

CLINICAL APPRAISAL OF TISSUPOR[®]

1. INTRODUCTION

- We are pleased to report hereafter, the experience gained in Argentina with the use of TISSUPOR[®].
- The purpose of this summary is to submit a clinical appraisal on 42 patients treated with TISSUPOR[®], all treated by Dr. Neven Sostaric.
- No case has had to be suspended because of failed therapy.
- Patients no 23-29-30-36-39-41 are still under treatment.
- TISSUPOR[®] has been used in a variety of diagnostics as described below.
- We have complemented the appraisal with the following qualitative aspects:
 - Overall results.
 - Pads vs. Embroidery.
 - Concomitant therapy (Ringer Solution and Rifocina).
 - Performance of TISSUPOR[®] in chronic and acute wounds.
 - TISSUPOR[®] in infected wounds.
 - Aetiology of the wounds.
 - Treatment scheme, sequence and duration.
 - TISSUPOR[®] in specific cases.
 - Statistics of the patients treated with TISSUPOR[®].
 - Conclusions

2. PATIENTS TREATED WITH TISSUPOR®

CASE #	INITIALS	SEX	AGE	DIAGNOSTIC	DBT?	Chronic?
1	JC	M	55	Chronic infected ulcers.	No	Yes
2	ES	F	72	Infected and painful bilateral Aquillian ulcers.	Yes	Yes
3	EC	F	86	Dog biting on leg front face.	No	No
4	CA	M	65	Finger traumatism with partial amputation.	No	No
5	FV	M	86	Plantar, sacro-ischiatic multiple ulcers.	No	Yes
6	JA	M	78	Spontaneous ulcer of the dorsum of foot.	No	No
7	NT	F	62	Left leg vascular ulcers.	Yes	Yes
8	AFS	M	65	Scalp ulcer with headbone exposure.	No	Yes
9	EP	F	75	Front face left leg scalp.	No	No
10	AH	M	50	Post-operative open wound of left cheek.	No	No
11	ES (see 2)	F	73	Foot complicated with gangrene of hallux.	Yes	No
12	JA (see 6)	M	78	New spontaneous ulcers of the foot.	No	No
13	CK	F	70	Cellulitis of the forearm.	No	No
14	AY	F	60	Cellulitis secular to erispelia with left leg ulcer.	Yes	No
15	MT	F	70	Traumatic acute ulcer of the front right leg.	No	No
16	CF	F	76	Ulcer with multiple exposed fractures on right heel.	No	No
17	AFP	M	60	Subungual Melanoma of left hand thumb.	No	No
18	AM	F	22	Gigantic plantar "verruca vulgaris" (left foot).	No	No
19	AJT	M	84	Traumatic infected ulcer of front face of right leg.	No	No
20	GC	M	65	Post-op abdominal wall ulcer.	Yes	Yes
21	LG	F	76	Vascular ulcer of the right leg inner side.	No	Yes
22	RG	M	69	DBT-Foot relapse with gangrene.	Yes	Yes
23	AI	M	56	Multiple ulcers (both feet+right hand)	Yes	Yes
24	AA	M	60	Right-hand trauma.	No	No
25	JCP	M	40	DBT-Foot infected ulcer.	Yes	No
26	SD'A	F	42	Severe cellulitis of forehead following trauma.	No	No
27	LF	M	76	Aquillan right foot ulcer + amputated hallux.	Yes	Yes
28	JP	M	74	Right leg lateral ulcer.	Yes	Yes
29	CL	F	76	Necrotic and infected right inner leg ulcer.	Yes	Yes
30	EDB	M	59	Left internal side ankle ulcer.	No	Yes
31	JB	M	72	Multiple ulcers on right inferior limb.	Yes	Yes
32	FI	M	45	Back infected wound of juvenile Type 1 DBT.	Yes	No
33	HS	M	78	Ulcerated skin cancer of the back.	No	No
34	RM	M	84	Necrotic vascular ulcer of the right ankle.	No	Yes
35	MM	F	77	Post-op ulcer as a result of basal cell carcinoma.	No	No
36	MV	F	62	Necrotic ulcer upperside and hallux of right foot.	No	Yes
37	MP	F	73	Dog bite, amputation of left arm, infected ulcer.	Yes	Yes
38	AK	F	22	Traumatic ulcer of right leg.	No	No
39	NM	F	73	Infected huge painful ulcer of left leg	No	No
40	RS	F	72	Painful infected right leg ulcer	Yes	Yes
41	RF	F	89	Traumatic ulcer anterior leg with necrotic skin	No	No
42	HM	M	80	Carcinoma of the temporal area of the head	No	No

- Each case is documented (with photographs) in individual attached reports.

