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Update on Efficacy of Generic Finasteride

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Finasteride 5mg was approved by the U.S. Food and Drug Administration (FDA) in 1992 for the treatment of benign prostatic hyperplasia, and in 1997 for male pattern hair loss (MPHL) in the 1mg dose. For many years, because of cost and availability issues of finasteride 1mg, physicians, especially outside of North America, have suggested that patients divide brand or generic 5mg finasteride into quarters. Recently, numerous hair transplant physicians have commented on anecdotal reports by their patients of increased shedding and progressive hair loss noted after changing from brand to generic finasteride 1mg. This raises several questions about generic medications: how does the efficacy compare to brand, how are generic drugs regulated, are there variations among generic manufacturers, and is the active ingredient evenly distributed in the tablet?

Using bioequivalence as the basis for approving generic copies of drug products was established by the "Drug Price Competition and Patent Term Restoration Act of 1984," also known as the Hatch-Waxman Act. This Act expedites the availability of less costly generic drugs by permitting the FDA to approve applications to market generic versions of brand-name drugs without conducting costly and duplicative clinical trials. At the same time, the brand-name companies can apply for up to five additional years longer patent protection for the new medicines they developed to make up for time lost while their products were going through the FDA's approval process. Brand-name drugs are subject to the same bioequivalence tests as generics upon reformulation.

According to the FDA website, a generic drug is identical or bioequivalent to a brand-name drug, and must follow the same standards as the innovator drug:

- Contain the same active ingredients as the innovator drug (inactive ingredients may vary).
- Be identical in strength, dosage form, and route of administration.
- Have the same use indications.
- Be bioequivalent.
- Meet the same batch requirements for identity, strength, purity, and quality.
- Be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products.

In order to obtain FDA approval to market a generic drug, companies must submit an abbreviated new drug application (ANDA). The ANDA process does not require the drug sponsored to repeat preclinical (animal) and clinical (human) research on ingredients or dosage forms already approved for safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug). Bioequivalence is often demonstrated by studies measuring the time it takes the generic drug to reach the bloodstream in 24-36 healthy volunteers. This determines the rate of absorption, or bioavailability, of the generic drug, which is then compared to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug. Bioavailability is usually assessed by measuring the area under the plasma concentration-time curve (AUC).¹

For FDA approval, a generic manufacturer must demonstrate that the 90% confidence interval for the ratio of the mean responses (usually of AUC and the maximum concentration, C_{max}) of its product to that of the brand-name drug is within the limits of 80% to 125%. While AUC refers to the extent of bioavailability, C_{max} refers to the rate of bioavailability.²

The 80-125% criterion is used to compare two treatments to evaluate bioequivalence. The bioequivalence test states that we can conclude that two treatments are not different from one another if the 90% confidence interval falls completely within the range 80-125%. The 80-125% criterion cannot conclude that the drugs are the "same," only that they are not "different." For drugs with a narrow therapeutic index range, small differences in dose or serum concentration may have therapeutic failures or adverse events, and the acceptance range of 80-125% may need to be smaller.³

PLAN TO ATTEND!

www.ishrs.org/AnnualMeeting.html



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President's Message

Sharon A. Keene, MD, FISHRS *Tucson, Arizona, USA* skeene@ishrs.org



I am pleased to share with you that ISHRS member response to the new affidavit, confirming our members' commitment to performing "critical to quality" aspects of surgery themselves, has been a success. Current membership renewals remain at the same high percentage rate, and overall membership continues to grow. I would like to express my personal appreciation to all those who have shown their support for this important policy.

There have been occasions where respected peers have had to re-think their practice management approach, understanding there is no way to allow unlicensed technicians to perform surgery "under their watchful eye" without contributing to the growing problem of unlicensed medical practice, and violating the ISHRS position that unlicensed personnel should not be making incisions or excisions on any patient. Patients who seek hair restoration surgery deserve and expect to have a hair restoration doctor perform their surgery. But just as importantly, we have yet to identify a legal governing body in any country that supports unlicensed medical personnel performing incisions/excisions on a patient.

