President’s Message

Can a medical business be ethical and financially successful?

In the latest ISHRS Needs Assessment Survey, members called for improved measures to contribute to higher ethical standards and enhanced professional credibility. Having taken the Hippocratic Oath, ethical standards should be integral to everything we do. Many physicians struggle to balance the notion that ethics can be accommodated in a profit-making medical practice. I believe rather than viewing ethics and running a profitable practice as separate and conflicting issues, the two are almost symbiotic.

The six values of Medical Ethics are:
1. Autonomy—the patient has the right to refuse or choose their treatment
2. Beneficence—a practitioner should act in the best interest of the patient
3. Non-malefianence—“first, do no harm”
4. Justice—fairness and equality
5. Dignity—the patient and doctor have the right to be treated with dignity
6. Truthfulness and honesty—the concept of informed consent

Modern Business Ethics are based on the Triple Bottom Line:
1. People—social
2. Planet—ecological
3. Profit—economic

As medical practitioners, we have learned the technical skills to remain ethical in medicine. As ISHRS members, we have learned to deliver the “gold standard” in surgical hair restoration. However, we have not been taught the skills to maintain a stable and financially successful business. Hence, I am keen to encourage more programs for educating members in practice management.

Already, at hair-related meetings around the world, we are seeing higher demand for programs to teach our physicians business skills. Recent meetings in Turkey, Thailand, and India have all included lectures that deal with business management.

Practice management and other business skills provide valuable support tools for upholding high ethical and medical standards. If you have the business skills to run a business-oriented medical practice with sustainable cash flow and ongoing financial stability, there is less pressure to cut corners both medically and financially to make ends meet. Cutting corners in medicine and business inevitably leads to unhappy patients and poorer medium- to long-term professional standing and financial results.

The “Gold Standard” in hair restoration is delivered by physicians who practice the highest attention to detail, who commit to their own ongoing professional development while also investing in staff training. A physician’s ability to consistently do this is certainly dependent on skill level and ethics, but also on employing the business principles that will support this vision. The public rightfully demands transparency and accountability. Therefore, maintaining your professional reputation is imperative.

Talk of profits does not sit comfortably with many doctors, particularly those of us who are old enough to remember 1980’s style Gordon Gekko “Greed is good” mantras. But the business community has learned that while deceptive practices and unrestrained greed may bring short-term profits, the pain caused almost certainly results in inevitable demise. Hence, all financial and business systems need to be shaped by a strong ethical framework.

Continually attracting our patients’ discretionary dollar depends on our ability to deliver a high standard of surgical hair transplant coupled with the ability to market ourselves to the public. It is fitting that modern business practice now promotes the principles of not causing unwarranted harm, fairness principle, preserving human rights principle, autonomy and veracity. The modern business principles outlined here are not discordant with our own medical values. When shaped by appropriate business principles, it is possible to run a profitable medical business that provides a strong framework for exemplary ethical standards and the surgical excellence the ISHRS so proudly promotes.

Any feedback from our membership regarding the above paradigm would be appreciated.
Co-editors’ Messages

Nilofer P. Farjo, MBChB Manchester, United Kingdom editors@ISHRS.org

When I look at what 2012 has in store, I am pleased to see that hair transplantation continues to be the focus of media attention. The past couple of years have brought reports of a number of celebrities speaking freely about their hair or hair surgery. This has been great for business and it has also resulted in an increase in doctors wanting to train in our field. Unfortunately, though, many of these colleagues have never seen a hair surgical procedure or read anything about hair loss. There isn’t a week that goes by that we are not contacted by someone wanting to train. The spectrum of doctors contacting us is very wide, ranging from juniors who have not yet completed their post-graduate training to those who one would think are ready to retire. Although we don’t offer a fellowship course, we do invite doctors to come and observe for a day. It is amazing the number who come along thinking that this is an easy procedure that takes a couple of hours to do. They are clearly just jumping on the bandwagon without necessarily a true interest in hair loss. One country in particular where there is a boom in hair restoration is India. An Indian dermatologist in the UK planning to return to India and open a private practice was told don’t even consider it unless you offer hair transplants!

With this boom and the resulting Internet frenzy to grab patients by offering cheap deals, many people are travelling abroad for lower prices. This is great if you do your background checks and make sure the doctor and facility has a good reputation. But if Joe Public just wants a cheap transplant then that’s what they’ll get. Groupon (a web based company that offers deals of the day) has recently started getting clinics to offer cheap online vouchers for surgery as low as £1000. But what do you get for this? My concern with this “boom mentality” is that there is a resultant drop in standards. Recently, I saw a well-established hair restoration clinic advertising that they will come to your home to perform the procedure if you are a celebrity (something that is illegal in the UK). Well we know of one very high profile celebrity where this home treatment went sadly wrong and the doctor is now in jail.

