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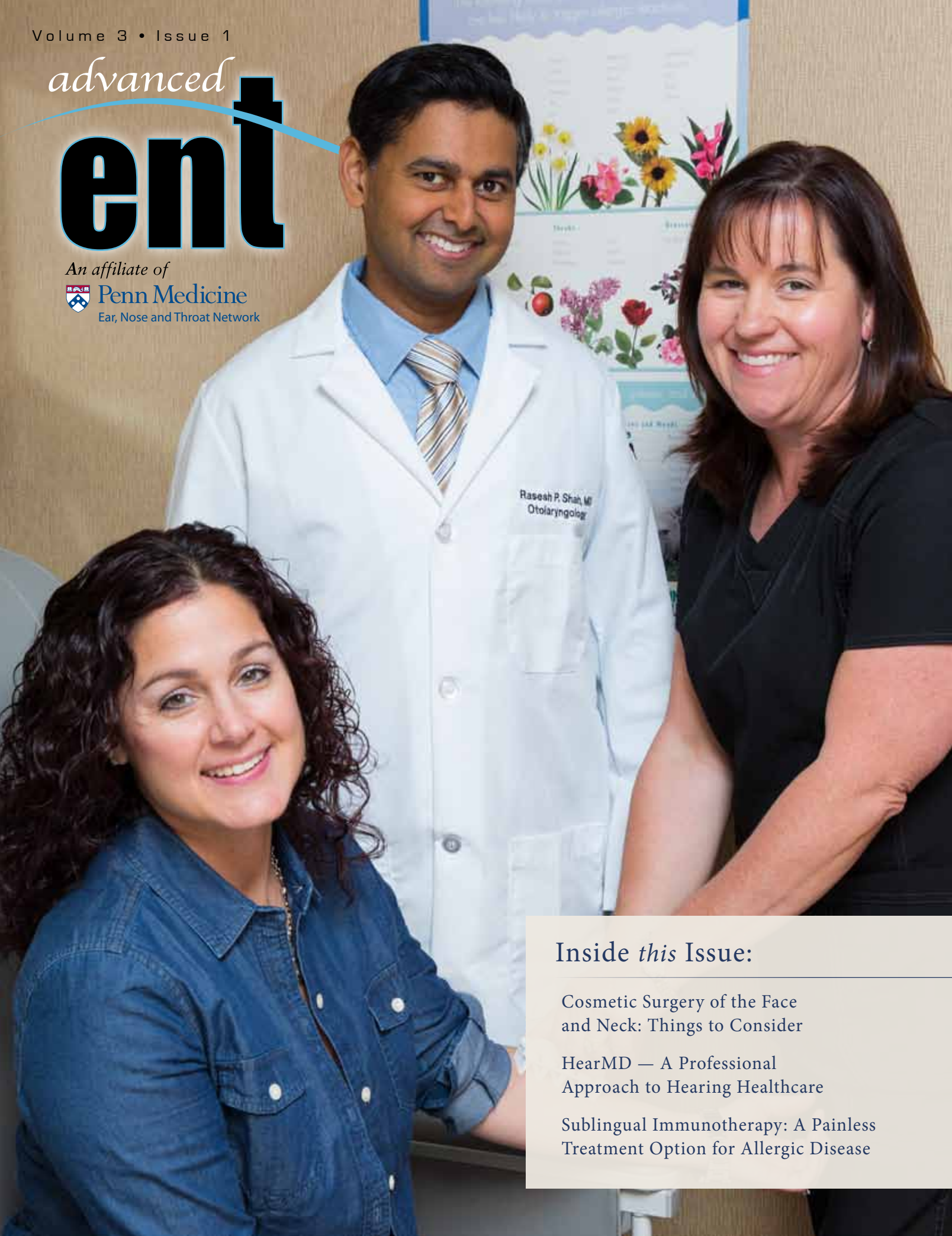

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Welcome

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Our latest edition of Advanced ENT magazine highlights our Allergy department. Featured on our cover is Dr. Rasesh Shah, M.D., Medical Director of Allergy Services, and Manager, Debbie Musumeci, CMA.

Ear, nose and throat allergy is one of the most common disorders of adults and children seen in our practice. Allergies to inhalants, chemicals and foods most often present as an upper aerodigestive track complaint. Allergy is one of the causes of chronic sinusitis and may present as persistent nasal congestion, repetitive sneezing, itchy and watery eyes, runny nose, post nasal drip, chronic cough, indigestion and headaches.

Since the inception of our practice, we have dedicated ourselves to the diagnosis and treatment of the allergic patient. Our doctors and technicians have received specialized training in this aspect of Otolaryngology. Our Allergy Department provides personalized care, continuity and ongoing support that creates a superior patient experience.

