



AAD: Botox Cosmetic Long-Term Safety Data Unveiled

NEW YORK, NY -- July 29, 2004 -- The pioneers of Botox Cosmetic® (botulinum toxin type A) will present today the first-ever long-term safety data on Botox® for cosmetic use at the American Academy of Dermatology (AAD) Summer Meeting in New York City. The Canadian husband- and- wife team Jean Carruthers, M.D., and Alastair Carruthers, M.D., both from the University of British Columbia, are presenting a retrospective review of safety data compiled during more than 15 years of Botox® use for the treatment of facial lines, beginning with their discovery of cosmetic applications for Botox® in 1987. Data from this long-term study demonstrate that treatment with Botox® for facial aesthetic procedures is safe and well-tolerated when used for multiple treatment sessions over extended periods of time and when administered by a qualified and trained healthcare professional.

About the Study

The Carruthers' data found that in 853 treatment sessions with Botox® over time periods extending up to nine years, there were no adverse events in 99 percent of treatment sessions recorded. Further, no adverse events were rated as serious or severe and all adverse events were temporary. They included two cases of bruising, one case of injection discomfort and four cases of brow or eyelid ptosis (drooping). The risk of adverse events did not appear to increase with the number of treatments or to be related to the interval between treatments.

"Although we now have extensive clinical experience with the cosmetic use of Botox® and the procedure becomes more popular by the day, to our knowledge this is the first study to assess the safety of Botox® with long-term use in the aesthetic practice setting," explained Dr. Alastair Carruthers, Clinical Professor of Dermatology at the University of British Columbia.

The results of this retrospective analysis demonstrate that long-term treatment with Botox® for facial aesthetic procedures is safe and well-tolerated when used for multiple treatment sessions over time periods extending up to nine years.

The Carruthers' safety review was an independent retrospective chart review of 50 patients with a history of at least 10 treatment sessions with Botox® for cosmetic use. The median number of treatments per patient was 19 (range 10-30), the median cumulative dose was 690 units (range 244-1603) and the average duration of time between the first and last treatment was 5.95 years (range 2.82 - 8.99 years). The mean age of the patients was 42.8 years and 92 percent were female. Most subjects received treatment in multiple areas: 82 percent received treatment in two areas or more, and 68 percent received treatment in three areas or more. Of the 50 subjects, 49 were treated

for glabellar lines, 35 for crow's feet and 32 people for forehead lines. Botox® was the only botulinum toxin type A formulation used.

Husband-and-Wife Team Discover Leading Aesthetic Enhancement Treatment
Dr. Jean Carruthers, an ophthalmologist, and her husband Dr. Alastair Carruthers, a dermatologist, serendipitously discovered the cosmetic use of Botox® based on feedback from a patient with a rare eye disorder.

Dr. Jean Carruthers, Clinical Professor of Ophthalmology at the University of British Columbia, specialized in treating patients for blepharospasm, a rare, debilitating eye disorder that involves excessive blinking and can lead to functional blindness. "One of my blepharospasm patients who was successfully treated with Botox® requested ongoing treatment even though her symptoms were no longer present," said Dr. Jean Carruthers. "I asked her why and she told me that each time she received the injections the wrinkle between her brows seemed to disappear and she would have this relaxed, untroubled expression. Needless to say, I was eager to share this interesting cosmetic result with my husband."

"You can say it was over pillow talk that one of the world's most popular drugs was discovered," said Dr. Alastair Carruthers. "It was the response of Jean's blepharospasm patient coupled with the extensive ophthalmic data on the safety and efficacy of Botox® that convinced me that it could be used to enhance appearance."

As the story goes, Dr. Jean Carruthers had the drug, and Dr. Alastair Carruthers had the patients. Dr. Jean Carruthers said, "We are so pleased to be part of the history of this unique, versatile product that has literally changed the lives of millions of people with serious conditions such as blepharospasm, cervical dystonia and juvenile cerebral palsy, as well as those who have benefited from its cosmetic use." Dr. Alastair Carruthers added, "When we tried it, we never expected that Botox® would become the most sought after cosmetic procedure among women and men today. It is gratifying to know that this safe and effective medicine continues to make people look more natural, relaxed and feel better about themselves."

According to the American Society for Aesthetic Plastic Surgeons (ASAPS), Botox® Cosmetic was the number one non-surgical cosmetic procedure in the U.S. in 2003. Botox Cosmetic® is also the most common cosmetic procedure offered by physicians in Canada, according to a recent survey conducted by Medicard® and The Rotman School of Business, University of Toronto's MBA program.

About Botox®

Botox Cosmetic® was approved in 2001 for the treatment of glabellar lines (frown lines between the eyebrows). As a separate product, Botox® has also been approved in Canada for blepharospasm (1990), strabismus (1990), cervical dystonia (1995), juvenile cerebral palsy (1999), adult spasticity (2001), and hyperhidrosis or excessive sweating (2001).

SOURCE: NATIONAL Public Relations