Recently, there have been questions raised regarding robotic operations in hair restoration surgery (HRS). This issue has been discussed with several of our members who have been operating robots. In particular, Past President and Follicle Award recipient Dr. Paul Rose has been a strong supporter of the ISHRS position to curtail the activity of unlicensed technicians in HRS. He has recently clarified his support for the ISHRS policy that requires all incisions and excisions be under the control of a licensed medical professional practicing within their legal capacity. He made clear he supports a paradigm where only licensed medical providers would operate the controls of this sophisticated and complex machine. It is the case that just because unlicensed personnel could be trained, doesn't mean they should be trained to do this. Past experience has shown that allowing this type of behavior fostered improper activity where some technicians actually performed surgery for doctors who did not know how to do it themselves. As was shared previously, HRS embodies more than the technical aspects of surgery—appropriate diagnosis, pre-operative care, intra-operative management of medical issues, and post-operative care depend on appropriate medical education and training. In other fields where complex machines are used, such as radiology, technicians are required to have education, certification, and licensure as well as continuing medical education requirements.

While many hair restoration surgeons feel they have talented and loyal staff—individuals who could "learn anything"—that is not how medical licensure works. Patients and governments do not allow us to legally "lend our license"—even to those who we think are skilled and intelligent—if they haven't earned the right to practice medicine. Most doctors could teach a patient with high blood pressure what medications to use to control their blood pressure or how to treat their asthma, but we do not allow patients to prescribe to themselves. The same is true for many minor surgeries; a trained patient could do it themselves, but we don't allow that. Governments grant medical licensure to individuals who have the ability to integrate complex medical information because they have completed necessary education, testing, and training, and have promised a commitment to continuous medical education, ethical devotion to a patient's best interests, and are subject to medical board oversight.

Increasingly, fewer members recall the "old days" of punch and plug surgery. When done poorly it could be very disfiguring; when done with mediocrity, it could still be unsightly. Today, with follicular unit grafting, even some of the most mediocre transplant results do not result in disfigurement—just disappointing cosmesis for patients who are learning to have high expectations, and sometimes a waste of donor hair. Nevertheless, despite innovations in surgical techniques, devastating consequences remain possible with improperly performed surgery or poor patient selection. One of the planned sessions at our annual meeting will review surgical complications—some

Co-editors' Messages

Mario Marzola, MBBS *Adelaide, South Australia* editors@ISHRS.org

Professor Rodney Sinclair was a featured speaker at our Kuala Lumpur conference last year. Currently, I have been helping him to add surgical hair restoration to his well-established practice of general dermatology and medical hair restoration in Melbourne, Australia. What a stark reminder this has been of just how many little things are needed to get it going. So much has to fall into place before we can perform an operation with any degree of comfort, let alone to any great standard. The Operating Room table, the chairs, the lights, the microscopes and their lights, all the instruments, disposables, drugs, drapes, feeding and watering the patient and staff, the music for ambience, and of course, good coffee! Staff? Yes, staff is the most important and most difficult. Good, experienced, reliable, caring, and professional staff is gold. Thankfully, Dr. Russell Knudsen, who also practices in Melbourne, has allowed us to use some of his surgical technicians when they are not needed in his office. Together with my staff we are gradually building local knowledge from the ground up. Don't let anyone tell us that hair restoration surgery is a simple procedure. To achieve anywhere near high standard results takes an enormous amount of organization without too many compromises. So many things can conspire to diminish the experience and outcome for us and the patient. As Murphy said... if it can go wrong, it will go wrong.

It's been a big challenge and still is, so why do it? Well quite simply the ethos in Professor Sinclair's office of con-

tinual questioning, teaching, and learning is addictive. Post graduate students and researchers abound, so brain stretching conversations happen every day.

Your editors are very happy with our new column, "Ask the Fellows." What a brilliant way of checking something that may have concerned us recently. All available with a quick scan over the subjects that we can pass or home into depending on our interest. They are well written and concise and showcase the depth of knowledge we have in the ISHRS, which is also freely shared. A warm thank-you to all our contributing Fellows.

