

**EVIDENCE FOR THE LONG TERM SAFETY AND MEDICAL
EFFECTIVENESS OF THE XTRAC SYSTEM (EXCIMER LASER GENERATED
308-nm UVB RADIATION)**

A basic, and very important, question that must be answered about new medical services is the extent to which the results of clinical trials, often involving small numbers of patients, can consistently predict medical outcomes in the real world of medical practice. Patients, physicians and health plans also want assurances that the long-term use of a new therapy does not introduce new and unacceptable risks or complications.

In the case of the XTRAC System for the treatment of mild to moderate psoriasis, the answers can be found in three places: (1) the data from trials and clinical practice since the Excimer laser (308-nm UVB) was first applied to psoriasis in 1997; (2) the literature on the use of ultraviolet light (particularly UVB) to treat psoriasis developed over the last 70 years; and, (3) the studies published on the use of lasers in dermatology and other fields of medicine.

The XTRAC System is a marriage of two well established medical technologies (narrow band UVB light and the 308 nm Excimer laser) with a robust research history involving many patients; therefore, physicians, patients and health plans can have confidence in the effectiveness of the new treatment and its relative safety for patients with mild to moderate psoriasis.

THE EXCIMER LASER AND PSORIASIS

In 1997, Bonis et al first reported that the 308-nm XeCl Excimer laser was useful in the treatment of psoriasis (attachment 1). They further reported that 8 of the 10 patients in the original study remained symptom free on the laser treated areas after two years (attachment 2). The findings of the 1997 study were confirmed by Anderson et al in 1999 and dosing levels were refined (attachment 3). Unpublished data from other centers (data on file at PhotoMedex) affirms the effectiveness of the treatment (attachment 4).

Although the use of Excimer laser therapy for psoriasis dates only from 1997, it builds on the extensive literature about the use of ultraviolet light, especially UVB, to treat psoriasis. It was largely for this reason that the Food and Drug Administration approved the XTRAC System in January 2000 on the basis of the dose response study of 13 patients. (attachment 5 summarizes the clinical literature and was submitted to the FDA).

As the Bonis et al article makes clear, narrow band UVB phototherapy was already a well established treatment for psoriasis. The action spectrum for the phototherapy of psoriasis was known in 1981 and the wavelength of the laser is within the spectrum. The safety of this laser to treat other skin conditions was also well established by 1991 and initial

investigations of the use of lasers to treat psoriasis were reported in the literature as early as 1984.

ULTRAVIOLET LIGHT AND PSORIASIS

UVB phototherapy has an established role in the treat of psoriasis. The first experiments with phototherapy were carried out in the 1920's. There is a deep and well established understanding of the risks and benefits of this therapy (attachment 6).

LASERS AND DERMATOLOGY

Lasers have been in use in dermatology for more than 20 years and dermatologists have investigated the use of the laser for psoriasis at least since 1984. There has been a continuous improvement in the equipment. Dermatologists have greatly expanded the number of diseases and conditions that can be successfully treated with the technology. Psoriasis is the latest in a long history of medical progress using laser technologies (attachment 7).

CONCLUSION

Bonis et al knew that UVB phototherapy was a well established and widely used treatment for psoriasis. They also knew that the 308 nm XeCl excimer laser had long been used by dermatologists to treat skin tumors and tattoos and that the wavelength of the laser was within the action spectrum for the phototherapy of psoriasis. The relative safety of the laser in dermatological use was also established. These facts are all based on years of clinical studies involving thousands of patients. The hypothesis that the laser would effectively treat mild to moderate psoriasis was substantiated by the first cohort of 10 patients. Subsequent studies and the experience of dermatologists in their practices have confirmed that result.