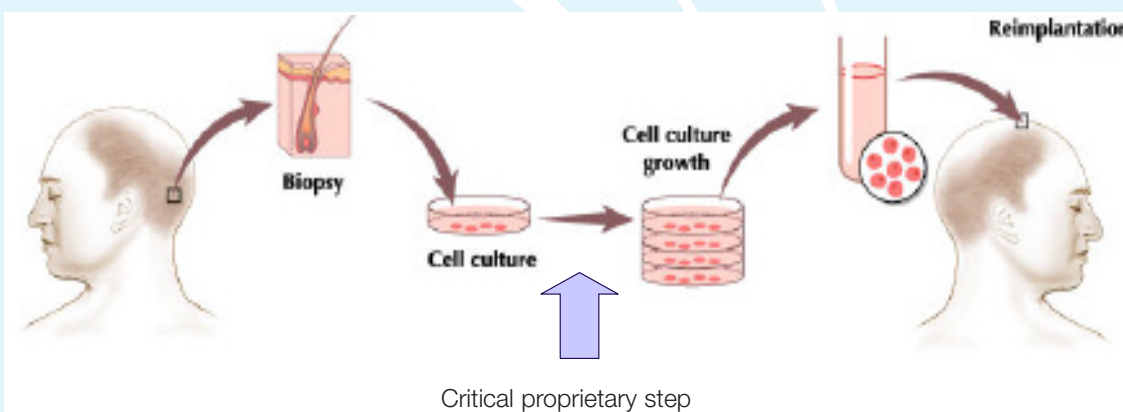


ICX-TRC



Intercytex

PIPELINE	Pre-clinical	Phase I	Phase II	Phase III	Registration	Launch
ICX-TRC	Hair Loss					



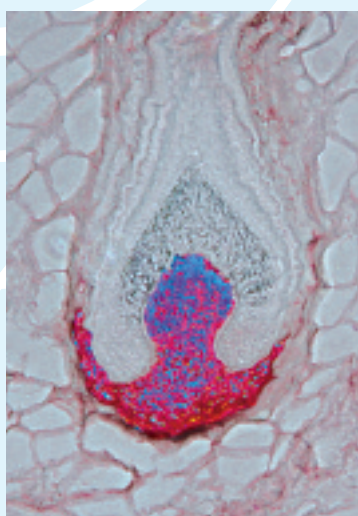
ICX-TRC is an autologous hair regeneration therapy intended for the treatment of male pattern baldness and female diffuse alopecia.

A small sample of hair follicles will be taken from the patient during a simple 30 minute operation carried out under local anaesthetic at a hair or skin clinic.

The clinic will send the biopsy to Intercytex' manufacturing facility where the hair-inductive dermal papilla cells will be dissociated from the rest of the follicle. These cells will be cultured and expanded in proprietary media over three weeks and subsequently returned to the clinic in a sterile suspension.

Using a specialised delivery system, the hair-inductive dermal papilla cells will be microinjected intradermally into the patient's scalp.

The treatment will be performed under local anaesthetic and comprises a single procedure of superficial injections, each injection delivering a minute volume of media containing dermal papilla cells capable of inducing new hair growth. Following the procedure, new hair growth should become evident after approximately three months.



Micrograph showing basal area of a hair follicle (from which dermal papilla cells are extracted)

It is intended that ICX-TRC will be used by specialists in hair transplant centres, dermatologists and plastic surgeons to treat patients with hair thinning or hair loss.

Key Terms

Autologous cells are sourced from the patient.

Dermal papilla cells are responsible for the formation of new hair and are found at the basal region of the hair follicle. In the adult hair follicle these cells play a crucial role in the dermal-

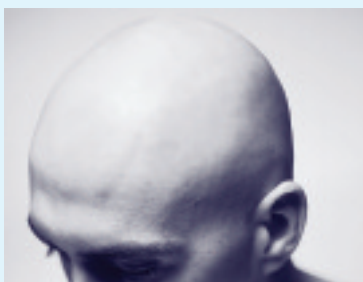
epidermal interactions that control hair production and hair cycling.

Female diffuse alopecia is the gradual thinning of hair, especially on the top of the head although the hairline generally remains intact. It progresses more slowly than male pattern baldness because of the small amount of male hormones in a woman's body. A hormone imbalance may make the problem worse. Temporary hair loss may result from any shock to the body's systems, including starvation, systemic infection, childbirth, thyroid or immunologic disorders, drugs (especially chemotherapy for cancer), or stress. Hair follicles can be destroyed permanently by scarring from burns, severe scalp infections, X-ray therapy, or skin disorders. Damage may also result from tight hairstyles over a long period of time, chemical treatments such as hair colouring or permanents, or the habitual pulling out of the hair.