Maintaining standards in a fickle world may be considered difficult but as doctors we have a duty of care to our patients. Not only is this true if we have our own practice but more so if we work for someone else. The media may be doing us a favour at the moment but it takes only one bad case to have them turn against us. Just look at the fervour surrounding the PIP breast implants. The company that produced the implants is quite rightly being prosecuted for using non-medical grade materials even though the evidence that they are harmful is tenuous. With all the press coverage associated with these implants, governments have now had to act to reassure the public. Luckily for us with the finasteride scares, there have been some recent studies that have backed up the original clinical trials on safety (see Dow Stough’s editorial). But this just shows how the Internet can easily work against you with one case of side effects turning into class action suits. So my message is that we must continue to strive forward in a positive way by maintaining standards and continually trying to improve our techniques. In this edition, we see how some of our colleagues are doing just that.

William H. Reed, MD La Jolla, California, USA editors@ISHRS.org

I appreciate how generous our members are with the time that’s required to share their ideas—it’s this group effort that keeps moving our specialty forward. This issue is case in point. There is much food for thought contained in each of the articles, and I encourage you to chew the food well.

An issue that has been of interest to me of late, is the question of whether we are doing all we can do to support graft survival. So, in addition to drying and crushing, what else can affect how we manage our grafts? Can something be learned from elsewhere in medicine? For instance, there is a rich literature concerning storage solutions and the physiology and biochemistry of the ischemic and post-implantation reperfusion stage, wherein the graft is waiting to be reconnected to the body’s circulation.

With increasing frequency, a growing number of physicians (e.g., Drs. Parsley, Cooley, Cole, the Farjos, Sadick, Ziering) have been lecturing on the importance of storage solutions or the biochemistry of the grafts resulting from the ischemia and their reperfusion after implantation. At the outset, I had the opinion that perhaps many of you have: interesting, but my grafts seem to grow well. I would be inclined to attribute the focal areas of poor growth that I occasionally saw to something that was being done by the technicians—drying while dissecting or placing or traumatic insertion—and I would try to address that with protocols and other quality control measures. Or perhaps it was something unusual with the patients such as sun damage, smoking or small vessel disease. However, thanks to the sharing of ideas, often via the ISHRS, I feel this subject of poor growth is far more complex and interesting than such simple hypotheses. In my opinion the surgeon needs to make as rich a buffer to poor graft growth as possible and that means both developing good quality control protocols as well as nurturing the cells in all stages of their transplantation.

Many issues open up when we start thinking about the biochemistry of transplantation and they spread outward to encompass much of our procedure. Take for instance graft density. It’s not difficult to see that the biochemistry of the recovering recipient area is radically different in 1 graft/cm² vs. 55/cm². Where is the safe zone for a satisfactorily large percentage of our patients? 20? 30? 40 grafts/cm²? Should they be chubby or skinny? How deep should the site be at what density? In no time at all your thoughts spin out from the physiology and biochemistry of ischemia and reperfusion to encompass the entirety of what we do. When your read Dr. Cole’s article on page 17, a deeper level of inquiry will open up to you and I encourage you to seek out the more detailed studies referenced.

Another topic discussed in this issue is whether the non-physician should be allowed to perform hair transplantation under the supervision of a physician. This will no doubt be the subject of much future discussion (and editorials) but, suffice it to say here, a physician can distinguish him/herself by applying what was uniquely given us by our education: the ability to delve into rather esoteric topics in biochemistry and physiology to help guide and interpret what we are seeing in our patients’ results.
January/February 2012

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Reed Message

(from page 3)

(for very few of us had a medical education that entitled us
to feel we deserved exclusive ownership of knowing what is beauty
and optimal aesthetics of hair.) Arguably, delving into subjects
such as graft survival is what can give the physician some rightful
claim for exclusive rights to perform hair transplantation.

So, is normal saline good enough for grafts that are out of
the body for 6-10 hours? “Yes” was the answer given in Boston
(October 2010) by a majority of ISHRS surgeons who were asked
how they stored their grafts and whether they chilled their grafts
(see Figures 1 and 2). Possibly we are managing our grafts opti-

mally, but, as you will discover in reading Dr. Cole’s article
in this issue, that would run counter to all of the transplant literature
of every other transplanted organ from the heart and lungs down
to the liver and kidneys to the intestines. I would think we
had better have good quality survival studies of grafted hair before
we ignore that body of literature and say, “Yes, chilled normal
saline is just fine.” I view questions such as this as very exciting
and enriching to the practice of what we love to do.◆

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

1. 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.