In this edition of Advanced ENT magazine, Dr. Rasesh Shah explains immunologic therapy (SLIT) which eliminates injections in favor of painless, effective sublingual drops.

Fellowship trained, board certified Facial Plastic and Reconstructive Surgeon, Dr. Patrick Hall, MD addresses common cosmetic surgeries of the face and neck and considerations to employ before making a decision.

Audiologist, Deborah Burke, M.Ed, CCC-A, cautions "buyer beware," and emphasizes physician partnering with Hear MD professionals for the medical diagnosis of hearing loss and the proper fitting of hearing aids with ongoing support.

Earlier this year, Advanced ENT welcomed Dr. Edward D. Scheiner, D.O., and his patients to our practice. Dr. Scheiner has been providing care for ENT patients for over 29 years in the SJ area, and his ethics, integrity and philosophy of practice align definitively with those of Advanced ENT. We continue to expand as the largest provider of comprehensive ENT services for adults and children in Southern New Jersey, never losing sight of our mission to provide effective, compassionate and responsible care to our patients. We thank our advertising sponsors for their support in the publication of this resource. Above all, we thank YOU, our esteemed physician colleagues.

Sincerely,

The physicians and staff of Advanced ENT

Cosmetic Surgery of the Face and Neck: Things to Consider

by Patrick J. Hall, M.D., F.A.C.S.

THE DECISION TO HAVE cosmetic surgery is a difficult one. This difficulty is worsened by the emphasis that is placed on beauty in our society. The improvements in physical appearance, which can be obtained with modern surgical techniques, and advancements in skin care can be dramatic. Cosmetic surgery has been glamorized by countless TV shows and the mass media, making cosmetic surgery more mainstream and accepted by the general public. However, this media surge often minimizes the inherent risks in these procedures, and can generate unrealistic expectations for those seeking cosmetic improvement in his or her appearance. There are many factors to consider before proceeding with any cosmetic operation:

Why are you considering cosmetic surgery?

The best reason to undergo cosmetic surgery should be self-motivated. Having surgery to save a marriage, please a significant other or keep a job are examples of poor reasons to have aesthetic refinement. Even if the surgery is technically successful, patients motivated by others are often unhappy following surgery, and often do not achieve the goals, which initially motivated the decision to have surgery.

Be comfortable with your physician

Be sure the surgeon is board certified in his or her specialty and has been properly trained in the procedures being discussed. Ask the surgeon about his or her credentials, numbers of cases performed and for pictures of patients who have undergone similar procedures. A cosmetic consultation should be a discussion and exchange of information, not a one sided lecture dominated by the physician.

Be financially prepared

Cosmetic surgery and treatments can range from a few hundred dollars to several thousand. Do not strain your finances in an attempt to proceed with surgery. The financial consequences can be devastating. Ask about more cost effective approaches if money is a factor. Payment plans are new commonplace. Remember the additional cost of facility fees, anesthetic and pharmacy charges.

Be aware of the risks of the procedure

The overwhelming majority of cosmetic procedures are successful with no complications. However, every procedure and operation has risks. Know what the risks are and if adverse outcomes are temporary or permanent. Know the chances of having a complication for the procedure planned and what factors may increase the chance of an adverse outcome.

Have realistic expectations

The glamorization of cosmetic surgery has resulted in a distortion of what may be achievable for each individual patient. Expecting to have results similar to a famous actor or model may simply be impossible depending on the patient. Be wary of any physician who claims that they can alter the appearance to mimic a celebrity.

Take time to recover

Many cosmetic procedures require no downtime, but more advanced surgical procedures often require a recovery period of days to weeks. Be prepared. Do not try to cram an operation into a narrow period of time or before important events such as a wedding or graduation. The doctor should honestly and thoroughly review the expected recovery time, appearance following surgery and physical limitations, which result from the surgery.

If these factors are properly addressed, then the patient should feel comfortable about proceeding with cosmetic refinement. The decision to have cosmetic surgery should be an exciting one that brings happiness. A positive mental attitude is extremely important for any medical or surgical procedure.

This positive attitude is usually achieved with education and open discussion between the patient and the physician. Together you can put your best face forward.

The options for cosmetic surgery of the face and neck have increased over the past decade. The ever increasing emphasis on beauty in western society coupled with the “hustle

and bustle" of an active life make cosmetic enhancement with limited down time for recovery desirable. Expanding applications of filling agents such as Restylane, new, minimally invasive surgical approaches, LASER Therapy and Botox can all achieve these goals. Below is a brief list of common facial plastic and reconstructive procedures. Each of the procedures has its own advantages and disadvantages. Be sure to have a thorough consultation with your board certified surgeon for the best possible outcome.

