

Thermage, A Non-surgical Facelift Procedure, May Have Long-lasting Complications That Are Not Easily Corrected, According To Advanced Facial Plastic Surgery Center.

For Immediate Release

DALLAS/EWORLDWIRE/Sep. 13, 2004 --- Dallas Facial Plastic Surgeon, Dr. Benjamin Bassichis, medical director of the Advanced Facial Plastic Surgery Center and Clinical Assistant Professor at University of Texas-Southwestern Medical Center, has received complaints from a number of patients across the country about the Thermage procedure, a radiofrequency treatment intended for facial rejuvenation. In particular, post-Thermage complications including scars, indentations and dimpling of the facial skin have been described by patients as being very devastating.

Published in April of 2004, Dr. Bassichis warned in his research that, "damage and loss of facial fat pads" was a possibility. Since that time, the Thermage website now states that, "a rare (0.2%) but longer lasting side effect described as a skin depression has also been reported."

The recent inquiries regarding the procedure prompted Dr. Bassichis to review the adverse events reported to the FDA from December 2002 through August 2004. During that time, 63 adverse events had been reported, including one death and 52 serious injuries. The majority of the serious events include skin scars, indentations, dimpling, and surface irregularities. Out of the 52 adverse events noted, 20 reported additional cosmetic procedures to correct complications from Thermage. An interesting fact found in the data from the FDA report is that Thermage had been notified about the adverse events and reported that the treatment devices were functioning normally. The opinion of Dr. Bassichis is that the serious complications resulting from the use of this device are not from a malfunctioning machine, but from a device that is causing a thermal injury deeper and more significant than intended.

Dr. Bassichis believes that an in-depth understanding of facial surface architecture can help explain why these problems are occurring. The surface of the skin is made of two layers, the superficial layer called the epidermis and the deeper layer called the dermis. Thermage is designed to treat the dermis, without damaging the epidermis. The next layer deep to the dermis is the subcutaneous fat layer. In some areas of the face, this layer is thick enough to form a fat pocket. These facial fat pockets and underlying subcutaneous fat are important for maintaining facial contours and youthful appearance. Loss of fat can result in denting or dimpling of the skin, giving patients a hollowed-out and aged look. After potential thermal damage to the facial fat layers by the Thermage procedure, the dermis can adhere to the connective tissue layer beneath the fat, called the superficial musculo-aponeurotic system, or SMAS. Adherence to the SMAS by the dermis is a very difficult problem to correct. Plastic surgeons who perform liposuction in the neck and face understand the dangers of overly aggressive fat removal leading to problematic scarring. Although there are dermal fillers that exist to temporarily correct slight skin dimpling, at this time there are no effective permanent fillers available for correction of indentation and dimpling.

The prospect of a non-surgical, no downtime option for facial rejuvenation is very appealing to patients. The potential financial reward for the treating physicians is also very appealing. However, Dr. Bassichis urges caution when undergoing treatments that cause severe consequences that may outweigh the benefits of the procedure. During the course of Dr. Bassichis' research with Thermage, the procedure only produced beneficial results in approximately one-third of patients.

Dr. Bassichis chooses not to use the Thermage device in his private practice, as the patient satisfaction rate was only 28% in the study published earlier this year. "Studies done by others have described patient satisfaction rates as high as 50%, which is about 40-45 percentage points lower than an acceptable level of patient satisfaction in my practice," states Dr. Bassichis. He goes on to conclude that, "emerging trends in cosmetic surgery are necessary, but they must be met with cautious enthusiasm until they are well documented to work predictably and effectively, with benefits that outweigh the risks. At this point, Thermage has failed to be predictable, failed to be effective in the majority of patients for a long period of time, and it has had complications that are proving to be long-lasting and devastating to those patients affected."

For more information about possible complications from Thermage, as well as options for correcting the defects, please contact the Advanced Facial Plastic Surgery Center.

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