Because our patients need to take finasteride over a long time, it is understandable that they seek the most economical way of sourcing the drug. In our lead article, Dr. Edwin Epstein describes all the problems that may arise with the use of generic finasteride and in tablet splitting. This is good basic knowledge that will guide us in our directions to our patients. We've been taught to look for counterfeit dollar notes but now counterfeiting drugs may also become a problem.

We hope you enjoy reading our second issue for 2015, packed as usual with news and views. ♦



Robert H. True, MD, MPH, FISHRS *New York, New York, USA* editors@ISHRS.org

How would you reply to this question from a patient? "Doctor, after my surgery, can I shave my head without there being any way for others to see that I had a hair transplant?" I have to answer this question based on my own experience with both FUT and FUE by answering, "Probably not. Most, if not all, patients will have to leave their hair 2–3 mm or longer to conceal signs of harvesting by either method." I think many of us do have patients in our practices who heal so well with trichophytic scars and with well dispersed small punch FUE that it is truly difficult to see the scars when the head is shaved. However, I do not see how any of us could answer this patient question with an unequivocal "Yes." If you disagree, and can show evidence to the contrary, please write to us.

Related to this question, is the promise of "scarless surgery." Unfortunately, the advertisement of FUE as scarless surgery has become relatively commonplace. There are even some who advertise and promote FUE as a "non-surgical" treatment. On an objective level, such claims are just medically false. Biopsies of extraction sites do show scarring. Therefore, such advertising is misleading and unethical. I see many young men in my practice who come to me for an opinion about their "unsightly scarring" from FUE procedures performed elsewhere. For many of these patients, I do not see scarring and spotty hairless areas beyond the norm with well-performed FUE, however, they feel they were misled because they had been told there would be no scar even with their head shaved.

I have also had some patients in my practice, despite my telling them there are scars with FUE, who also feel that they have to wear their hair longer than they want to conceal the extraction sites.

As physicians who seek to be ethical practitioners, we all owe it to our patients and to the public perception of the integrity of our profession to be fully honest and forthcoming in describing and promoting our services. I believe the ISHRS can and will take a stand on this issue, something I will welcome. But it also is incumbent for each of us individually to assure our own practices measure up in ethical advertising and also to challenge those practitioners who are in clear violation, whether they be members of the Society or not.

I hope and expect you will enjoy this issue of the *Forum*. Thanks to our excellent contributors, there are some very interesting articles. Remember this is the *Forum*, which means we depend on you and our membership to share opinions and experiences. Please consider making a submission. ♦



INTERNATIONAL SOCIETY OF HAIR RESTORATION SURGERY

Vision: To establish the ISHRS as a leading unbiased authority in medical and surgical hair restoration.

Mission: To achieve excellence in medical and surgical outcomes by promoting member education, international collegiality, research, ethics, and public awareness.

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Editorial Guidelines for Submission and Acceptance of Articles for the Forum Publication

- Articles should be written with the intent of sharing scientific information with the purpose of progressing the art and science of hair restoration and benefiting patient outcomes.
- If results are presented, the medical regimen or surgical techniques that were used to obtain the results should be disclosed in detail.
- Articles submitted with the sole purpose of promotion or marketing will not be accepted.
- Authors should acknowledge all funding sources that supported their work as well as any relevant corporate affiliation.
- Trademarked names should not be used to refer to devices or techniques, when possible.
- Although we encourage submission of articles that may only contain the author's opinion for the purpose of stimulating thought, the editors may present such articles to colleagues who are experts in the particular area in question, for the purpose of obtaining rebuttal opinions to be published alongside the original article. Occasionally, a manuscript might be sent to an external reviewer, who will judge the manuscript in a blinded fashion to make recommendations about its acceptance, further revision, or rejection.
- Once the manuscript is accepted, it will be published as soon as possible, depending on space availability.
- All manuscripts should be submitted to editors@ishrs.org.
- A completed Author Authorization and Release form—sent as a Word document (not a fax)—must accompany your submission. The form can be obtained in the Members Only section of the Society website at www.ishrs.org.
- All photos and figures referred to in your article should be sent as separate attachments in JPEG or TIFF format. Be sure to attach your files to the email. Do NOT embed your files in the email or in the document itself (other than to show placement within the article).
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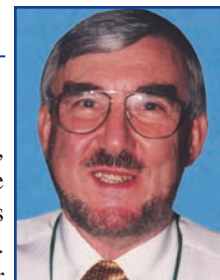
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 October 5 for November/December 2015 issue



