critical piece of the therapeutic market is fiber delivery: the beam has to be brought to the patient if the technology is to have broad surgical application. The difficulty has been that ultrafast lasers—the only technology capable of athermal ablation—generate extremely high peak power and, consequently, ablate the conventional optical fibers meant to transport the beam. Despite this technical challenge, Raydiance has secured a strong intellectual property position on delivering femtosecond pulses on target. The company is in the process of developing and demonstrating its approach to fiber delivery.

Presented below is a brief sampling of therapeutic applications work we have done in our Petaluma, California labs.

Soft Tissue – Pig Skin

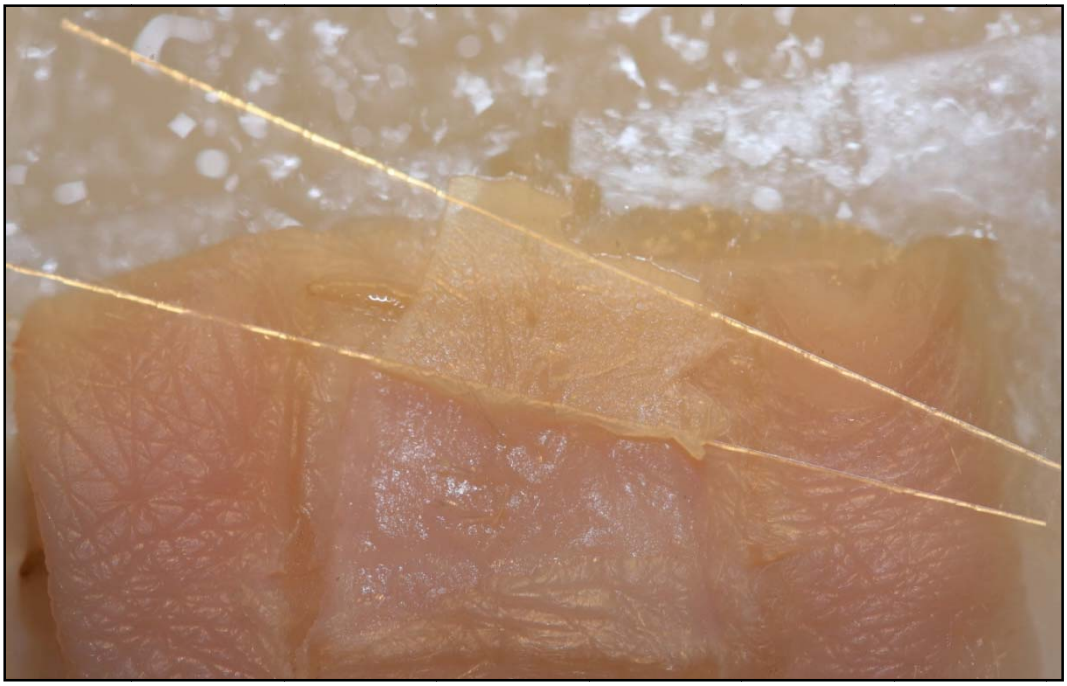

Figure 1: *Sub-surface ablation with Raydiance Smart Light created this 80 micron flap.*

