SUPRATHEL: THE FACTS

Suprathe – an innovative epithelial replacement for the treatment of burns injuries

When it comes to the therapeutic consequences of treating victims of serious burns we distinguish between two groups of patients.

In one group we have those with extensive burns, which are mainly categorised as superficial to deep second degree, where by regeneration of the skin is still possible in principle. The other group includes victims of serious burns with larger areas of third degree burns, which always require skin replacement.

In all burns treatment centres there is universal agreement that with the first group transplantation with natural skin should be proceeded with caution, in order that no more skin has to be removed than absolutely necessary. Around the outside of these rather superficial burns and scalds unnecessary scars also occur due to the fact that the transplanted natural skin is raised above the surface of the healing epithelial layer (otherwise known as “overgrafting”). However, in the well-intentioned effort to treat second-degree burns conservatively, even today these burns victims are still bathed daily under local anaesthetic and with disinfecting ointments. This kind of treatment is expensive and causes a lot of pain for patients. Apart from this, the ointments normally used at present have shown evidence of restricting the healing process in the epithelium as it regrows. As such, it is not surprising that in many burns treatment centres permanent dressings are used, which may be left on the wound for longer periods.

With the conventional materials used in the past a distinction is made between substances which are artificially produced, and those which are biological.

In the latter case lyophilised pigskin, human corpse skin and human amnion are mainly used. Amnion has often been used with children with scalds. What all three materials have in common is that they can never be entirely excluded. However, with amnion especially good wound healing results have been achieved with low incidence of pain on the surface of the wound. Even though the artificially produced materials that have been used usually pose no biological risk, in terms of handling and application they are unsatisfactory. With thin film materials infections frequently occur. In a cooperative venture between the Institute of Textile Research and Chemical Engineering in Dorkendorf and the Accident Surgery Clinic at the Marienhospital in Stuttgart a project was initiated, whose aim was to develop a new type of permanent bandage.

This material should combine the advantages of biological and artificially produced substances without their disadvantages.

In 2004 Suprathe was launched in Germany and Austria.

Suprathe is a membrane made of polylactide, so it essentially consists of lactic acid. It is therefore absorbable and dissolves in water and carbon dioxide after approximately four weeks on a wound. In the trials required for its approval, which were carried out at the Marienhospital in Stuttgart and the Accident Hospital Berlin, there was evidence of considerable pain reduction compared with previously used materials. In routine applications it soon became clear that Suprathe’s handling is also superior to other materials. The membrane’s properties ensure that Suprathe adheres to a wound immediately. Suprathe can be moulded and is therefore easy to apply to difficult areas such as the face, fingers and toes.

Suprathe is usually combined with a layer of lipid gauze, in order to prevent the dressing lying over it from sticking. However, the lipid gauze is also left on with the Suprathe until the wound has healed completely. The additional dressing is required if there is mechanical stress on the Suprathe, as is the case with arms and legs, for example. Polylactide possesses an additional anti-infection component. Second-degree burns heal under Suprathe undisturbed and the material falls off by itself after epithelisation is complete after 7 to 20 days (depending on how deep the burn is). At this point the Suprathe can usually be peeled along with the lipid gauze at the edge and it is then cut off next to the areas to which Suprathe still adheres. The procedure required here is painless.

At the burns centre of the Marienhospital Stuttgart Suprathe has been rapidly integrated in the treatment of serious burns victims.

Even with the group of burns patients with extensive areas of third-degree burns, by using Suprathe it has been possible to reduce the area to be transplanted. Since Suprathe was introduced no human corpse skin has been used again as a skin substitute. In the group of patients with extensive, mixed second-grade burns some astonishing successes have been achieved without any need for transplantation at all. Thus with Suprathe it was possible for one patient with 95% of 2a to 2b scalding to the body to achieve virtually complete healing within four weeks. But even with minor burns and abrasions, which are treated in outpatient departments, Suprathe has proved to be an epithelium substitute that is easy to apply and comfortable.

Children especially can be treated by their GPs without pain and without changing dressings every day under anaesthetic.

However, this is provided the doctors in question know how to treat patients with Suprathe. The manufacturers and distributors provide workshops for interested hospitals and practising doctors, where they can learn how to use Suprathe for various indications.

Dr. Christian Uhlig, Marienhospital Stuttgart

Source: www.cicatrix.de/verbrennungen_suprathe.html

Suprathe presented by: Stapline

Medizintechnik

www.stapline.com
Artificial skin saves life

For the first time a patient has been saved, who had lost 95% of his skin in an accident – thanks to a new kind of artificial "second skin".

When in autumn 2005 a 38-year-old man was admitted to the serious burns unit at Stuttgart’s Marienhospital with the most severe case of scalding, he had little hope of survival. Caustic lye had destroyed up to 95% of the patient’s skin. The tragic occupational accident had occurred during routine maintenance work. The technician had climbed inside a large industrial washing drum when it suddenly filled up with cleaning lye. "The only part of his skin that was undamaged was on the soles of his feet and around his waist", says Helmut Hierlemann, a chemist at the Institute of Textile and Chemical Engineering (ITV) in Denkendorf, which is part of Stuttgart University.

