#### A. The Clinical test protocol

1. Title of the Project

## Using Elasto Gel in different types of wounds and stages of wound healing. Specially in burn in Childhood

2. Researcher Responsible for the Clinical Trial and Professional or Scientific Degree

Dr. Joseph BAKSA

3. Institution or Hospital where the Trial will be Conducted Dept. of Pediatr. Surg. and Burn Unit. Hospital:St.János Hospital, Diosarok u.1, H-1125 Budapest, Tel./Fax: +36 1 156 0318

4.Sponsors

Southwest Technologies Inc.

5. Monitors Committee

Dr. Sandor GYORI and Dr. Andrea VERESS

6.-Scientific Committee

Dr. Pol SOMLO and Dr. András SZUCS

St. János Hospital is one of the main Hospitals of Budapest Council.

#### **B.** Materials and Methods

Who were the patients and how many patients were treated?

The patients were admitted to the Department or to the Burn Unit.

They were children aged from 2 weeks -18 years.

The time of the Clinical Trial was from Sept. 1993 until July 1996.

The number of patients: 183

- **C.** Trial from Sept.1993 until July 1996-The number of patients:183
- **<u>D.</u>** Observation date for each patient: maximum time: 3 yrs.
- **E.** What items were checked?

The exact results of the wound healing; time and quality of healing were checked.

**F.** How long were observations done?

The observation is still gong on (at the time of writing up this publication).

#### Report of all cases

#### I. Study design

In our clinical trial was used an "Expert analyst protocol." The trial was carried out on 183 patients of both sexes and the results were compared with those patients cases who have got other local therapy, e.g. SSD, SN03, etc.

Patients in group:

122 males (including babies) 61 females The main age was 4 years

#### **II. Treatment Modalities**

- a. -patients with acute burn
- b. -patients having scars after wound healing.
   The treatment was continued in all cases until complete healing of wounds had been achieved.
- Study of effects on healing: the objective criterion available for assessing the effect on
- healing was the **time criterion**. In addition to assess the quality of healing, on essentially clinical criteria, consisting in the presence or absence of functional or cosmetic problems was only possible to judge.
- Study of tolerance of the Elasto-Gel on systemic and local level.
- Study of effect on infection.
- Effect on oedema and exudate
- Side-effects, allergic reactions, toxicoderma, etc...

The protocol based on a combination of the time to healing, the quality of wound healing and the tolerability of the local agents. This protocol gives a global assessment of the effect of Elasto gel and it gives a possibility for comparative study too.

#### III. Patient characteristics and number of cases.

Distribution of the 30 child cases:

- I. Using Elasto Gel (EG)
- for management of superficial burn (a)
- and donor sites (b)

= 5 cases

- II. For cleaning and preparing of wound surface (after surgical removal of necrosis), before grafting. = 5 cases
- III. For "biotransforming" therapy of torpid and hypergranulated wounds = 5 cases
- IV. For preventing and treating of hypertrophic scars. =15 cases

#### I.a.

## 1.-Anna K.,3 yrs, girl

Dg: Combustio dorsi pedis sin.gr.II/1, 1%

Time of burn: Nov.15.1994

EG therapy: Nov.20-27 (till the complete wound healing)

## 2.-Balázs M.,2 yrs, boy

Dg: Combustio multiplex, trunci, extremit. Sup, et inf.1.u./ gr.II/1-2,gr.III.40% TBSA

Time of burn: Oct. I.1994.

Op.-necrotomy on Oct.5. /on left leg EG therapy, on right leg Xenograft therapy-pigskin-for comparing the two kinds of products.

Result: after a week complete wound healing under the EG,

the xenografts were taken sticking closely on the wounds (dry healing).





#### I.b.

#### 3.-Maria G.13 yrs, girl

Dg: Contractura cicatrisans axillae 1.s.p.comb. At the grafting on the wound surface of thigh were a comparative study using different products covering the donor sites.

Results: Under the EG was complete wound healing and under some other products to, after 8 days, but the finest quality was found under EG.

## 4.-Szabolcs U.,11 yrs, boy.

Dg: Cicatrix /hypertrophic scar/ femoris 1.s.p.comb. /after healing of burn spontaneously/

For the disposition of pathologic scarring was EG used on the donor sites and grafts. The use of EG was continued in the follow up period until 2 Moths without

any pathologic scar developing. After the graft was taking it took 8 day to heal the

wound on the thigh.

#### 5.-Veronika Sch.,5 yrs, girl

Dg: Contractura multiplex cicatrisans /digit.man.utr., pedis utr.,et carpi utr./p.comb. gr.II/1-2,gr.III. 55-60% TBSA

Dec.2.1994. Op. necrotomy tangential. Using EG for 4 days and Dec.5.operation .auto grafting onto a perfect clean surface. After the surgery was a complete wound healing found.

#### Ш

#### 1. -Eszter B.15 Months, girl

Dg: Combustio fem.1.d.gr.II/2 3 % TBSA Time of burn: 2 weeks before the admission. Dec.2.1994.op.:necrectomy tangentional.