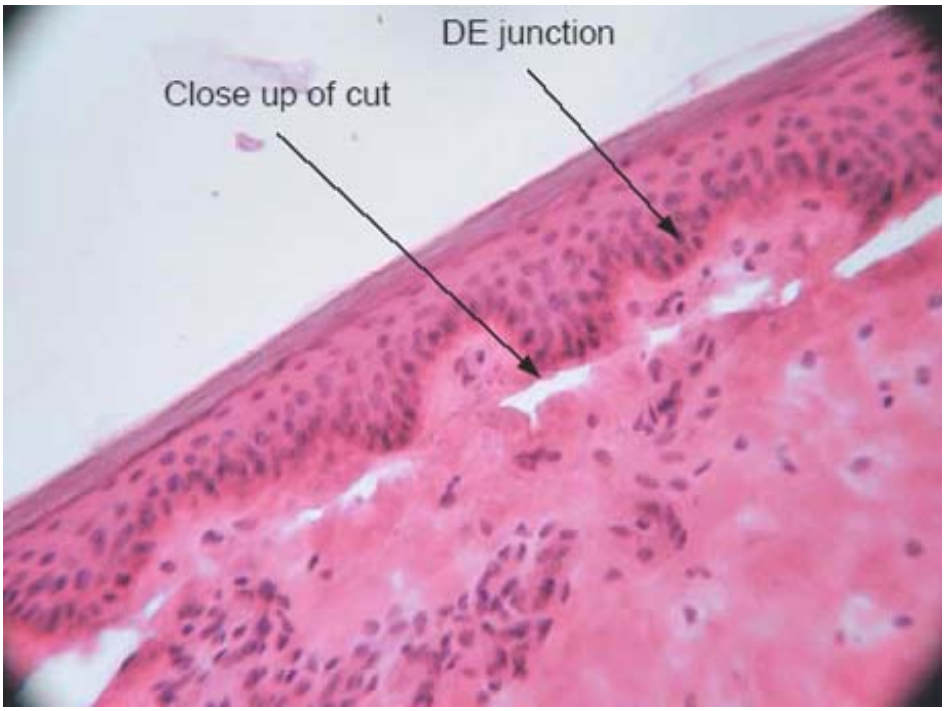

Figure 2: *Side view of a 100 µm flap cut in pig skin. The sample was ablated, mounted, stained then photographed.*

Soft Tissue – Pig Aortic Tissue

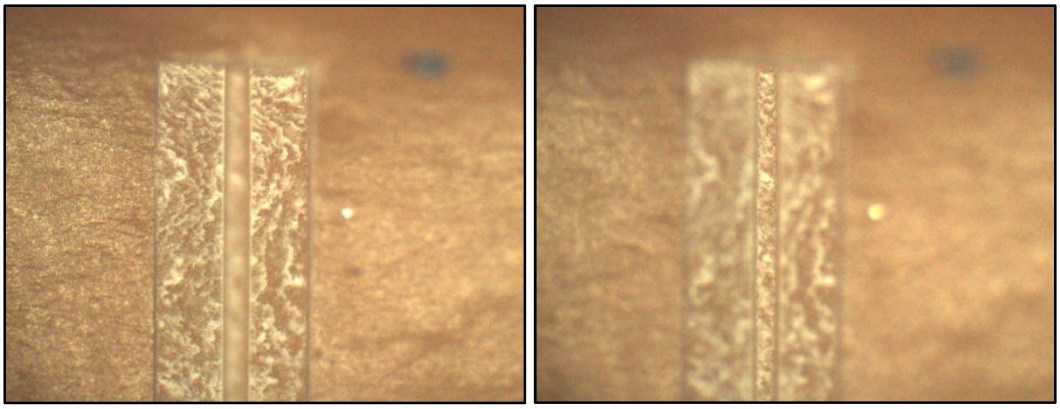

Figure 2: *Pictured here are two channels ablated in pig aortic valve tissue. The first channel is approximately 500 µm wide and 250 µm deep. The second channel, centered over the first is approximately 50 µm wide and 50 µm deeper. The picture on the left is focused at the surface showing the edge quality of the cut. The picture on the right is focused to the bottom of the channel.*

Soft Tissue – Pig Cornea

Figure 3: *At left is a pig cornea as a flap for a simulated LASIK procedure is being created with the ultrafast beam (a harmonic of the beam can be seen (green color) at center left). The beam is cutting from right to left. At right is the finished flap, approximately 200 µm thick. The clarity of the flap indicates that there were no thermal effects of the ablation.*

Hard Tissue – Human Tooth

Figure 4: *Smart Light™ was used to machine a 1.5 mm x 5 mm trench approximately 1 mm deep in this human tooth. The feature cut through the enamel into the dentin without introducing cracking or thermal damage.*