2. If results are presented, the medical regimen or surgical techniques that were used to obtain the results should be disclosed in detail.

3. Articles submitted with the sole purpose of promotion or marketing will not be accepted.

4. Authors should acknowledge all funding sources that supported their work as well as any relevant corporate affiliation.

5. Trademarked names should not be used to refer to devices or techniques, when possible.

6. 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.

7. Once the manuscript is accepted, it will be published as soon as possible, depending on space availability.

8. All manuscripts should be submitted to editors@ishrs.org.

9. 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.

10. 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).

11. We CANNOT accept photos taken on cell phones.

12. Please include a contact email address to be published with your article.

Submission deadlines:
February 5 for March/April 2012 issue
April 5 for May/June 2012 issue

Figure 1. How physicians handle grafts during dissection.

Figure 2. Percent of physicians who keep grafts chilled during the graft preparation process.
Battered and bruised, finasteride’s image has been tarnished by accusations ranging from inciting prostate cancer, depression, and permanent sexual adverse events to stimulating male breast cancer. It’s no wonder that hair transplant surgeons have paused in their routine prescribing habits. Class action lawsuits founded on anecdotal reports confirm that 5-ARIs now join the rest of the drugs on the planet as the subject of questionable lawsuits.

Recently, a silver lining has emerged with the advent of two studies on finasteride detailed in the following articles:


Both articles were published in the fall of 2011. These authors are to be congratulated on their original research and important contribution to the literature. A brief overview of each article follows.

### Sato Study

The Sato study is significant in that it involved over 3,000 men. This is the largest trial ever conducted with finasteride. The investigators evaluated the efficacy and safety of finasteride in Japanese men with AGA in a time period from January 2006 to June 2009. All men took the same dose of finasteride, 1mg per day. Of the 3,177 patients statistical parameters were obtained in 2,561 men by modified global photographic assessment; the photographs were assessed using the previously validated 7 point rating scale. Safety data was assessed by interviews and laboratory tests in all men enrolled in the study. They demonstrated that approximately 87% of men had experienced a positive effect on hair growth. The numbers break down as follows: 11.1% were classified as greatly increased, 36.5% as moderately increased, and 39.5% as slightly increased.

Were there any surprises in this study? Yes, the investigators found that the response rate improved with increasing duration of treatment. The authors noted that the proportion of greatly increased hair growth was relatively low in patients with hair loss duration of 10 years or more. However, more than 85% of patients with hair loss duration of 15-20 years or more exhibited moderately or slightly increased hair growth. Some well-known medical hair experts have stated that finasteride will not work well in men with long-standing hair loss. Time to re-evaluate those remarks! Keep in mind the difference between long-standing hair loss and advanced male pattern baldness. The former refers to duration and the latter to extent.

This study tells us that finasteride works fairly well across the board. Without going into great detail, the assessment methods that these authors used were standardized and involved fairly sophisticated statistical analysis performed with SAS software. Efficacy analysis was conducted using several demographic factors including age at first visit, age at onset of hair loss, duration of hair loss, treatment period, and the presence of stress.

### Classification Based on Pattern and Degree of Loss

It should be noted that classification by a category of “diffuse hair loss group” was necessary when dealing with an Asian population. The Norwood-Hamilton does not fit for the entire Asian population. The response rates among those classified with the Norwood-Hamilton Scale and those classified as diffused hair loss group were relatively the same (i.e., 87.1% and 86.8%), once again consistent with previous studies.

### Age at Onset of Therapy

When the patients’ response rate was calculated for the various age groups, it was fairly consistent, ranging from an 83.6% to 90.5% response. The efficacy of this drug proved itself across all age groups. While the original studies on finasteride were conducted in men 18-41 years of age, subsequent studies have confirmed a positive response of the drug well beyond the age groups indicated by the Propecia® prescribing information packet. We should now have confidence in prescribing this drug to men who are considerably older than 41 years of age.

### Duration of Hair Loss

When the patients were stratified according to the duration of hair loss, there were no surprising finds. The response rate was relatively even across all groups ranging from a 79.2% response rate for those who had hair loss for less than 1 year to a high of 89.8% for those with 20 years or more of hair loss. The latter deserves a discussion. It is felt by many hair restoration surgeons that individuals who have had 20 years or more of hair loss will not respond as well as those who have had hair loss for 5 years or less. Such was not the finding of the study and this should merit a moment of applause. This drug works well in those with early (less than 5 years) as well as those with greater than 5 years of hair loss.