Using EG for 4 days and Dec.o5.op.autografting /onto a perfect cleaned wound surface/After surgery was a complete healing.

## 2.-Sàndor B.1 yr, boy.

Dg: Combustio cruris 1.utr.gr. 2% .TBSA

Burned: Dec.03.1994. Dec.07.op.:necrectomy tangentional

EG used every day changed dressing for 5 days.

Dec.11.op.autografting /cleaned wound surface.

After grafting was a complete wound healing found.

#### 3.-Richárd L. 2 yrs, boy

Dg: Combustio multiplex extrem.inf.l.u.gr.lI2-gr.lII

Burned Dec.23.1994.

Using EG on his right thigh for cleaning role of the wound /gr.II/2/from Dec.23 till Jan.9.1995. When an autograft surgery was performed successive.

In this case EG was used without necrotomy!

#### 4.-Benjamin P.,2 yrs, boy

Dg: Combustio extrem.sup.1.d.grll/2 cca 5%

Time of burn: Dec.3.1994.

Dec.5.Necrectomy tangential and use of EG for 3 days and Dec.7.an autografting was performed without any problem. The wound healing was complete.

#### 5.-Anikó F.,4 yrs, girl

Dg: Combustio multiplex TBAS 50% 'ARDS, Sepsis. Time of burn: April. 26.1993.

She was admitted again at our Dept-because of her ulcerated scars of both thighs on August.24.1994.

EG was used for cleaning the wounds. After some days (4-5 days) the ulcers became clean and the use of EG was continued till 3 weeks when the ulcers healed

#### III.

#### I.Andrea Sz. 2 yrs, girl

She was admitted at the Dept. <u>after 6 weeks scald burns!</u> There were hypergranulation on the surfaces of the wounds: face and chest. After 5 days EG therapy was possible to undergo a success grafting.



Boy on admission, painful wounds with gauze dried in burn wound.



Wounds after removing of gauze and 5 days of Elasto-Gel treatment. Notice yellow film consisting of glycerine and fibrine.



4 days after skin grating operation



Wound 7 days after skin grafting operation .

## 2.Szildra B.,3 yrs, boy

He was admitted on the <u>22th.postburn day</u> It was a necrotomy and on the next day was used Iruxol /Santyl, a proteolytic enzyme -product, (Knoll,USA) for enhancing the cleaning effect of EG. This complex therapy was success and on the 4th. day the wound-bed became ready for grafting.



Wound just after removal of debris and necrosis



Cleaning effect of Iruxol and Elasto-Gel. Wound ready for grafting



Wounds just after skin grafting operation



5 days after operation.

#### 3. Görgy B.,12 yrs, boy

Dg: Combustio multiplex gr.II/1-2,gr.III.55-60 % TBSA Time of burn: June 29.1994.

He was admitted at the Department after a week of this accident. There was a torpid wound surface of his back (15x3x 10 cm) remaining. Between Aug.24 and 26.was used EG for preparing the torpid wounds, he underwent surgery on Aug.26. After grafting was a good and successful wound healing.

#### 4.Jenifer T., 1 yr, girl

Dg: Combustio antebrachii 1.u.gr.II/2-gr./III Time of burn: April.3.1994. Admission at the Dept. June 14.!!!

Use of EG during a week and on June 21 a grafting on her right forearm and on the other one only EG was used till the healing of wounds. June 28. Both on her forearms were used EG till November and on both regions were only ideal scars!

#### 5.Andrea Sz.P.,22 yrs, girl

She had burn on the Achilles region of her foot before a Month by a motorcycle accident. There was a thick and rough, hypergranulated wound surface (3 cm). Using EG for 3 days and then became possible to perform surgery/grafting/ with good results

#### IV.

#### 1.Zsuzsanna M.,4 yrs, girl.

After burn healing was used EG therapy because of her hypertrophic scars on the neck and shoulder regions from June 29..1994.

After a Month of EG therapy the scars became light, soft, smooth and pliable. Later was not recidiva seen.

#### 2.Zoltán H.,14 yrs, boy

It was an operation on Dec.1994 because of syndactylia

after burn. A line-like scar developed on the ventral surface of the 5th finger causing a moderate contracture.

From Febr.12.1995.until 2 weeks we used a plastic splint with EG. After this treatment the child could extend his finger perfectly. For two weeks he needed EG therapy but only at night.

#### 3.Milán N.,2 yrs, boy.

He had burn in 1993.He had hypertrophic scars on the submandibular ans praesternal regions. Oct.3.1994. it was excised the scar of the face. From Oct.20 EG was used and later.

Nov.23. a pressure garment (Mainat) was used also.

At the control examinations the result was good, normal scar.

Jan.24. and March 17.1995

## 4.Szabolcs U.,11 yrs, boy

Time of burn: Sept.19.1993.

Hypertrophic scar developed after the burn healing.

Dec.12.1994 was made an excision of this scars and grafting.

After a normal (uneventful) wound healing was begun.

Dec.30 EG therapy for preventing of recidiva with pressure garment.