Rhinoplasty:

Rhinoplasty is cosmetic enhancement of the nose. This operation can produce dramatic changes in facial appearance by de-emphasizing a prominent or deformed nose. Improvement in breathing and the sense of smell can also be obtained in patients with internal nasal deformity.

Blepharoplasty:

Blepharoplasty is cosmetic enhancement of the eyes. The surgery can be performed on the upper eyelids, lower eyelids or both. The goal is to eliminate excess skin, bags and reposition natural fat to give the eyes a youthful more rested appearance. Surgical approaches often leave no visible scars.

Rhytidectomy:

Rhytidectomy or face-lift refines the neck, jaw line and midface by removal of excess skin, elimination of fat and repositioning of deep tissues. The operation can produce dramatic improvements in appearance.

Otoplasty:

Otoplasty corrects lop ear deformity and protruding ears. Lop ears are the result of poor development of the normal curvatures of the ear cartilage. This procedure can be performed at any age after six.

Botox:

No other cosmetic procedure has grown in popularity as rapidly as Botox injections. Botox is used to treat deep lines and wrinkles created by facial expression. "Crow's feet," "frown lines" and "worry lines" are all casual names applied to these unsightly creases that can make a person appear angry or tired. Botox interrupts the muscular actions, eliminating the creases. The injections are quick with minimal discomfort and dramatic results can be achieved with no recovery time.

LASER Therapy:

Cosmetic lasers have multiple applications including elimination of moles and growths, tightening of skin laxity, elimination of fine lines and wrinkles and improvement in redness of the face and nose. LASERS apply intense wavelengths of focused light to achieve those results. A physician experienced in LASER use is paramount to a successful outcome.

Filling agents and Injectables:

These products can be injected to fill areas of deficiency such as thin lips or frown lines to enhance the appearance of the face and provide a more youthful look. A variety of injectables with varying degrees of success are available on the market. Careful patient selection and education of the patient on the available products is necessary for a successful experience. These products can often be substituted for more expensive surgical procedures and provide temporary improvement.

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Advanced ENT is pleased to welcome **Dr. Edward D. Scheiner, D.O.** to our practice. Dr. Scheiner has been practicing Otolaryngology in the South Jersey region for over 30 years. He will continue to see patients at the Stratford office, as well as at our Voorhees, Haddonfield and Washington Township locations. Please call to schedule an appointment.

Robert B. Belafsky, MD	Mark E. Friedel, MD	P. Todd Rowan, MD
Howard J. Bresalier, DO	Stephen P. Gadomski, MD	Edward D. Scheiner, DO
Harry Cantrell, MD	Ashmit Gupta, MD	David N. Schwartz, MD
Roy Carlson, MD	Patrick J. Hall, MD	Rasesh P. Shah, MD
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Robert B. Belafsky, M.D., F.A.C.S.

Dr. Robert B. Belafsky is certified by the American Board of Otolaryngology-Head and Neck Surgery. He received premedical training at the George Washington University in Washington, D.C., and earned his medical degree from the State University of New York at Downstate Medical College in Brooklyn, New York. Dr. Belafsky served his residencies at Lankenau Hospital and at Thomas Jefferson University Hospital, both in Philadelphia, Pennsylvania. He is a fellow of the American College of Surgeons and the Philadelphia College of Physicians. Dr. Belafsky is Chief of Otolaryngology at Lourdes Medical Center-Burlington County.

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Dr. Howard J. Bresalier is certified by the American Board of Otolaryngology – Head and Neck Surgery. He received premedical training at Emory University in Atlanta, Georgia, and earned his medical degree from the University of Osteopathic Medicine and Health Sciences in Des Moines, Iowa. Dr. Bresalier served his residency at Botsford General Hospital in Detroit, Michigan. He is a member of The American Osteopathic Association, and is a fellow of the American Osteopathic College of Otolaryngology. Dr. Bresalier serves as Section Head of Otolaryngology at Kennedy Health System.

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Dr. Patrick J. Hall is certified by the American Board of Otolaryngology-Head and Neck Surgery as well as the American Academy of Facial Plastic and Reconstructive Surgery. He received premedical training at the Philadelphia College of Pharmacy and Science, and earned his medical degree from the University of Medicine and Dentistry in Newark, New Jersey. Dr. Hall served his otolaryngology residency at the University of South Florida in Tampa, Florida. He completed fellowship training in Facial Plastic and Reconstructive Surgery with Dr. Richard Farrior in Tampa, Florida. He is a fellow of the American College of Surgeons and serves as Chief of Otolaryngology and Facial Plastic Surgery at Underwood Memorial Hospital.