The fact that the man survived the accident and was able to leave hospital only six weeks later with virtually completely reconstructed skin, is due to the artificial "second skin", which was developed at the ITV.

The paper-thin skin substitute, of which more than two square metres were applied to the man’s body, undertakes life-essential physical functions for badly injured patients with extensive and deep skin wounds until a natural transplant grown from their residual skin is available.

"What is vital initially is protection from infections and evaporations", says Hierlemann. Normally the body releases 20 ml of water per square metre per hour. With extensive skin injuries this can soar to 10 times the amount. But the substitute skin not only has to protect the patient from dehydration. In order to prevent germs from colonising, it has to let through sufficient water vapour, which is continuously supplied by the wound fluid. The material is also intended to promote the formation of new skin and gradually make room for the regrown tissue by itself, in order to avoid painful changes of dressing, which delays the healing process. These are properties of polylactic acid itself, a biodegradable material that has been tried and tested in clinical use. It serves as the supporting substance for the substitute skin.

"The material is fusion polymerised and can then be turned into a membrane, which contains a great number of extremely fine pores. These are so dense that no bacteria can find their way to the surface of the body but they still allow a sufficient amount of water vapour to be released", explains developer Hierlemann. Substances embedded in the pliable microcomposite provide additional protection from infection and have an analgesic function. Because the material is transparent when applied to the wound, the doctor is able to observe the healing process at all times.

For three years the artificial skin, which was named “Suprathel”, went through clinical trials at the Marienhospital. The Stuttgart are particularly proud that for the first time ever they succeeded in saving someone who had lost 95% of his skin. Several European burns treatment centres already use this artificial skin themselves. Altogether, over 1,000 patients have been successfully treated with it. In the meantime, Stuttgart researchers have sold their patented development to a manufacturer of medical equipment, who intends to launch it in the US.

Source:
www.welt.de/data/2006/09/12/1032406.html/

Suprathel® in use

A five year old boy. Typical 2a-scalding of the back of the hand and parts of the palm. This is an extremely painful type of injury; debridement can only be carried out under anaesthetic.

Suprathel has to be left on along with the paraffin gauze until the material falls off itself as epithelisation proceeds.

Following debridement on the day of the accident Suprathel and paraffin gauze were applied. The dressing was changed after four days without any pain and no need for painkillers.

In the meantime epithelisation is complete and healing without scarring has occurred within 12 days. During the entire period of treatment the patient felt no pain at all.
New hope with extensive wounds

In autumn 2005 for the first time a patient was saved at Stuttgart’s Marienhospital, whose skin had been 95 percent destroyed following an accident with hot lye. The man who was facing almost certain death owes his life to an artificial “second skin”, which was developed at the Institute of Textile and Chemical Engineering (ITV) in Denkendorf, which is part of Stuttgart University. Under the brand name Suprathel it has since been used in leading burns treatment centres throughout Europe.

In order to maintain vital functions of the skin and avoid infections, when there are deep and extensive injuries, the wounds have to be occluded at an early stage. The best way of doing this in the past was split skin transplants, which were taken from other parts of the patient’s body. However, with extensive burns in particular but also with older people and children there are limits to this – especially as the additional wound causes the patient considerable pain, poses further risk of infection and actually restricts the mobility required at an early stage. But even with conservatively treated second-degree burns the change of dressings required every day is a torment for patients and medical staff. As the wound secretions cause the dressing material to stick to the wound, it is constantly torn open again when the dressing is changed. This delays the healing process and often leads to scarring.

In order to minimise these adverse effects, ITV developed a skin substitute called Suprathel in close cooperation with the serious burns unit at Stuttgart’s Marienhospital as well as the manufacturer PolyMedics Innovations. This absorbable, paper-thin membrane is placed on the destroyed areas of skin, which have been cleansed and attached to the wound by wound fluid and blood. All that is added is a protective bandage of paraffin gauze. As Suprathel is pervious to water vapour, the substitute skin prevents wound secretions from accumulating as well as the wound from drying out. This kind of “dressing” does not have to be changed or removed. The membrane promotes the formation of new skin until finally the wound is completely occluded. It then falls off or can be removed without causing pain.

Definitely less pain

“This provides enormous benefits to the patient”, explains ITV head Professor Heinrich Planck, professor of textile engineering at the university and coordinator of the Interuniversity Centre Stuttgart-Tübingen for Medical Technology (IZST). While conventionally treated burns victims often complain about their almost unbearable pain, Suprathel patients suffer considerably less. In clinical tests on a scale of zero (no pain) to 10 (maximum pain) wound pain exceeded the value of three in only 11 percent of cases. All the others were below this. As such, the pain-relieving effect occurs immediately after the substitute skin is applied and persists during the entire treatment procedure.

