

Future of Derasurgery Is Exciting, but Uncertain

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CORONADO, CALIF. — Over the next 2 decades, dermasurgery will transform into a field in which noninvasive treatments and nonsurgical approaches rule the day, said Dr. Ronald Moy at the annual meeting of the Pacific Dermatologic Association.

“What we’re doing today is going to be considered barbaric if we look 15-20 years

down the road,” said Dr. Moy of the University of California, Los Angeles, and the association’s immediate past president.

One key aspect of dermasurgery’s future will involve treatment of skin cancer nonsurgically with a cocktail of immunomodulators. “We’ve done projects in our lab where we can put interleukin-2 into skin cancer and get a 90% cure rate,” he said.

Hair transplants won’t be necessary because hair cloning will be readily available,

and lasers will be used to prevent wrinkles, remove hair and fat, tighten and resurface skin, and for the early treatment of vessels and lentigos. “Lasers will be handheld and will be used by patients,” he added.

Dr. Moy also expects that Botox will be replaced by the permanent relaxing of muscles; resurfacing of the skin will improve with new fractional resurfacing technology; tightening of the skin will improve with new energy devices; and permanent facial fillers, such as those

derived from stem cells, will become mainstream.

Facelifts will fall in popularity because of new resurfacing and tightening devices. DNA repair enzymes, growth factor, and other futuristic creams will treat and prevent aging skin at a molecular level.

The American Society for Dermatologic Surgery is the second largest dermatology organization in the world, after the American Academy of Dermatology, and “dermatologic surgery procedures are the fastest growing and most commonly preferred procedures,” he said. “The future promises that new technology will make these procedures better.”

However, certain trends in today’s practice environment threaten dermasurgery’s future. Dr. Moy called the proliferation of nonphysicians performing Botox injections, microdermabrasion, chemical peels, and other cosmetic procedures as “our greatest threat right now. Everybody’s doing what we’re doing. We might be able to change some of that with legislation, but we won’t be able to [prevent] other physicians [from] practicing dermasurgery.”

To complicate matters, there is a shortage of dermatologists in the United States, said Dr. Moy, who has served as vice president of the Medical Board of California.

“That’s only going to get worse. Even if we double the enrollment of all the California medical schools, we won’t come close to the need.”

The looming possibility of a national health insurance program also could affect the development of dermasurgery. Such a program probably would be modeled on dental insurance, he explained, “where your health insurance will be for catastrophic conditions. But all the little things that we do in dermatology will be on a cash basis.”

On the bright side, increasing numbers of women are entering medical school and dermatology residency programs, and the dermatologists of tomorrow have a strong sense of volunteerism. “They’re going to be better trained, and they’ll be embracing new technology,” he said.

Dr. Moy disclosed that he is a member of the scientific advisory boards for Rhytec Inc. and Bioform Medical Inc.



A patient is shown before use of Sculptra, a filler for improving facial volume.



The patient is shown 2 months later, after 2 shots of the long-lasting treatment.

PHOTOS COURTESY DR. RONALD MOY

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Typhoid Vi Polysaccharide Vaccine Typhim Vi®

Rx Only

Brief Summary: Please see package insert for full prescribing information.

INDICATIONS AND USAGE

Typhim Vi vaccine is indicated for active immunization against typhoid fever for persons two years of age or older.

Immunization with Typhim Vi vaccine should occur at least two weeks prior to expected exposure to *S typhi*.

Typhim Vi vaccine is not indicated for routine immunization of individuals in the United States (US).¹

Selective immunization against typhoid fever is recommended under the following circumstances: 1) travelers to areas where a recognized risk of exposure to typhoid exists, particularly ones who will have prolonged exposure to potentially contaminated food and water, 2) persons with intimate exposure (ie, continued household contact) to a documented typhoid carrier, and 3) workers in microbiology laboratories who frequently work with *S typhi*.¹

Typhoid vaccination is not required for international travel, but is recommended for travelers to such areas as Africa, Asia, and Central and South America where there is a recognized risk of exposure to *S typhi*. Current CDC advisories should be consulted with regard to specific locales. Vaccination is particularly recommended for travelers who will have prolonged exposure to potentially contaminated food and water. However, even travelers who have been vaccinated should use caution in selecting food and water.²

An optimal reimmunization schedule has not been established. Reimmunization every two years under conditions of repeated or continued exposure to the *S typhi* organism is recommended at this time.