Notes from the Editor Emeritus

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*Don't throw the past away
You might need it some rainy day
Dreams can come true again
When everything old is new again*

So goes the 1974 song penned by my fellow countryman Peter Allen in conjunction with American singer Carole Bayer Sager. So it is also with hand-operated biopsy punches and scalp reductions. I thought I had demonstrated the superiority of motorized punches as far back as the 1970s when I introduced our ultra-sharp carbon steel Australian punches to the Hot Springs meetings in 1975 and 1979. I did not bother to take out a patent and they were copied extensively throughout the world.

At around the same time, many of us agreed that around 3.5mm was the smallest size punch that could be reliably cut without causing follicular damage. Pierre Pouteau, the celebrated and vastly experienced Parisian transplanter, was using 2.0mm punches, which certainly gave a less tufted effect, but his growth rate per graft seemed unacceptably low to me. I was wrong again, and the "top guns" of today are using dull punches of 0.8mm diameter and a claimed transection rate as low as 3%. I notice that they do not claim it is easy, and I wonder how the average HT surgeon scores with this meticulous procedure?

Now let us turn our attention to the scalp reduction or alopecia reduction operation, which has been virtually "dead" since 1996. This was introduced to the hair transplant world by the Blanchard Brothers of Montreal and Dr. Martin Unger of Toronto almost simultaneously in 1978. A more widely read paper on the same subject by surgeons at the Bosley Clinic in Beverly Hills served to further promote this procedure. Around 1980, it took off with patients and surgeons alike and within 2 years the Transform Clinic in the UK, of which I was Director of Surgery, had done 2,000 cases. By 1983, I was regrettably able to coauthor a paper on the complications we had seen.

The big attraction was that within 30 minutes the patient could rise from the operating chair minus about 35cm² of his baldness. This procedure could be repeated at intervals of 3-6 months. Like most miracles, there were drawbacks and the residual scalp could stretch back some 30-50% in this period. Note that this stretch was in the adjacent scalp, not the central scar, which was generally less than 1mm wide. Thus, to remove a 10cm bald area was not possible in 3 procedures of 3.5cm each, but because of the stretchback and increasing tension within the scalp, it could take 4, 5, or even 6 operations to close the bald area (typically 3.5 + 3.0 + 2.5 + 2.0 + 1.5cm).

Dr. Patrick Frechet later introduced an ingenious Scalp Extender, which was inserted under the scalp to speed up the process by increasing the advancement of the hairy sides and preventing stretchback. This enabled him to remove a 10-12cm bald area within 3 surgical procedures.

The other problem was that the more one tried to close the bald area, the more the hair direction appeared to be abnormal and, with a central scar, the patient looked as if he had been struck on the head with a meat cleaver. A variety of different

surgical approaches were introduced. C, J, Y, U, and M shape excisions were the most popular, but each had its drawbacks and one was still left with a detectible scar. Z-plasty only seemed to make the scar worse so the ever-inventive Dr. Frechet developed his ingenious Triple Flap procedure and received our 1st Annual Golden Follicle Award for his efforts in 1994. The only drawback was that although the procedure worked well in the hands of Dr. Frechet, very few had his touch and experience, scalp reductions were becoming unpopular, and the method gained very few adherents. More would have tried had it not been that "mini-grafting" from scalp strips was slowly creeping onto the scene and was being refined by microscopic dissection of the actual follicular units. While labor-intensive, it was safe and much of the work could be delegated to trained staff. Furthermore, the final results were extraordinarily natural in appearance.

This is the situation we have reached in 2015. Although experiments continue with attempts to prevent temporary loss of transplanted hair and speed up the procedure with robotic machines, there seems to be no move to return to reductions and flaps.