Male pattern baldness is also known as androgenetic alopecia. It is the most common type of hair loss effecting men, caused by hormones, and affects the central and frontal area of the scalp.

Microinjection is the delivery of small quantities of fluid and cells using fine gauge needles.

Both male pattern baldness and female diffuse alopecia result in hair-loss or slowing of hair growth. They may be caused by physical damage to the hair itself or to the hair follicles, but commonly arise as a consequence of changes in the natural growth cycle of hair generally resulting in fewer dermal papilla cells. Approximately 95% of all cases are of genetic origin. Hair loss affects approximately 40% of men and 20% of women aged 50 and over. In the US there



are an estimated 40 million men and 12 million women suffering from some degree of baldness. The estimated market size for hair regeneration products and treatments is currently \$1.7 billion for both men and women but only 2% of patients suffering hair loss currently seek any treatment indicating a potentially far higher market size*.

Existing conventional treatments, involving the transplant of whole hairs, represent the only means of regenerating bald or thinning areas. This is a highly costly (\$10,000 - \$20,000) specialist procedure. Extensive tissue is required - this is obtained by the removal of a large section of scalp leaving a significant scar at the donor site. Individual follicles are removed from the dissected scalp by specialised technicians and then individually re-implanted into surgical incisions created in the scalp. This procedure usually takes place during two, eight-hour implant sessions performed under a local anaesthetic. A lengthy recovery period may be required during which time the patient may suffer from pain, bleeding and swelling of the scalp. In general the cosmetic effect is excellent, however in all cases, the quality of outcome is limited by the amount of donor hair available. Moreover, many individuals electing to undergo this procedure do not progress to transplant surgery as they have insufficient transplantable hair follicles to benefit from the technique as between 2,000 – 5,000 follicles are often needed for this procedure.

Conventional transplant

Extensive donor tissue removal (2,000 – 5,000 follicles)

Donor site is large – an ellipse or slice of scalp is removed and scarring results

Two operations of eight hours each, to remove scalp, dissect hair follicles and re-implant into surgically created cavities

Lengthy recovery time, pain, bleeding and swelling during and after implantation

Final outcome is limited to amount of donor hair available – there may be insufficient transplantable hair follicles

Currently unregulated

ICX-TRC procedure

Minimal donor tissue removal (approximately 120 follicles)

Donor site is small – a single biopsy with a minimal scar site

30 minute operation to take biopsy and approximately two hours intradermal microinjection of dermal papilla cells

Negligible recovery time; minimal pain, bleeding and swelling during and after microinjection

Repeat procedures possible from a single biopsy

Regulated

Comparison between a conventional hair transplant and ICX-TRC hair regeneration therapy

The ICX-TRC procedure is significantly less problematic than conventional hair transplants. In terms of the amount of tissue taken from the patient, only a small sample - approximately 120 follicles are needed. As a consequence, trauma suffered by the patient during the procedure may be dramatically reduced. Furthermore, as dermal papilla cells can be derived from a very small area of hair-bearing scalp, a much higher population of patients will be able to benefit from ICX-TRC than conventional transplantation. Superficial injection of cultured cells into the scalp causes far less tissue damage than implanting multiple hair follicles and is a considerably simpler, shorter and less painful process.

Clinical and Commercial Development

Phase I clinical trials (safety) have been completed in seven volunteers at a single UK transplant centre. No safety issues have arisen and five out of seven patients have shown increased hair numbers. Recruitment for a Phase II clinical efficacy trial on patients with male pattern baldness has commenced in the UK with an initial cohort of up to 20 subjects which will be followed by variations in delivery technique in further similar sized cohorts. The trial is designed to demonstrate efficacy of ICX-TRC, the dosage regime and the delivery device. Preliminary data from this trial are expected during the first half of 2007.

Intercytex will develop ICX-TRC through all stages of clinical development and registration to launch, initially to treat male pattern baldness, expanding its use to treat female diffuse alopecia.

Intercytex is planning to set up its own specialist sales force to sell aesthetic medicine products in the UK and certain other countries in Europe. For the US market, the company plans to appoint suitable distribution partners.

Intercytex will manufacture ICX-TRC for Europe and the US from its own GMP manufacturing facilities. In October 2006, Intercytex was awarded a grant from the DTI to develop a robotic system with The Automation Partnership for the commercial scale production of patients' autologous dermal papilla cells. The robotic system has an established track record in processing many different cell samples simultaneously, so that at this scale, in which large numbers of different patients' cells are handled, all samples remain isolated throughout the multiplication process.

*Source: Coldwater (Market Research)

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