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Steven M. Leoniak, MD earned a BA, Biology from Johns Hopkins University, Baltimore, MD. He received his medical degree from New York Medical College and served his internship and Otolaryngology residency at Thomas Jefferson University Hospital, Philadelphia, PA. He is a member of the American Academy of Otolaryngology and the American Academy of Otolaryngic Allergy.

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Edward D. Scheiner, D.O., F.O.C.O.O.

Dr. Edward D. Scheiner is certified by the American Osteopathic Board of Otolaryngology-Head and Neck Surgery. He earned a B.S. in Pre-Medicine at The Pennsylvania State University, and his medical degree from Philadelphia College of Osteopathic Medicine. He served his internship at Kennedy Memorial Hospitals – Cherry Hill Division, and his Otolaryngology residency at Kennedy Memorial Hospitals/UMDNJ/School of Osteopathic Medicine. He is a member of the American Osteopathic Association, and a member and fellow of the American Osteopathic College of Otolaryngology. Dr. Scheiner serves as Chief of the Section of Otolaryngology at Kennedy Memorial Hospitals, and is also Otolaryngology Section Head at Rowan University/SOM (formerly UMDNJ/SOM).

David N. Schwartz, M.D., F.A.C.S.

Dr. David N. Schwartz is certified by the American Board of Otolaryngology-Head and Neck Surgery. He received premedical training at the College of William and Mary in Williamsburg, Virginia. He attended Boston University School of Dental Medicine earning a degree in dentistry followed by a medical degree from Boston University School of Medicine in Massachusetts. Dr. Schwartz completed his surgical and otolaryngology residencies at the State University of New York in Syracuse, New York. He is a fellow of the American College of Surgeons.

Rasesh P. Shah, M.D., F.A.C.S.

Dr. Rasesh P. Shah is certified by the American Board of Otolaryngology-Head and Neck Surgery. He completed an accelerated seven-year medical program, receiving premedical training at the New Jersey Institute of Technology, and earning his medical degree from New Jersey Medical School at the University of Medicine and Dentistry in Newark, New Jersey. Dr. Shah completed his internship and residency at UMDNJ in Newark, New Jersey as well. He is Program Director of Otolaryngology at Lourdes Specialty Hospital. He is a fellow of the American College of Surgeons.

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HearMD —

A Professional Approach to Hearing Healthcare

By Deborah Burke, M.Ed., CCC/A

IN TODAY'S WORLD of hearing healthcare, there are many providers from which to choose. Our mission at HearMD is to address the individualized needs of each patient with compassionate, professional and progressive hearing health care. Our goal is to improve the quality of our patients' lives and relationships through better hearing. To accomplish this, we work closely with the physician team of Advanced ENT to determine the cause of one's hearing loss and if medical intervention is a viable treatment option.

If there is no medical intervention option, the next step is a thorough hearing assessment which is necessary for the proper fitting of hearing aids. Our professional and caring hearing healthcare staff of HearMD is experienced in diagnosing and treating all types and degrees of hearing loss. After a complete hearing evaluation, our staff will take the time to explain the test results and will discuss how the hearing loss might be affecting your daily life and relationships. We pride ourselves on providing accurate and up-to-date information about hearing and hearing loss so that our patients can make educated hearing healthcare decisions. We do this because in our practice, we place high value on patient education. By working together in this way, we will create realistic goals to improve your hearing.

One of the ways that we strive to help you hear better is by providing complete hearing aid dispensing services in all of our offices. Unlike many other hearing healthcare practices, our licensed hearing health professionals dispense hearing aids from many different reputable and well-known manufacturers. Therefore, we have the freedom to choose which product and/or manufacturer we feel is best for each individual patient's hearing loss and lifestyle needs. In addition, our HearMD staff is always quick to evaluate and to dispense new hearing aid technology as it becomes available.

While there are many places you can choose from to purchase hearing aids, it is also extremely important to remember that hearing aids are classified by the US Food and Drug Administration as medical devices, not consumer retail items. You should be careful to not "shop" for hearing aids like you would shop for a toaster. Today's hearing aids are complex and they are not just simple sound amplifiers as they were in the past. It takes knowledge and skill to fit them properly. The actual fitting and adjustment of the hearing aids is just as

At HearMD, we place a high value on patient education. By working together in this way, we will create realistic goals to improve your hearing.

important as the quality of the hearing aids themselves. That is why choosing an experienced, well-informed hearing healthcare professional like those at HearMD is crucial to a successful hearing aid fitting.