### Adverse Reactions

The safety evaluation of adverse reactions was recorded during the entire study. It seems a bit unusual that adverse reactions occurred in only 0.7% of the population (23/3,177) during the entire study. I would have expected a slightly higher incidence of adverse events. The reactions reported include decreased libido (N=8), hepatic disorder (N=3), and unilateral mammary hypertrophy (N=2). Seven of the 23 patients classified with adverse events discontinued treatment due to the adverse reactions. These included decreased libido (N=3); hepatic functional disorder, disturbance of memorization, and unilateral mammary...
Notes from the Editor Emeritus

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hypertrophy (N=1 each); and palpitations and headache (N=1). The investigators classified the adverse reactions as mild and stated that some of the follow-up data is unknown because of loss of contact with participants. Keep in mind that during the entire period of the study the patients were queried as to their adverse reactions. It would be interesting to go back to this 3,000+ group of Japanese men and once again inquire of any persistent adverse reactions.

The discussion section of the paper is well written in their review of previous studies. The authors make the following comments:
1. The present study was conducted for 3.5 years in 3,177 men.
2. Finasteride maintained a higher response rate of more than 80% even after a 2-year treatment period. The response rate may be due to the fact that Japanese men have hair of less density, larger diameter, and black color of the hair shafts. This will show a marked contrast of color of hair compared to the thinner and lighter color of the scalp and hair in Caucasians. Therefore, subtle changes in scalp hair growth in the Asian population can be easily identified by a global photographic assessment leading to a higher response rate in these men.
3. The response rate improved with increasing duration of treatment.
4. There was no increase in the incidence of adverse reactions due to longer treatment time periods.

Rossi Study

Next, from the Department of Dermatology and Plastic Surgery, University “Sapienza” of Rome CASPUR (Inter-University Consortium for Supercomputing), Italy comes a much needed study to assess efficacy of finasteride in men with androgenic alopecia treated for more than 5 years.

As previously shown, finasteride 1mg was well tolerated and the long-term treatment led to sustained improvement in hair growth in maintenance parameters. Like the Sato study, this study also demonstrated that subjects older than 30 years demonstrated better hair growth over the long term. Once again, finasteride efficacy was not reduced over time. This was especially noted in the older group. The following points are worth highlighting:
1. Out of the 113 patients followed for 10 years, only 14% worsened.
2. 86% of patients benefited from treatment.

Side effects were observed on 5.9% of patients. This equated to 7 patients out of 113. A total of 4 patients elected to stop treatment due to reduced libido and 4 elected to stop treatment due to erectile problems.

There is so much good data and findings from the Rossi study that it is difficult to criticize the investigators. However, this Editor Emeritus did have considerable problems with the interpretation of their statistical analysis. Readers may have difficulty discerning the detailed transitional probabilities listed in the tables. Perhaps the more scholarly statistical-minded individuals in our Society would care to publish an explanation and interpretation of the tables presented in this article.

Finally, mention needs to be made to another Japanese study, “Oral finasteride improved the quality of life of androgenetic alopecia patients” (Yamazaki, M., et al. J Dermatol. 2011; 38(8):773-777). This study was conducted in order to ascertain whether treatment by oral finasteride can improve the quality of life of these patients. Oral finasteride improved the quality of life based on several questionnaires administered to patients. However, oral finasteride did not alleviate the patients’ anxiety, as shown by validated anxiety questionnaires.

Summary

Finasteride, much maligned by anecdotal reports in the press and on the Internet, has emerged with a silver lining. It not only works well in all age groups, but it keeps on working. It also improves the quality of life of our patients. Once again we are indebted to all the authors for their important contribution and look forward to hearing more from these groups.

A note from Dr. Paco Jimenez, Program Chair of 2012 meeting in Las Bahamas: I strongly encourage you to attend the “Finasteride Symposium” that will be held at the 2012 ISHRS Annual Meeting in Las Bahamas and moderated by Dr. Stough. I would like to announce that Dr. Sato from Japan has already confirmed his presence, presenting us with the opportunity to find out in greater detail the results of his long-term finasteride study. We also felt it was important to hear the opinion of someone from a different perspective to enrich the discussion. With this in mind, we have invited Dr. Stephen Freedland, a clinical researcher and professor of Urology from Duke University, who will speak about the true extent of the side effects of finasteride, which have lately been the subject of so much Internet attention.◆

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A widow’s peak was present in 81% of the subjects. Lateral mounds were identified in 98% of the subjects, 86% had bilateral lateral mounds, and 12% had a unilateral mound. Of the subjects with bilateral mounds, 64% had a more prominent mound on the right. Of the subjects with a unilateral mound, 83% had the mound located on the right. Lateral mound prominence determined by visual impression was confirmed by lateral mound dimension measurements ($p < .01$). Hairline cowlicks were present in 64%: 61% had one cowlick, 3% had two cowlicks, and one subject (0.3%) had three cowlicks. Of those with one cowlick ($N=219$), 70% had the cowlick on the left, 17% were on the right, and 13% had midline cowlicks (Figure 5). The result of distance measurements are shown in Table 1.