Typhim Vi vaccine has efficacy against typhoid fever caused by *S typhi* infection but will not afford protection against species of *Salmonella enterica* serovar *typhi* other than *S typhi* or other bacteria that cause enteric disease.

For recommended primary immunization and reimmunization see **DOSE AND ADMINISTRATION** section.

Typhim Vi vaccine should not be used to treat a patient with typhoid fever or a chronic typhoid carrier.

CONTRAINDICATIONS

TYPHIM VI VACCINE IS CONTRAINDICATED IN PATIENTS WITH A HISTORY OF HYPERSENSITIVITY TO ANY COMPONENT OF THIS VACCINE.

WARNINGS

Allergic reactions have been reported rarely in the post-marketing experience (see **ADVERSE REACTIONS** section).

The safety and immunogenicity of Typhim Vi vaccine in children under two years of age has not been established. As with other polysaccharide vaccines, the antibody response may be inadequate. The decision whether to vaccinate children under 2 years of age depends upon the risk incurred by the child on the basis of the epidemiological context.

Typhim Vi vaccine provides protection against the risk of infection related to *Salmonella typhi*, but gives no protection against *Salmonella paratyphi A* or *B*.

If the vaccine is used in persons deficient in producing antibodies, whether due to genetic defect, immunodeficiency disease, or immunosuppressive therapy, the expected immune response may not be obtained.

As with any intramuscular injection, Typhim Vi vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection (see **DRUG INTERACTIONS** section).

As with any vaccine, vaccination with Typhim Vi vaccine may not protect 100% of individuals.

PRECAUTIONS

GENERAL

Care is to be taken by the health-care provider for the safe and effective use of Typhim Vi vaccine.

EPINEPHRINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE FOLLOWING IMMUNIZATION SHOULD AN ANAPHYLACTIC OR OTHER ALLERGIC REACTIONS OCCUR DUE TO ANY COMPONENT OF THE VACCINE.

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the patient’s history with respect to possible hypersensitivity to the vaccine or similar vaccines.

Acute infection or febrile illness may be reason for delaying use of Typhim Vi vaccine except when in the opinion of the physician, withholding the vaccine entails a greater risk.

A separate, sterile syringe and needle or a sterile disposable unit must be used for each patient to prevent the transmission of infectious agents from person to person. Needles should not be recapped and should be properly disposed.

Special care should be taken to ensure that Typhim Vi vaccine is not injected into a blood vessel.

Safety and immunogenicity data from controlled trials are not available for Typhim Vi vaccine following previous immunization with whole-cell typhoid or live, oral typhoid vaccine (See **ADVERSE REACTIONS** section).

DRUG INTERACTIONS

There are no known interactions of Typhim Vi vaccine with drugs or foods.

No studies have been conducted in the US to evaluate interactions or immunological interference between the concurrent use of Typhim Vi vaccine and drugs (including antibiotics and antimalarial drugs), immune globulins or other vaccines (including common travelers vaccines such as tetanus, polio, hepatitis A, yellow fever and meningococcus). (See **ADVERSE REACTIONS** section.)

As with other intramuscular injections, Typhim Vi vaccine should be given with caution to individuals on anticoagulant therapy.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Typhim Vi vaccine has not been evaluated for its carcinogenic potential, mutagenic potential or impairment of fertility.

PREGNANCY CATEGORY C

Animal reproduction studies have not been conducted with Typhim Vi vaccine. It is not known whether Typhim Vi vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Typhim Vi vaccine should be given to a pregnant woman only if clearly needed.¹

When possible, delaying vaccination until the second or third trimester to minimize the possibility of teratogenicity is a reasonable precaution.³

NURSING MOTHERS

It is not known if Typhim Vi vaccine is excreted in human milk.