Should we be doing more scalp reductions and flaps?

I put this question to former AR guru and ISHRS Past President Mario Marzola and in part his reply was:

"I don't think the routine alopecia reductions will ever make a comeback! The same applies to flaps and 4mm grafts. In accidents or burns or large excisable areas of scarring alopecia, maybe there is still a place, and certainly in hairline lowering where, associated with scalp expansion, it still has a role."

It is a fact that undesirably high hairlines in females can be easily moved a centimeter or two by a frontal advancement procedure (even more with prior insertion of an inflatable tissue expander). The residual scar is barely detectible and seldom requires improvement. Unwanted transplants or frontal scars in men can similarly be removed with one or two easy procedures.

Another former *Forum* Editor and ISHRS Past-President Russell Knudsen commented:

"I think that AR is now a repair procedure for those who know its value and have been trained in how to do it correctly. Lateral AR can 'lift' the balding margin to the previous grafts or remove cicatricial alopecia. Not much other value I am afraid. If used in extensive male pattern baldness to 'reduce' the bald area, it must have widely spaced galeal sutures to minimize stretchback as described by the late Dr. Gerard Seery in 1997. I don't know of anyone doing this today. Of course, strip surgeons doing 3,000+ grafts practice the same technique in the donor area. Can we call this 'donor reduction'?"

Lateral, posterior, and U-shaped reductions are still employed to help bridge an area of baldness that has appeared since the first transplants some decades earlier. Hopefully, the use of finasteride

Editor Emeritus *from page 57*

over the past 15 years has minimized this baldness progression, but there are probably a vast number of former patients who have not used the drug or who even know about it.

Should Reduction techniques be taught at ISHRS teaching courses?

I believe that this should be occurring regularly, rather than adventurous young surgeons working alone without the benefit of our vast collective experience. As far as I know, I was the only person to perform a scalp reduction at a hair meeting within the past 20 years (Sydney, 2005). Drs. Marzola, Martin Unger, and I did three to packed operating rooms and temperatures of 90+ degrees at a meeting in Rio de Janeiro in 1992. The procedure was not made easier by large video cameras lenses almost at the wound margins and massive bleeding due to the heat. Although a relatively simple surgical procedure, there are the usual traps for young players and valuable tips can be passed on by those of us who have learned from experience. I have seen more serious flap and reduction problems caused by overconfident Plastic Surgeons without specific training than by members of the more cautious and trained hair transplant fraternity.

Medico-Legal Barriers

A recent barrier to the use of alopecia reduction and advancement and pedicle flaps has been instituted by our Medical Insurers. Many modern policies will only permit Board-certified surgeons to perform these procedures or alternatively they charge a much higher annual premium for others who plan to do them. The fact that strip removal and any associated undermining prior to closure is almost identical to a scalp reduction seems to have “slipped under the radar.” Perhaps this is why all hair transplantation in places like France and Singapore is now restricted to Plastic Surgeons.

Bibliography

See the excellent book chapters listed below for detailed accounts of past and present ancillary procedures and many references.

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2. Marzola, M. Surgical Female Hairline Lowering. I In: S.M. Lam, Ed. *Hair Transplant 360*. JayPee Press, 2014. (with accompanying DVD)◆

President's Message *from page 54*

caused by unlicensed technicians performing hair restoration surgery. Unlicensed technicians generally do not see patients in follow-up to know when they make an error. In contrast, we as doctors are accountable and must learn from our mistakes. I would like to encourage all members to gather any cases they feel will assist in this learning process and submit them for the planned Complications Panel at the annual meeting in Chicago.

Despite our ongoing efforts to eliminate the unlicensed practice of medicine among former doctors' assistants—most of whom were at one time employed by hair restoration doctors, the ISHRS recognizes the majority of our staff are honest, loyal, and respected team members. We continue to reward them with special recognition at our meetings, and to encourage their participation in training fellow assistants at sponsored workshops. It is with great pride that the ISHRS in conjunction with Dr. James Harris is sponsoring the first “stand alone” Surgical Assistants

Workshop. I encourage anyone who has recently hired new staff to utilize this valuable training opportunity.