LIBS of Aquamarine

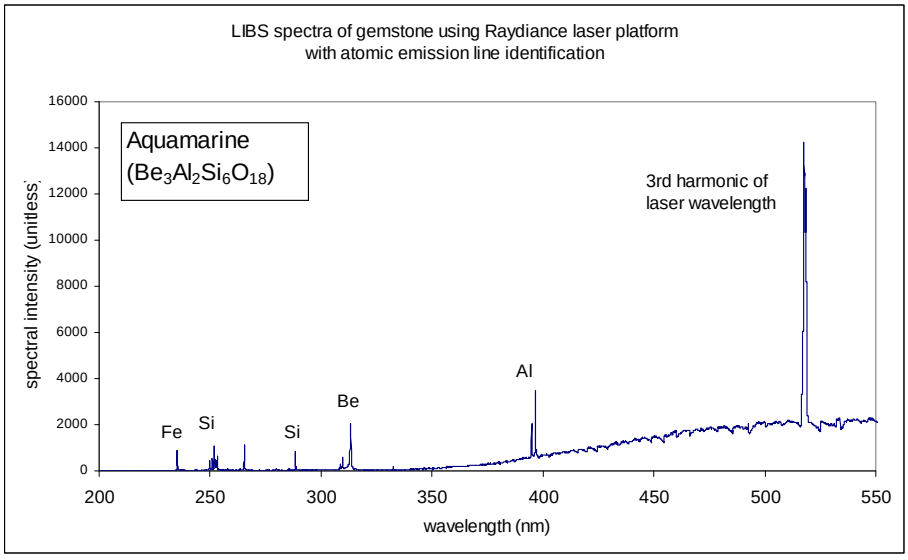

Figure 5: *Representative spectrum from evaluation of LIBS spectrometer with Raydiance ultrafast platform. Elemental assignments are consistent with aquamarine gemstone composition, with trace iron signature. The 3rd harmonic of the 1552 nm laser wavelength is a dominant feature of the spectrum, as is a common feature of surface ablations with ultrashort laser pulses.*

Summary

We have demonstrated here the ability to ablate both hard and soft tissue with no thermal effects. Though these are simple proof-of-concept experiments, the results signal the potential therapeutic applications of Raydiance ultrafast technology. This ablative capability packaged with integrated software control and operating system provides a powerful platform for potential automated surgical techniques, as well as real-time pathology analysis and feedback. The development of a fiber capable of delivering these high power pulses will greatly expand the capabilities of Smart Light.

About Raydiance

Raydiance is a next-generation laser company that has integrated photonic, computing and software technologies to create the world's first commercial-grade ultrafast laser. Raydiance's breakthrough technology brings "intelligent" control and small form factor to ultrafast laser light—extremely brief and powerful light pulses capable of precisely ablating virtually any material without generating heat.

The unique capabilities of ultrafast light have been demonstrated in research laboratories for years, however, the transformative potential of the technology has been held back by its size, complexity and expense. Raydiance has taken this compelling but commercially impractical technology and has liberated it from the lab. By miniaturizing ultrafast hardware and then imparting it with brains—an easy to use software operating system that controls every aspect of the laser—Raydiance offers the power of ultrafast as a practical and reliable platform technology.

Raydiance Smart Light MD™ is a "plug and play" device that operates on standard 90 - 230 VAC, occupies the footprint of a microwave oven, and is typically up and running out of the shipping crate in 30 minutes. With the Smart Light™ platform, Raydiance has taken the industry lead in defining the fundamental standards of commercial-grade ultrafast: performance, reliability, and integrated software design. Those standards make possible the deployment of Raydiance ultrafast in diverse commercial applications, including micro-medical devices, thin film photovoltaic cells, glass display technology, and microelectronics.

The central thrust of Raydiance's business plan is to take the industry lead in building volume commercialization of this transformative technology. By aggregating markets onto its platform, the company will use volume-manufacturing techniques to drive costs down, which, in turn, will open opportunities in additional markets.