Some patients and consumers are choosing to purchase hearing aids from non-traditional sources such as through the Internet. It is wise to be wary of hearing aids sold over the Internet. The hearing evaluations performed at home via the computer prior to purchase of hearing aids from the Internet are not as accurate and detailed as those performed at HearMD and other professional audiology facilities. Online hearing evaluations are often nothing more than a basic hearing screening. Also, without seeing a physician for medical clearance to be fitted for hearing aids, some potentially serious hearing health issues might be missed. If follow up is needed for fine tuning of the hearing aid purchased from the Internet and local professional support is necessary, there are additional fees incurred for those appointments. Those costs then add to the overall cost of the hearing aids. The "bargain" price might not end up being such a bargain.

In addition, hearing aids are also being sold at "discount" warehouse stores. These places offer attractive pricing but often are lacking in product quality and service. When considering this option, please understand that you might not be comparing "apples to apples" when looking at different models of hearing aids and levels of hearing aid technology. You might think you are getting a great price on a "premium" technology hearing aid but the comparison is not accurate when compared to what is available at a traditional audiology/hearing aid dispensing practices such as HearMD. The salesperson may try to convince you that their products are the same by offering so much information that it can be confusing to some patients and consumers.

If you choose to purchase hearing aids at HearMD, in addition to offering the best and latest technology hearing aids, we will continue to provide top-quality hearing healthcare by including our Premium Care Plan. This plan is included as part of every hearing aid fitting. As part of our ongoing commitment to your hearing health, we include our Premium Care Plan at no charge in order to provide you with exceptional worry-free hearing aid care at no additional charge for 5 years from the date of purchase. The Premium Care Plan includes: complimentary in-office "clean & check" maintenance visits every six months for 5 years and complimentary batteries dispensed in six-month supply quantities at the end of your trial period (and at subsequent semi-annual "clean & check" maintenance visits) for 5 years. The Premium Care Plan also includes (if applicable) tone hooks and tubing changes for Behind-the-Ear (BTE) hearing aids, in-office earmold and shell modifications, hearing aid reprogramming following manufacturer's repair and wax filters.

In conclusion, please know that a state of the art hearing aid(s) or assistive listening device will not benefit you as greatly or live up to your expectations if it is not fit and programmed properly for your hearing loss and your listening needs by an experienced hearing healthcare professional. If you or someone you know is suffering from hearing loss, let the audiologists and hearing aid dispensers of HearMD help you begin your journey to better hearing for better living.

Sublingual Immunotherapy
A Painless Treatment Option For Allergic Disease

By Rasesh Shah, MD, FAAOA, FACS

ALLERGIC DISEASE and the increased response of the immune system have been described for centuries (1). There has been an incredible increase of these reactions in the developed world over the past twenty years. It is estimated that 20% of the world population suffers from allergies (2). Ideal treatment of these reactions has been elusive, but attempts have been made for years. As early as 1891, Ehrlich demonstrated that mice can develop tolerance to ricin after receiving increased doses (3). The first treatments with immunotherapy were developed for the treatment of hay fever in the early 1900s. Our comprehension and treatment of allergies has been evolving for over one hundred years. We currently attempt to decrease the response to allergens for patients by systematically increasing the dose and concentrations of specific antigens. This is a common thread in both subcutaneous immunotherapy (SCIT) and sublingual immunotherapy (SLIT). This concept of treatment is a well accepted method for treating various forms of allergic disease.

In the United States, SCIT is the most common method of delivering antigen-specific extracts to patients. There are multiple well established techniques for this treatment modality. It is still the gold standard of immunotherapy and what other techniques are measured against. There are countless studies demonstrating its long term effectiveness. Until recently this was not the case, and before the 1980's there was no standardization of allergy extracts. This resulted in vast variations in allergen concentrations depending on the lot numbers. There have been dramatic changes and advances in this type of therapy. The latest frontier of allergy treatment avoids the needles and involves sublingual drops. There have been descriptions of oral desensitization of allergic disease since the early 1900s. In 1986, the first study examining this SLIT came out of Europe and it is much more accepted as allergy therapy in several European nations. In 2009, the World Allergy Organization (WAO) released a position paper on SLIT, creating the first global consensus on this form of treatment (2).

The precise physiologic mechanism of SLIT is still under investigation. Instead of a primarily hematologic response, as in SCIT, the evidence suggests local immunological responses in the oral mucosa and submucosal tissue. There is minimal systemic absorption that accounts for its incredible track record of safety. The immunologic alterations of the body are similar with both techniques. There is a decrease in antigen specific IgE and increases in both IgG and IL-10. There are several theories concerning the mechanism of developing these results.