Finally, for those who have been reading the series on low level laser therapy (LLLT), the third and final part has been completed, but for space constraints will not be included until our next edition. I do not promote or critique any one device. My intention with this series was to educate and elicit a critical look at the science as well as the devices that apply it, in order to assist members in making their own decisions and recommendations to patients. Hopefully, every doctor will be able to determine whether a particular device may be helpful to treat hair loss for their particular patient. What I can say for certain, questions remain about the optimal device and dosing schedules, and like clothing—no matter what the tag may say—there is no such thing as “One size fits all”!◆

**ISHRS 2015 PRACTICE CENSUS**

On a biannual basis, the ISHRS collects practice data from members in an effort to analyze trends and properly report to media on the state of Hair Restoration Surgery. The 2015 Practice Census Survey will be e-mailed to ISHRS Physician Members in April. We ask that you please complete the survey. It is very important to get a solid response rate.

It is shorter in length this year, and we are offering several incentives for participation. The data report will be released to all members and published on the ISHRS website.

Thanks in advance!

Generic Finasteride *from front page*

The Federal Food, Drug and Cosmetic Act (FFDCA) established the “180-day exclusivity” period, during which the FDA will not approve other ANDAs for the same product. Dr. Reddy’s, an international generic pharmaceutical company based in India, was awarded a 180-day period of marketing exclusivity for finasteride 1mg on January 2, 2013, which expired on July 1, 2013. Since then, the following generic manufacturers also produce finasteride 1mg and 5mg: Accord Healthcare Inc., Actavis, Aurobindo, Camber, Hetero Labs, Mylan, Sun Pharma, Teva, and Zydus (5mg).

Increasingly, generic pharmaceutical active ingredients are made outside of the United States. This has raised concerns about drug quality and regulation in various countries, and the potential for counterfeit drugs. The FDA reported that 40% of finished generic drugs, and 80% of active ingredients, are coming into the United States from overseas sources.⁴ In July 2012, Congress passed the Food and Drug Administration Safety and Innovation Act (FDASIA). In summary, it allows the FDA to inspect foreign facilities, to increase penalties for adulterated or counterfeit products, and to collect user fees from industry to fund the reviews of innovator and generic drugs, medical devices, and bio-similar products, and to expedite the development, review, and approval of “breakthrough therapies.” On February 14, 2014, The New York Times published an article titled “Medicines Made in India Set Off Safety Worries,” which noted that “India is the second-largest exporter of generic and OTC drugs to the U.S., supplying 40% of the US market.” They reported that the FDA has increased inspection of Indian plants, with new penalties and warning letters, and expressed concerns about potential counterfeit operations in China, and frustration with their efforts to increase inspections.

Counterfeiting occurs throughout the world, but it is most common in countries where there are few or no rules about making drugs. An estimated 10-30% of medicines sold in developing countries are counterfeit. In the industrialized world (countries such as the United States, Australia, Japan, Canada, New Zealand, and those in the European Union), estimates suggest that less than 1% of medicines sold are counterfeit.⁵ The only way to know if a drug is counterfeit is through chemical analysis done in a laboratory. Counterfeit drugs may look strange or be in poor-quality packaging, but they often seem identical to the real thing. In March 2013, the FDA formed a new Cyber Crimes Investigation Unit, a special team within their Office of Criminal Investigations (OCI), devoted to combating rogue Internet pharmacies. This unit works with other domestic and international agencies to track down the operators and suppliers of websites that illegally sell prescription drugs.

Tablet splitting is a widespread practice to allow for dose flexibility and cost advantages for consumers. On July 21, 2009, the FDA posted “Tablet Splitting: A Risky Business” on its consumer site (www.FDA.gov), which noted: “FDA does not encourage the practice of tablet splitting unless it’s specified in the drug’s professional prescribing information. If a patient is considering splitting a tablet, FDA recommends that the patient gets advice directly from his or her doctor or pharmacist to determine whether it is appropriate or not for a particular drug.” Possible risks to consumers include confusion over the dose, as people may forget to split them, and tablets may be difficult to



The many different pill shapes and sizes.

split evenly due to size, shape, and technique. Several studies have shown weight variability of unscored split tablets, even those split by pharmacists.⁶ These concerns are especially relevant in drugs with a narrow therapeutic index.