This therapy was followed till 4 Months with almost ideal scars.

There were no recidiva (1996) neither on the surface of donor sites nor, on the grafted areas.!

#### 5.Luca M.,12 yrs, girl

Time of burn: Febr.1995.

EG was used on May 1995 on both sides of thighs because of hypetrophic scars with pressure garments supplementary. After 2 Mths EG therapy the scars decreased essentially.

#### 6. Veronika Cs., 3 yrs, girl

Time of burn: Jan.28.1994. Localisation of burn: chest

EG was used from May 30 because of hypertrophic scars until 3 Mths. At the control examinations /Dec.ol.1994,and 1995,1996 did not develop recidiva. The scars were soft and pliable.

#### 7. Viktoria K., 11 yrs, girl

She have got a flap plasty on her perineal region /after excision the hypertrophic scar/ and for prevention of recidiva was used EG during 2 Mths. From Dec.2.1995, with extra good results.

## 8.Adám R.,2 yrs, boy

The burn on the chest-wall was healed after conservatively therapy and grafting till April 1994. EG was used from Aug. till November 1994 for hypertrophic scars.

At the control examination (Dec.14) the scar had extreme good quality.

#### 9. Márton L., I yr, boy

From June 1994.he has got EG therapy because of his pathologic scars on back, but in October the scars decreased <u>only</u> slowly and very little. In 1995 after a year the scars were hard and overpigemented.

#### 10.János M.,2 yrs, boy.

He had a contact burn both on his soles .For the deep thickness burn he was grafted on the right foot. Hypertrophic scars developed and EG using was necessary from July till October 1994 with success!

## Studies apart form case reports

Comparative study between CicaCare and Elasto-Gel



Initial assessment



arm = Elasto-Gel , trunk is treated with silicon sheets (CicaCare)



Result after two months of CicaCare (Smith & Nephew Ltd)



Start with Elasto-Gel



After two months treatment with Elasto-Gel.

## **Biotransforming effect.**

After excision of hypertrophic scar and grafting.



Use of EG for 3 months



After one year Elasto-Gel treatment.

## Comparative study between several dressings on donor site

Comparative study between Comprigel (gauze), Tegasorb (hydrocolloid), Duoderm (hydrocolloid), Elasto-Gel (hydrogel), Cuticerin (nylon gauze), Sorbsan (Alginate) and Inadine (gauze with Polyvidone Iodine).





All different dressings on the same donor site wound.



All dressings are saturated with wound fluid. Elasto-Gel was able to absorb most exudate.



After 6 days the epithelialization under DuoDerm is more evolved than than the other dressings. Under the other dressing is crust formation with odour. Under Elasto-Gel we see some fibrin formation and a start of epithelialization. The Elasto-Gel is still able to absorb a lot of exudate.

# A CASE STUDY ON HYPERTROPHIC AND KELOID SCARS TREATED WHOLLY WITH CICA CARE

PROTOCOL consists of INITIAL assessment, 1st Monthly, 2nd Monthly and 3rd Monthly inspections DATA

#### **Patient Details**

- 1.Patient initials
- 2.Case study
- 3.Date of birth
- 4.Sex
- 5.Ethnic group

#### **Details of Scar**

- 6.Aetiology of scar
- 7. Histbry of scar
- 8. Duration of scar
- 9.Location of scar
- 10. Previous treatment regimes

#### **Assessment of Scar**

- 11.Dimensions of scar
- 12.Colour of scar
- 13.Texture of scar
- 14. Advised other measurements for...

#### **Patients Opinion**

- 15.Irritation, physical discomfort
- 16.Any embarrassment
- 17.affecting the functions

#### **Commencing Treatment**

- 18. Ease of cutting Cica Care
- 19. Ease of application
- 20. Materials used, if any, to secure Cica Care

Comparative study between Elasto Gel and a silicon product.

## **PATIENTS**

- 1.-Zs'.H.. 7 yrs.,,. girl: Scars on the forearm and thigh
- 2.-B.G. 4 yrs-, boy: Scars on trunk, upper limb, extremities, groin reg.
- 3.-P.T. 11 yrs, boy: Scars on face, treated area
- 4.-B.B. 15 yrs, boy: Scars on forearm
- 5.-V.Sc. 6 yrs, girl: Scars on hands, foot /for preventing using the products.

#### COMPARATIVE CLINICAL TRIAL

SILICON gel product

ELASTO GEL /glycerogel/

silicon oil /v.s./

EFFICIENCE

65% glycerine

suitable size

USING by

simple

exact prescription

PRESCRIPTION

no need

very easy

APPLICATION on

easy /fixation/

yes:after 12 h.

CLEANING, WASHING

no need

some

COMPLICATIONS

nothing

sometime

SIDE-EFFECTS

no

putrid, odour

ODOUR

no

after 2 weeks

BROKES to pices

after 3-5 weeks

3 Months

TIME of USING

3-4 Months

quick

EFFECT

slow

no

RECIDIVA

no

no cheap

COST of product

cheap

extreme good

RESULT

good-extreme good