The safety and efficacy of SLIT has been shown in over 50 randomized double-blind placebo controlled trials. All clinical trials have shown that it is a safe treatment and that most reactions are local and mild. Review of the literature by Leatherman has demonstrated that the vast majority of studies reveal that SLIT was an effective treatment for allergic rhinitis, conjunctivitis and/or asthma. The trials show that treatment is consistently superior to placebo. There is controversy about the comparison of SCIT and SLIT. There are several papers that document equal effectiveness between the two modalities, but there are also reports that oral treatment is inferior to traditional injections in the improvement of symptoms (4).

Sublingual treatment has a superior safety profile when compared to the subcutaneous method. There is a reported systemic reaction rate of 0.005% to 2.9% with no deaths using SCIT (5). Severe general reactions are extremely rare and there are several studies that include children. The most common side effects include oral irritation and pruritis (4). This treatment has been commercialized and used in most European countries, South American countries, Australia and Asian nations for several years. Sublingual immunotherapy was still considered investigational and not officially approved by the FDA in the United States until April of 2014. There are very few products approved for use and SLIT is still considered to be a new treatment modality. (2).

The method of treatment of SLIT and SCIT are similar. Both start at a low dose and are systematically escalated until a

maintenance dose is achieved. The period of escalation SLIT is brief and is performed over a period of 10 days. The antigen spray is taken at home with the patient administering the medication daily. The duration of therapy is similar to injections, lasting three to five years. The convenience is tremendous compared to SCIT because of the ability to administer the drops at home without the need to travel to the physician's office. This will prevent any loss of work or school and result in enhanced patient compliance.

In summary, sublingual immunotherapy is another treatment option to treat the challenging problems of allergic disease. The gold standard of treatment is still subcutaneous immunotherapy. However, the newer treatment has been proven to be effective with remarkable convenience and has an impressive safety profile.

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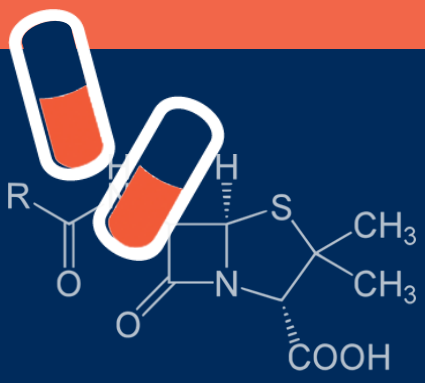

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who report as penicillin allergic are not when assessed by skin testing.[1]

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[1] Salkind, JAMA, May 16, 2001 - Vol. 285, No. 19

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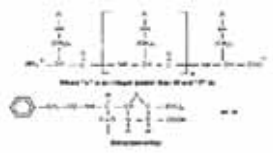
PRE-PEN® (benzylpenicilloyl polylysine injection USP) Skin Test Antigen

DESCRIPTION:

PRE-PEN® (benzylpenicilloyl polylysine injection USP) is a sterile solution of benzylpenicilloyl polylysine in a concentration of 6.0 X 10-5 M (benzylpenicil¬loyl) in 0.01 M phosphate buffer and 0.15 M sodium chloride. The benzylpeni¬cilloyl polylysine in PRE-PEN is a derivative of poly-l-lysine, where the epsilon amino groups are substituted with benzylpenicilloyl groups (50-70%) forming benzylpenicilloyl alpha amide. Each single dose ampule contains 0.25 mL of PRE-PEN.

PRE-PEN is a skin test antigen used in assessing a patient's allergic status to penicillin. The structural formula of PRE-PEN is:



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PRE-PEN reacts specifically with benzylpenicilloyl IgE antibodies to initiate release of chemical mediators which produce an immediate wheal and flare reaction at a skin test site. All individuals exhibiting a positive skin test to PRE-PEN possess IgE against the benzylpenicilloyl group which is a hapten. A hapten is a low molecular weight chemical which, when conjugated to a carrier, e.g., poly-l-lysine, has the properties under appropriate conditions of an antigen with the hapten's specificity. The benzylpenicilloyl hapten is the major antigenic determinant in penicillin-allergic individuals.

It is to be noted that individuals who have previously received therapeutic penicillin may have positive skin test reactions to PRE-PEN as well as to a number of other non-benzylpenicilloyl haptens. The latter are designated as minor determinants, in that they less frequently engender an immune response in penicillin treated individuals than does the major determinant, benzylpenicilloyl. The minor determinants may nevertheless be associated with significant clinical hypersensitivity.