There is no data to warrant the use of this product in nursing mothers for passive antibody transfer to an infant.

PEDIATRIC USE

Safety and effectiveness of Typhim Vi vaccine have been established in children 2 years of age and older.^{4,5} (See **DOSE AND ADMINISTRATION** section.) FOR CHILDREN BELOW THE AGE OF 2 YEARS, SAFETY AND EFFECTIVENESS HAVE NOT BEEN ESTABLISHED.

ADVERSE REACTIONS

Adverse event information is derived from clinical trials and worldwide post-marketing experience.

DATA FROM CLINICAL TRIALS

Safety of Typhim Vi vaccine, the US licensed liquid formulation, has been assessed in clinical trials in more than 4,000 subjects both in countries of high and low endemicity. In addition, the safety of the lyophilized formulation has been assessed in more than 6,000 individuals. The adverse reactions were predominately minor and transient local reactions. Local reactions such as injection site pain, erythema and induration almost always resolved within 48 hours of vaccination. Elevated oral temperature, above 38°C (100.4°F), was observed in approximately 1% of vaccinees in all studies. No serious or life-threatening systemic events were reported in these clinical trials.^{4,5}

Adverse reactions from two trials evaluating Typhim Vi vaccine lots in the US (18- to 40-year-old adults) are summarized in TABLE 1. No severe or unusual side effects were observed. Most subjects reported pain and/or tenderness (pain upon direct pressure). Local adverse experiences were generally limited to the first 48 hours.^{4,5}

TABLE 1^{4,5} PERCENTAGE OF 18- TO 40-YEAR-OLD US ADULTS PRESENTING WITH LOCAL OR SYSTEMIC REACTIONS WITHIN 48 HOURS AFTER THE FIRST IMMUNIZATION WITH TYPHIM VI VACCINE

REACTIONS	Trial 1 Placebo N=54	Trial 1 Typhim Vi vaccine N=54 (1 Lot)	Trial 2 Typhim Vi vaccine N=98 (2 Lots combined)
Local			
Tenderness	7 (13.0%)	53 (98.0%)	95 (96.9%)
Pain	4 (7.4%)	22 (40.7%)	26 (26.5%)
Induration	0	8 (14.8%)	5 (5.1%)
Erythema	0	2 (3.7%)	5 (5.1%)
Systemic			
Malaise	8 (14.8%)	13 (24.0%)	4 (4.1%)
Headache	7 (13.0%)	11 (20.4%)	16 (16.3%)
Myalgia	0	4 (7.4%)	3 (3.1%)
Nausea	2 (3.7%)	1 (1.9%)	8 (8.2%)
Diarrhea	2 (3.7%)	0	3 (3.1%)
Feverish (subjective)	0	6 (11.1%)	3 (3.1%)
Fever ≥100°F	0	1 (1.9%)	0
Vomiting	0	1 (1.9%)	0

No studies were conducted in US children. Adverse reactions from a trial in Indonesia in children one to twelve years of age are summarized in TABLE 2.^{4,5} No severe or unusual side effects were observed.

TABLE 2^{4,5} PERCENTAGE OF INDONESIAN CHILDREN ONE TO TWELVE YEARS OF AGE PRESENTING WITH LOCAL OR SYSTEMIC REACTIONS WITHIN 48 HOURS AFTER THE FIRST IMMUNIZATION WITH TYPHIM VI VACCINE

REACTIONS	N=175
Local	
Soreness	23 (13.0%)
Pain	25 (14.3%)
Erythema	12 (6.9%)
Induration	5 (2.9%)
Impaired Limb Use	0
Systemic	
Feverishness*	5 (2.9%)
Headache	0
Decreased Activity	3 (1.7%)

* Subjective feeling of fever.