Concerning the practice of splitting finasteride 5mg, two issues come into question: How evenly distributed is the drug in half or quarter fragments, and does splitting affect the clinical outcome? The U.S. Pharmacopeial Convention (USP) sets the standards for identity, strength, quality, and purity of medications, which are enforced by the FDA. The amount of active drug is never 100% evenly distributed in any tablet. One study looking at the uniformity of distribution of finasteride in 5mg halves and quarters showed a high mean average content in both (2.88, 1.33).⁷ Another study concluded that drug content variation in half-tablets appeared to be attributable primarily to weight variation during the splitting process, highly determined by the ability of patients to split tablets perfectly in half.⁸ A Veterans Affairs study noted that 4/12 products that failed the weight-uniformity test when split in halves, varied in tablet shape and hardness.⁹ Splitting devices also vary in quality and design. Among various manufacturers, finasteride 5mg tablets vary in size and shape; thus fragmentation, powdering, and fragment loss may occur with splitting. In addition, patients should be advised not to split more than one pill at a time to be stored for later use as exposure to heat, moisture, humidity, and other factors could affect drug efficacy.

A review of the clinical pharmacology of finasteride is relevant to its therapeutic index range. Finasteride is a competitive and specific inhibitor of Type II 5 α -reductase with preferential inhibition of the Type II isozyme, and is 100 \times selective for the Type II 5 α -reductase over Type I isozyme. For both isozymes, the inhibition by finasteride is accompanied by a reduction of the inhibitor to dihydrofinasteride and adduct formation with NADP⁺. The turnover for the enzyme complex is slow (t_{1/2} approximately 30 days for the Type II enzyme complex and 14 days for the Type I complex). This may explain its long relative clinical effect on hair loss. In terms of absorption, Merck’s original study in 15 healthy young male subjects, the mean bioavailability of finasteride 1mg tablets was 65% (range 26-170%), based on the ratio of area under the curve (AUC) relative to an intravenous (IV) reference dose. Relative to an

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intravenous reference dose, the oral bioavailability of finasteride is approximately 80%. The bioavailability is not affected by food. Maximum finasteride plasma concentrations are reached approximately two hours after dosing and the absorption is complete after 6-8 hours. The mean terminal half-life is approximately 5-6 hours in men 18-60 years of age and 8 hours in men more than 70 years of age.¹⁰

The concerns of adverse events and post-finasteride syndrome have initiated discussions among physicians in terms of titration of dose to potentially reduce symptoms, or patient concerns over potential side effects, yet still maintain efficacy for hair loss. In the original dose ranging study with finasteride for male pattern hair loss,¹¹ efficacy was demonstrated at 0.2mg for all end points including hair count, investigator and patient self-assessment of hair growth, and global photography. Efficacy results were similar at 1mg and 5mg doses, which were superior to the 0.2mg dose. Some suggested regimens are ¼ tablet every other day, ¼ three times per week, and a “titration” program of 1mg per week for 1 month, 1mg twice a week for 1 month, then 1mg every other day. Fewer side effects and better patient compliance, without reduced efficacy, have been observed.¹² However, controlled clinical trials using 1mg, 5mg, and placebo arms have not shown a dose-dependency relationship for sexual side effects in both androgenic alopecia and benign prostatic hyperplasia age groups.^{13,14}

Several hair transplant surgeons anecdotally report comments from patients that shedding occurred after switching from brand to generic finasteride, or the generic seemed less effective. Explanations for this might include placebo effect, counterfeit drug, or quality control differences in batches or processing. Based on my research of FDA requirements for generic approval, and the relative long effective half-life of finasteride Type II isozyme complex, the splitting of generic finasteride 5mg should be an equally effective alternative to the 1mg generic, or to the brand-name drug, despite the potential for fragment loss during splitting.

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