

**ANEXO III: TEXTO DE LA EXPERIENCIA EN  
CLASE.**

## Hair Regrowth Moderate in 40% after Topical Minoxidil

After 12 months of treatment with a 2% minoxidil solution, 40% of 619 patients rated their hair growth as moderate, while 8% termed it dense. This is one of the salient findings during Upjohn's recent trial of its topical minoxidil product, Regaine, on men with male pattern baldness. The drug has not yet been approved for use by the Food and Drug Administration, but the company released a preliminary report of its results to satisfy public disclosure requirements.

From 1982 through mid-1984, Regaine Topical Solution was tested at 27 centers; 2,326 patients were enrolled, of whom 1,833 finished the year-long study. Patients were randomly assigned to either a 2% or 3% solution of topical minoxidil, and a third group received a placebo during the first four months of the 12-month program. The placebo group was crossed over to active drug (the 3% preparation) after the first four months. In addition, 4,000 more patients participated in other studies that examined various questions about safety and mechanism of drug action.

Based on these comparisons, Upjohn says that the 2% concentration of minoxidil is optimal, since it shows the best benefit-to-risk ratio of any concentration studied. But even with the 3% solution, the company claims that although minoxidil blood levels were higher than those observed with the 2% concentration, they were still "low and not clinically significant."

Overall scalp hair growth in the initial bald area was assessed. And within a 1-inch-diameter area at the vertex of each patient's head, each hair was regularly counted and classified as a terminal hair (normal scalp-type hair), a vellus hair (downy hair), or an indeterminate hair (between vellus and terminal hair in length and consistency).

Patients' progress was assessed at months 4, 8, and 12. By the end of the fourth month, 26% of the 2%

group rated their hair growth as moderate, while 1% called it dense. At eight months, these figures had risen to 26% and 4%, respectively. By 12 months, comparable figures were 40% and 8%.

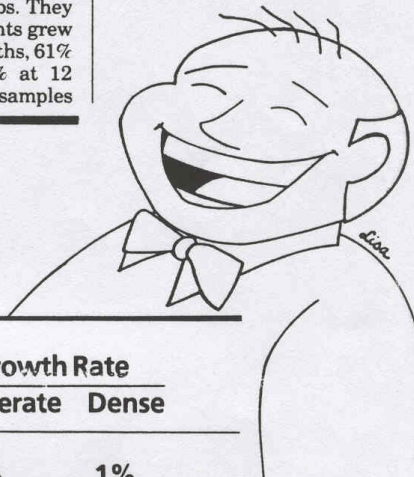
Even happier results were reported when investigators rated the events on the subjects' scalps. They noted that 32% of the patients grew non-vellus hair at four months, 61% at eight months, and 76% at 12 months. Biopsies of skin samples

such as itching, scaling, flushing, and dermatitis.

However, 10 deaths occurred among topical minoxidil users. None of these happened during the 12-month clinical study, but among the more than 1,000 patients who elected to continue on the drug under supervision of their physicians, five deaths have been reported from causes ranging from suicide to AIDS to cardiovascular conditions. In addition, there have

### 2% Minoxidil Solution Results

Months Growth	Growth Rate	
	Moderate	Dense
4 months	26%	1%
8 months	26%	4%
12 months	40%	8%



taken from volunteer's scalps showed a significant increase in the numbers of hair follicles, and the growth of additional hair. For some unknown reason, though, there was considerable variation in the extent of hair growth from one study center to another.

No changes were seen in any of the lab parameters measured throughout the study, including blood pressure and pulse rate. Nor were any side effects attributable to use of the drug. The only events that were considered by investigators to be probably or possibly related to drug use were dermatologic effects

been five other deaths, two in Upjohn alopecia areata studies and two among users of non-Upjohn minoxidil formulations. The tenth death was that of a man who had been in an Upjohn study for patients taking oral antihypertensive medications. The patient was on active drug for 16 days, then dropped out of the study; he died two months after leaving the study.

All of these cases, said Upjohn, have been reported to FDA, and the company believes there is no causal relationship between drug use and the deaths.

These results are the kind that

usually make stock prices soar, but at least one investigator, Mark Houston of Vanderbilt University Medical Center, had a caution or two about the new baldness remedy.

Houston has himself worked with the new product, and says it can have dangerous side effects. In his view of things, five deaths have been associated with applications of the drug to the scalp, but he also notes that otherwise healthy patients may be able to use it safely. The problem, he says, is transdermal absorption, which allows the drug to enter the bloodstream, where it can lower

blood pressure, speed up the heart rate, and cause dizziness and fainting spells.

In a report to the May 6, 1986, edition of the *New York Times*, Houston also stressed some other drawbacks of starting down the minoxidil road. Once you start using it, he reminded, "you're committed to it for the rest of your life—your hair will fall out if you stop." Nor does topical minoxidil come cheap: the twice-daily treatments add up to \$1,200 a year and the results—if it works at all—do not show up for three to six months. ☹