In the US Reimmunization Study, subjects who had received Typhim Vi vaccine 27 or 34 months earlier, and subjects who had never previously received a typhoid vaccination, were randomized to placebo or Typhim Vi vaccine, in a double-blind study. Safety data from the US Reimmunization Study are presented in TABLE 3.^{4,6} In this study 5/30 (17%) primary immunization subjects and 10/45 (22%) reimmunization subjects had a local reaction. No severe or unusual side effects were observed. Most subjects reported pain and/or tenderness (pain upon direct pressure). Local adverse experiences were generally limited to the first 48 hours.^{4,6}

TABLE 3^{4,6} US REIMMUNIZATION STUDY, SUBJECTS PRESENTING WITH LOCAL AND SYSTEMIC REACTIONS WITHIN 48 HOURS AFTER IMMUNIZATION WITH TYPHIM VI VACCINE

REACTIONS	PLACEBO (N=32)	FIRST IMMUNIZATION (N=30)	REIMMUNIZATION (N=46*)
Local			
Tenderness	2 (6%)	28 (93%)	44 (98%)
Pain	1 (3%)	13 (43%)	25 (56%)
Induration	0	5 (17%)	8 (18%)
Erythema	0	1 (3%)	5 (11%)
Systemic			
Malaise	1 (3%)	11 (37%)	11 (24%)
Headache	5 (16%)	8 (27%)	5 (11%)
Myalgia	0	2 (7%)	1 (2%)
Nausea	0	1 (3%)	1 (2%)
Diarrhea	0	0	1 (2%)
Feverish (subjective)	0	3 (10%)	2 (4%)
Fever ≥100°F	1 (3%)	0	1 (2%)
Vomiting	0	0	0

* At 27 or 34 months following a previous dose given in different studies.

DATA FROM WORLDWIDE POST-MARKETING EXPERIENCE

The following adverse events have been reported during post-approval use of Typhim Vi vaccine. These events have been very rarely reported; however, because they were reported voluntarily from a population of uncertain size, it is not always possible to reliably calculate their frequencies or to establish a causal relationship to Typhim Vi vaccine exposure.

- Gastro intestinal disorders
Nausea, vomiting, diarrhea
- General disorders and administration site condition
Local Reactions: injection site pain, injection site inflammation, injection site induration, injection site erythema, and lymphadenopathy.
Fever, asthenia, malaise, flu-like episode, abdominal pain.
- Immune system disorders
Allergic-type reactions such as pruritus, rash, urticaria, difficulty breathing, hypotension.
Serum sickness.
- Musculoskeletal and connective tissue disorders
Myalgia, arthralgia, cervical pain.
- Nervous system disorders
Headache, loss of consciousness, tremor.

Additional Adverse Events:

Post-marketing reports of glomerulonephritis, neutropenia, bilateral retinitis, and polyarthritis have been reported in patients who had also received other vaccines; however a causal relationship has not been established.

DOSE AND ADMINISTRATION

Before administration, parenteral drug products should be checked visually for any deviation from normal appearance including container integrity. The syringe or vial and its packaging should also be inspected prior to use for evidence of leakage, premature activation of the plunger, or a faulty tip seal. If evidence of such defects are observed, the syringe should not be used.

For intramuscular use only. Do NOT inject intravenously.

Typhim Vi vaccine is indicated for persons two years of age and older.

The immunizing dose for adults and children is a single injection of 0.5 mL. The dose for adults is given intramuscularly in the deltoid, and the dose for children is given IM either in the deltoid or the vastus lateralis. The vaccine should not be injected into the gluteal area or areas where there may be a nerve trunk.

A reimmunizing dose is 0.5 mL. Reimmunization consisting of a single dose for US travelers every two years under conditions of repeated or continued exposure to the *S typhi* organism is recommended at this time.¹

The syringe is intended for single use only, must not be reused, and must be disposed of properly and promptly following its use.

The skin at the site of injection first should be cleansed and disinfected. Tear off upper seal of vial cap. Cleanse top of rubber stopper of the vial with a suitable antiseptic and wipe away all excess antiseptic before withdrawing vaccine.

STORAGE

Store between 2°– 8°C (35°– 46°F). DO NOT FREEZE.

REFERENCES

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6. Keitel WA, et al. Clinical and serological responses following primary and booster immunization with *Salmonella typhi* Vi capsular polysaccharide vaccines. Vaccine 12: 195-199, 1994

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