Virtually everyone who receives penicillin develops specific antibodies to the drug as measured by hemagglutination studies, but (a) immediate skin tests to various penicillin and penicillin-derived reagents become positive in fewer than 10% of patients who have tolerated penicillin in the past; and (b) acute allergic responses to penicillin treatment are infrequent (less than 1%).

Many individuals reacting positively to PRE-PEN will not develop a systemic allergic reaction on subsequent exposure to therapeutic penicillin, especially among those who have not reacted to penicillins in the past. Thus, the PRE-PEN skin test determines the presence of penicilloyl IgE antibodies which are necessary but not sufficient for acute allergic reactions due to the major penicilloyl determinant.

INDICATIONS AND USAGE:

PRE-PEN is useful as an adjunct in assessing the risk of administering peni¬cillin (benzylpenicillin or penicillin G) when it is the preferred drug of choice in adult patients who have previously received penicillin and have a history of clinical penicillin hypersensitivity. In this situation, a negative skin test to PRE-¬PEN is associated with an incidence of immediate allergic reactions of less than 5% after the administration of therapeutic penicillin, whereas the incidence may be more than 50% in a history-positive patient with a positive skin test to PRE-PEN.

These allergic reactions are predominantly dermatologic. Because of the extremely low incidence of anaphylactic reactions, there are insufficient data at present to document that a decreased incidence of anaphylactic reactions following the administration of penicillin will occur in patients with a negative skin test to PRE-PEN. Similarly, when deciding the risk of proposed penicillin treatment, there are not enough data at present to permit relative weighing in individual cases of a history of clinical penicillin hypersensitivity as compared to positive skin tests to PRE-PEN and/or minor penicillin determinants.

It should be borne in mind that no reagent, test, or combination of tests will completely assure that a reaction to penicillin therapy will not occur.

CONTRAINDICATIONS:

PRE-PEN is contraindicated in those patients who have exhibited either a sys¬temic or marked local reaction to its previous administration. Patients known to be extremely hypersensitive to penicillin should not be skin tested.

WARNINGS:

There are insufficient data to assess the potential danger of sensitization to repeated skin testing with PRE-PEN.

Rarely, a systemic allergic reaction (see below) may follow a skin test with PRE-PEN. This can be avoided by making the first application by a puncture test and very carefully following the instructions below in administering the intra¬dermal test, using the intradermal route only if the puncture test is entire¬ly negative.

PRECAUTIONS:

General:

There are insufficient data derived from well-controlled studies to determine the value of the PRE-PEN skin test alone as a means of assessing the risk of admin¬istering therapeutic penicillin (when penicillin is the preferred drug of choice) in the following situations:

(1)Adult patients who give no history of clinical penicillin hypersensitivity; and

(2)Pediatric patients.

In addition, there are no data at present to assess the clinical value of PRE-¬PEN where exposure to penicillin is suspected as a cause of a current drug reaction or in patients who are undergoing routine allergy evaluation.

Furthermore, there are no reliable data relating the clinical value of PRE-PEN skin tests alone to the risk of administering semi-synthetic penicillins (phenoxymethyl penicillin, ampicillin, carbenicillin, dicloxacillin, methicillin, nafcillin, oxacillin, amoxicillin) ,cephalosporin-derived antibiotics, and penem antibiotics.

Recognition that the following clinical outcomes are possible makes it impera¬tive for the physician to weigh risk to benefit in every instance where the deci¬sion to administer or not to administer penicillin is based in part on a PRE-PEN skin test:

(1)A serious allergic reaction to therapeutic penicillin may occur in a patient with a negative skin test to PRE-PEN.

(2)It is possible for a patient to have an anaphylactic reaction to therapeu¬tic penicillin in the presence of a negative PRE-PEN skin test and a neg¬ative history of clinical penicillin hypersensitivity.

(3)If penicillin is the drug of choice for a life-threatening infection, successful desensitization with therapeutic penicillin may be possible irrespective of a positive skin test and/or a positive history of clinical penicillin hypersensitivity.

Pregnancy – Pregnancy Category C:

Animal reproduction studies have not been conducted with PRE-PEN. It is not known whether PRE-PEN can cause fetal harm when administered to a preg¬nant woman or can affect reproduction capacity. The hazards of skin testing in such patients should be weighed against the hazard of penicillin therapy with¬out skin testing.

ADVERSE REACTIONS:

Occasionally, patients may develop an intense local inflammatory response at the skin test site. Rarely patients will develop a systemic allergic reaction, manifested by generalized erythema, pruritus, angioedema, urticaria, dyspnea, and/or hypotension. The usual methods of treating a skin test anti¬gen-induced reaction — the applications of a venous occlusion tourniquet proximal to the skin test site and administration of epinephrine are recommended and will usually control the reaction. As a rule, systemic allergic reactions following skin test proce¬dures are of short duration and controllable, but the patient should be kept under observation for several hours.