Fast and consistent healing

In addition, the skin heals faster and more evenly and unwanted scarring usually does not occur. Wound infections or the onset of allergies have not been detected. In long-term comparisons the substitute skin also rates highly. While conventionally treated burns victims often complain about sensitivity to touch in affected parts of the body even years later, this phenomenon has never occurred with Suprathel patients. The assumption is that the damaged nerve endings are protected by the membrane and are thus able to regenerate undisturbed. But doctors and hospitals benefit too. As Suprathel becomes transparent after it is applied, the progress of the healing process can be evaluated effectively. Plus, treatment with Suprathel can save money. Of course, this miraculous material is not exactly cheap.

However, burns victims can be transferred sooner from a sterile room to the general hospital ward. As the special cubicles kept at 37 degrees cost around 2,000 euros a day, this is an added bonus from an economic perspective that should not be underestimated. In addition, patients can be discharged from hospital much more quickly too.

Mostly lactic acid

In terms of its chemistry Suprathel consists of a terpolymer based on polylactic acid. It is fusion polymerised and turned into a membrane. This results in a material that contains a huge number of extremely fine pores. They are so dense that no bacteria can penetrate but water vapour can be released through them. Suprathel is exceptionally pliable and it adapts to the body surface at body temperature immediately. Even difficult to treat areas such as fingers and toes can be covered properly.

The substitute skin developed by Dr. Helmut Hielemann, a chemist at ITV, is backed by around 12 years of research. It all started with a project funded by the German Research Foundation. It focused on the development of absorbable membranes, which slowly dissolve in the body. For three years Suprathel underwent clinical trials at the Marienhospital. Despite the amazing successes in treatment the doctors were initially sceptical. However, since then several burns treatment centres throughout Europe have implemented this artificial epithelium and have successfully treated over 1,000 patients. The manufacturer hopes to be able to launch Suprathel in the US soon as well. Miracle skin has more potential yet.

Definitely less pain

At the ITV scientists continue to research future fields of application. In the short term approval is to be extended for use on third degree burns. In the case of dental implants Suprathel could soon replace the previously conventional titanium or Teflon membranes, which are used to divide the fast growing gums from the slower growing bony substance. Because Suprathel is absorbable, the patient would not have to undergo a further operation to remove the membrane, according to Professor Planck, who sees many other potential ranges of application for this “miracle skin”. In the medium term the tissue is also to be used as a separating foil in adhesion prophylaxis. In conjunction with the IZST applications are also being researched in minimal invasie medicine. As such, these separate systems are inserted in the body using an endoscope in order to prevent complications due to the unwanted adhesion of various organs or tissues in relevant operations. Application areas are gynaecology or traumatology but the treatment of wounds that are slow to heal is a conceivable area too. The membranes can also be equipped with functions such as releasing active agents locally. “This opens up a wide area for new treatment systems for the benefit of patients but also lower costs in the health care system”, Planck emphasises.

Source: www.uni-stuttgart.de/uni-kurier/uk97/thema/th54.htm

This patient was treated on the left hand side of the body in a conventional manner with Corticotulle and on the right hand side with Suprathel. On the side treated with Suprathel epithelisation occurred more rapidly and evenly, which was noticeable three months after the injury due to a discrete difference in colour (slightly more redness on the left side of the body).
Suprathel® the absorbable epithelium substitute

Suprathel® consists of an absorbable polymer based on polylactic acid in combination with other biocompatible absorbable polymers, which are used as biomaterials for other clinical applications too.

Suprathel® is an absorbable epithelium substitute used to cover:
- Split skin removal sites
- Second degree burns (IIa and IIb) and partially third degree
- Skin transplantation sites
- Extensive abrasions
- Wounds in plastic surgery
- Tattoo removal

Clinical testing has been successfully carried out as part of a multi-centre study at the Marienhospital in Stuttgart and the BG Klinikum Berlin Marzahn. Numerous hospitals in Germany, Austria and Switzerland have used Suprathel® with great success since it was launched and became part of the clinical routine. Over 1,000 patients have been treated with Suprathel®. The CE mark was granted in May 2004.

Development of further applications with Suprathel is currently under way.

Please contact us if you have any further inquiries: info@stapleline.com
One of our representatives in your area will contact you immediately.

The benefits of Suprathel®:

- No need to change the Suprathel® primary dressing during the healing stage, with Suprathel® the wound remains protected during the healing stage and can heal undisturbed. Only the protective dressing is changed at various intervals.
- Healing process can be observed as Suprathel® becomes transparent after it is applied to the wound.
- Faster healing at the affected sites.
- After the skin heals Suprathel® drops off or can be carefully removed without causing pain.
- Significantly lower infection rates than with standard treatment.
- Less need for analgesics.
- Less nursing care required.
- Shorter hospitalisation times, patients discharged/treated as outpatients earlier.
- Significantly less pain during and after healing.
- Properties similar to natural skin in terms of:
  - elasticity
  - water vapour permeability
  - germ impermeability

Available in the following sizes: 9 x 10 cm; 18 x 10 cm, 18 x 23 cm

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