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Considerations for the use of medical devices in dermatology

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Abstract

This manuscript addresses the significant considerations concerning the development and use of medical devices in dermatology. With the rapidly growing demand and booming market for medical devices, especially lasers, it is crucial that dermatologists become familiar with the nuances associated with supporting clinical studies, consumer-driven marketing strategies, and the complex relationships that exist between physicians, industry, and consumers. An examination of these relationships includes an overview of the potential biases pertaining to advisory panels and treating clinicians. The aim of this paper is to serve as an introduction to the background of medical devices and to offer dermatologists important information on what should be considered before recommending treatment.

Keywords: medical devices; lasers; dermatology; aesthetics; physician patient relationship

Over the past several decades, there has been an explosion of medical devices introduced to the world of aesthetics. Although they each have intended purposes, the research supporting their claims is of variable quality. They are generally marketed with an overly optimistic assurance of promise. Although the Food and Drug Administration (FDA) plays an important role in establishing safety, there is less of an emphasis on efficacy. Thus, physicians are often handed the obligation of evaluating these devices in their clinical practices with only limited evidence of quality science and proof of benefit. Clearly, this is not always the case, but it is not unusual that clinicians will elaborate on the relative benefits (or lack thereof)

of a particular device after having had extensive clinical experience. It is therefore important that laser surgeons examine manufacturers' supporting data, decipher their claims, and have a thorough understanding of any bias at play among key opinion leaders (physician investigator-industry relationship) in order to deliver high-quality, patient-centered, and cost-effective care.

The use of medical devices for specific indications would ideally be determined with the assistance of data from long-term, high-quality research studies. However, device manufacturers are generally small-cap companies without the deep pockets to perform extended multi-center studies that are characteristic of larger pharmaceutical corporations. Holding them to similar standards would endanger their tremendous ingenuity and agility. With the FDA's Section 510(k) route, companies can submit information to establish that their devices are 'substantially equivalent' to those that are currently marketed and subsequently receive clearance for use [1]. As a result, the laser surgeon is often left with some doubt as to whether or not to recommend treatments based on this less rigorous analysis. One such example would be the recently introduced robotic hair transplant system, which was cleared by the FDA through the 510(k) route. Although revolutionary and groundbreaking compared to former manual techniques, limited studies exist and few clinicians possess familiarity with the device. In situations like this, specialized experts should be called upon to fill the gap between the literature and clinical practice. Clinicians are encouraged to seek guidance from those who are more experienced before attempting to use any of the newer devices.

Manufacturers rely heavily on consumer-driven marketing strategies in an effort to up-sell the use of their medical products [2]. Moreover, the media quickly follows their marketing, which is generally ahead of the science. In the aesthetic realm, advertisements often provide illusions of painless, quick cures with the promise of ageless beauty. This can create unrealistic expectations, and in the event that these expectations are unmet, patients may be unsatisfied with their care. Patients may be extremely impressed with devices (and in particular with 'lasers') and ignore their potential risks, perceiving them to be technological miracles regardless of the specific end user [3]. One such example is the use of lasers for the treatment of onychomycosis. Although the marketing of these devices has suggested a rapid cure, this is quite contrary to its rather low efficacy and lengthy timeline needed to achieve clinical improvement. In such situations, it is important for clinicians to correct any misconceptions, inform patients of the available data, educate them on safety profiles, and offer realistic expectations for what can be achieved.

It is also important for us all to realize that bias is inherent. In this regard, there are three types of clinicians: 1) Those who are intimately associated with the development of a device, who are likely to be the best informed but also the most biased, 2) Those who are not involved in the development but possess a good understanding, who are less informed but also less biased, and 3) Those who are non-specialists lacking any familiarity, who are the least informed but also the least biased. Which category a clinician falls into may influence opinions and treatment recommendations. It is important that we include all three categories in our decision making.

Nevertheless, in an effort to reduce the negative effects of bias, disclosure of industry relationships is now required. The Sunshine Act, which was built into the Affordable Care Act, requires medical device manufacturers to disclose any financial exchanges with physicians and make this information available to the public [4]. Hailed as a groundbreaking undertaking, it was meant to promote transparency and empower patients. It has been speculated that overall physician payments have declined owing to the increased attention on marketing and payment

practices. Although no solid data exists to determine its full effects, it was recently shown that plastic surgery exhibited the lowest prevalence (54.5%) of industry financial relationships following the enactment of the Sunshine Act when compared to other surgical subspecialties (57.9-87.8%, [5]). Though this may give comfort to some, others might lament the restrictions placed on our more scientifically-inclined specialists as they are discouraged from performing much-needed clinical studies for fear of being labeled as mischievous by the public.

In this burgeoning market, dermatologists and plastic surgeons largely serve as gatekeepers between the medical device industry and consumers. Clinicians have professional, moral, and ethical obligations to deliver efficient, safe, and cost-effective care to patients. They deserve nothing less than a thorough analysis of any new device that comes to market. Those who are considered key opinion leaders and those who have investigated these devices must not deviate from objectivity when reporting the outcomes at our national meetings and in our specialty journals. An association with industry is to be encouraged, applauded, and appreciated, especially when the outcomes are modest and reported as such.

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