DOSAGE AND ADMINISTRATION:

SKIN TESTING DOSAGE AND TECHNIQUE

Skin testing responses can be attenuated by interfering drugs (e.g. H1-antihistamines and vasopressors). Skin testing should be delayed until the effects of such drugs have dissipated, or a separate skin test with histamine can be used to evaluate persistent antihistaminic effects in vivo.

Puncture Testing:

Skin testing is usually performed on the inner volar aspect of the forearm. The skin test antigen should always be applied first by the puncture technique. After preparing the skin surface, apply a small drop of PRE-PEN solution using a sterile 22-28 gauge needle. The same needle can then be used to make a single shallow puncture of the epidermis through the drop of PRE-PEN. Very little pressure is required to break the epidermal continuity. Alternatively an allergy prick testing device (eg. duo tip or bifurcated needle) may be employed. Observe for the appearance of a wheal, erythema, and the occurrence of itching at the test site during the succeeding 15 minutes at which time the solution over the puncture site may be wiped off. A positive reaction is unmistakable and consists of the develop¬ment within 10 minutes of a pale wheal, sometimes with pseudopods, surrounding the puncture site and varying in diameter from 5 to 15 mm (or more). This wheal may be surrounded by a variable diameter of erythema, and accompanied by a variable degree of itching. The most sensitive individuals develop itching quickly, and the wheal and erythema are prompt in their appearance. As soon as a positive response as defined above is clearly evident, the solu¬tion over the scratch should be immediately wiped off. If the puncture test is either negative or equivocally positive (less that 5 mm wheal and little or no erythema, and no itching), an intradermal test may be performed.

The Intradermal Test:

Using a tuberculin syringe with a 3/8" to 5/8"long, 26 to 30 gauge, short bevel needle, withdraw the remaining contents of the ampoule. Prepare with an alcohol swab a skin test area on the upper, outer arm, sufficiently below the deltoid muscle to permit prox¬imal application of a tourniquet later, if necessary. Be sure to eject all air from the syringe through the needle, then insert the needle, bevel up immediately below the skin surface. Inject an amount of PRE-PEN sufficient to raise a small intradermal bleb of about 3 mm in diameter, in duplicate at least 2 cm apart. Using a separate syringe and needle, inject a like amount of sterile saline or allergen diluting solution as a control at least 5 cm removed from the antigen test sites. Most skin reac¬tions will develop within 5-15 minutes and response to the skin test is read at 20 min as follows:

Negative response — no increase in size of original bleb and no greater reaction than the control site.Ambiguous response — wheal only slightly larger than initial injection bleb, with or without accompanying erythematous flare and slightly larger than the control site; OR discordance between duplicates.

Positive response — itching and significant increase in size of original blebs to at least 5mm. Wheal may exceed 20 mm in diameter and exhibit pseu¬dopods.

If the control site exhibits a wheal greater than 2-3 mm, repeat the test, and if the same reaction is observed, a physician experienced with allergy skin testing should be consulted.

HOW SUPPLIED: NDC 65044-9997-5

PRE-PEN® (benzylpenicilloyl polylysine injection USP) is a clear, colorless, sterile solution supplied in ampoules containing 0.25 mL.

Box of 5 single dose ampoules. Ampoules are opened by snapping the neck of the vial using two forefingers of each hand. Visually inspect for glass chards before use. Each vial is for single patient use only—discard any unused portion.

PRE-PEN is optimally stored under refrigeration (2-8°C). It is recom¬mended that test antigenubjected to ambient temperatures for more than 24 hours be discarded. As with all parenteral drug products, PRE-PEN should be inspected visually for particulate matter and discoloration prior to administration.

Rx only

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Vision Statement

Advanced ENT constantly strives to provide services that are relevant and appropriate to the needs of our community in this changing environment of health care delivery.

Mission Statement

The mission of Advanced ENT is to provide effective, compassionate and responsible medical and surgical care to disorders involving the ears, nose, throat, head and neck.

Advanced ENT will provide this care through a comprehensive approach that encompasses our specialty services:

Adult Ear, Nose & Throat Care
Allergy
Audiology (Hearing Services)
Balance Disorders
Facial Plastic & Reconstructive Surgery
Head & Neck Cancer
Thyroid & Parathyroid Disorders
Pediatric Ear, Nose & Throat Care
Sinus Surgery
Endoscopic Skull Base Surgery
Skin Cancer Treatment & Reconstruction
Skin Care
Sleep Medicine
Voice & Swallowing Disorders

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