The shape of the temporal recession was described as follows: concave triangular in 61%, concave oval in 26%, convex in 9%, and straight in 3% (Figure 6). Ninety-nine percent of the subjects with concave triangular and concave oval temporal recessions showed miniaturized hairs within the temporal recessions.

No significant correlation was found between age of the subjects and shape of the temporal recessions or ME–FMP distance.

### Discussion

While hairline preservation is one of the features of female pattern hair loss (FPHL), some patients with FPHL require frontal and/or temporal hairline restoration. In addition, an increasing number of women are seeking hair restoration as an option for correction of congenital high hairlines or hairline deformities caused by previous facial cosmetic surgery.

While much has been written about guidelines for hairline design in male patients, most published descriptions of the female hairline define the position of the anterior hairline by measuring vertical facial proportions. The facial height is divided into upper, middle, and lower thirds beginning at the trichion and ending at the menton. Upper facial height, measured from the trichion to the supra-orbital area, is determined by computing the average of the middle and lower third facial height dimensions. One study of 50 volunteers determined that the average distance from the upper edge of the eyebrow to the hairline was 5cm. Our finding that the mean distance from the mid-eyebrow to the frontal midpoint was 5.5cm is consistent with this previous report. While we recommend a frontal midpoint height of approximately 5-6cm from the mid-eyebrow when restoring the female hairline, facial proportions and the intersection between the vertical forehead and horizontal scalp planes should be assessed and taken into consideration when determining the optimal height of the frontal midpoint.

The presence of mounds or protrusions along the frontal hairline has been described in the hair restoration literature, yet little has been written about their specific dimensions and location in women. Parsley describes the presence of 0-3 mounds in both men and women, the two lateral mounds on each side of a central mound (the widow’s peak). Our threshold was low for identifying small irregularities at the hairline and calling them a widow’s peak or lateral mound, which, of course, increased our reported frequencies of these structures. This is evidenced by our finding that 81% of the subjects showed evidence of a widow’s peak and 98% showed evidence of lateral mounds. Parsley also observed that the distance to the peaks of the lateral mounds from the frontal midpoint varies from 1.5-4cm. In our subjects, we observed a range of 1-6cm, with a mean of approximately 3.75-4cm. As determined by the distance ratios, the distance from the frontal midpoint to the apex of the lateral mound ranged from 0.22-0.79 (mean approximately 0.50, or half) of the distance from the frontal midpoint to the apex of the temporal point. It is the author’s (BN) personal observation that in women, the lateral mounds are typically larger and located at a more lateral location as compared to men. These lateral mounds are important structures that should be incorporated into the hairline design in order to impart a “feminine” look to the transplanted hairline.

It is generally recognized that women have a higher incidence of hairline cowlicks than their male counterparts. This was suggested by our data, which showed that 64% of the subjects had one or more hairline cowlicks. It is interesting to note that in the 219 subjects that had one cowlick, 70% were present on the left side. This predilection for one side versus the other was also observed with regard to lateral mounds, where 64% of the subjects with bilateral lateral mounds had a more prominent mound on the right and 83% of unilateral mounds were present on the right.

Although intuitively one might predict a positive correlation between age and a higher frontal midpoint or age and a higher frequency of concave temporal recessions, no such correlation was found, implying that these features are genetically programmed and not age dependent.
Because of geographic location, this study did not include subjects of all racial and ethnic backgrounds, and subtle differences may exist in the frequency and size of the hairline structures described. In the author’s experience, however, the results and guidelines described are universally applicable.

Based on our findings, the following are proposed guidelines for designing the hairline in women (Table 2):

1. Creation of a widow’s peak.
2. Frontal midpoint 5.5-6cm above the mid-eyebrow, considering facial proportions and vertical/horizontal plane (forehead/scalp) intersection.
3. Creation of lateral mounds with their apex at approximately 3.75-4cm from the frontal midpoint or halfway along the distance the frontal midpoint to the apex of the temporal point.
4. Temporal points with their apex located approximately 3.5-3.75cm lateral to the apex of the lateral mounds and 1cm posterior to a line projected vertically from the lateral canthus.
5. Concave triangular or concave oval temporal recessions with fine hairs within the recessions.

References

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