3. OVERALL RESULTS

In our experience, the use of this new material has shown very good results, both in the short time and the long time, e.g. in acute and chronic cases.

In no case the therapy with TISSUPOR® had to be discontinued because of lack of response or local intolerance to the product.

3 patients died before the end of treatment due to other complications.

4. PADS VS EMBROIDERY

According to our experience, Pads were used in deeper wounds or pressure sores, even in infected areas. Embroidery has a better performance in extensive and more superficial ulcers. Another advantage of the embroidery is that we could increase the ratio cost-benefit of the treatment when cut for several applications.

5. CONCOMITANT THERAPY (RINGER SOLUTION +RIFOCINA)

In our experience, the use of Ringer lactate has shown a reactivation of the ulcerated tissues as corroborated in numerous european papers on the beneficial effects of Ringer solution on tissues vs. saline solutions. In those cases where there was a contamination of the ulcers we combined it with Rifocina (topical).

6. PERFORMANCE OF TISSUPOR® IN CHRONIC VS ACUTE WOUNDS

TISSUPOR® showed an immediate response in the granulation of both acute and chronic ulcers. Of course, the time of healing was different, being much faster in the acute cases.

7. TISSUPOR® AND INFECTED WOUNDS

The wounds should be, at least apparently, uncontaminated to get a better answer. In those cases where there was infection, antibiotic therapy should accompany the local treatment and the pads should be removed more frequently (i.e. every day or every other day). The pads absorb the secretion and as a result, cleans the wounds.

8. AETIOLOGY OF THE WOUND

As a conclusion, we can state that the aetiology of the wound is not relevant for the treatment with TISSUPOR® and it is not a determining factor because the angiogenetic response with TISSUPOR® occurs in all cases with more or less intensity. The so-called intensity of this response is related to the depth of the scars or wounds, but it is always present.

9. TREATMENT SCHEME, SEQUENCE AND DURATION

In a first step, a good cleaning and the debridement of necrotic tissues should be performed. The second stage is a thorough washing with the Ringer solution and the fixing of TISSUPOR® on the wound. Topic solution of Rifocina (Rifampicina) could be added.

With regards to the sequence of treatment, the application of TISSUPOR® will allow to prepare the wounds for a skin graft should it not have epithelized in a first instance.

Duration of treatment depends on the cases: in chronic cases it will take a longer time; in acute cases the results will be quicker, but even in those chronic cases, TISSUPOR® showed a better performance from the very beginning compared with all the previous treatments the patients followed.

Chronic cases required an average of 10-12 applications of TISSUPOR® whereby in acute cases an average of 3-4 pads and/or embroideries were needed.

10. TISSUPOR® IN SPECIFIC CASES (bites, immuno-depressed patients, etc.)

We have tried it with satisfactory results in immunodeficient patients where every other local treatment had failed. (See case 20), i.e. kidney transplanted patients. In acute complicated wounds by animal (dog) bites, the use of TISSUPOR® has proved excellent and with fast results and without infection. See case 3 and case 36 (the latter to be included in the next report).

11. STATISTICS

# OF PATIENTS: 42	SEX	%	WOUND STATE	#	%	DBT PATIENT	#	%
22	MALE	52	CHRONIC	18	43	YES	15	36
20	FEMALE	48	ACUTE	24	57	NO	27	64

AGE GROUP	# OF PATIENTS: 38	%
UNDER 60	12	29
61-70	8	19
71-80	17	40
OVER 81	5	12

12. CONCLUSIONS

- TISSUPOR® represents a new alternative for the treatment of any type of wounds, from dog bites, severe trauma, amputations, diabetic foot to acute post-operative cases where a granulatory answer must be quick and uniform. This is an evident proof that the special tridimensional structure of the product acts with success in any wound and any location of that wound. Even in very chronic ulcers (with a history that exceeds the three years, we have seen excellent results with a rapid improvement of the wounds and in very difficult areas with a definite solution for the patients.
- In no case, where the “restitutio ad integrum” has occurred, have we experienced recurrences of the ulcers.
- Of all the cases treated with this device, we have had a negative answer in one of them (LG – with a history of 5 years), but we are perservering in the treatment and lately the granulatory answer is better. We have not found a specific cause for this slow response and probably it is idiosyncratic.
- We have also noted that TISSUPOR® in chronic ulcers reduces the pain which highly contributes to the patients’ comfort.
- In a few cases, TISSUPOR® had an immediate result (Shrinkage of the size of the wound) after the first applicaction. The evolution, however, slowed down afterwards. It would be interesting to know whether this has also been reported elsewhere and if yes, do we know to what factor it is due to?

Buenos Aires, July 2004