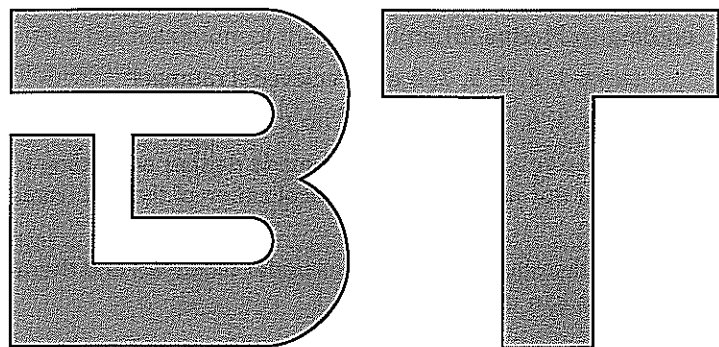


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FEATURE ARTICLE

Traumeel in Traumatic Soft Tissue Swelling

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Soft tissue swellings of the extremities of greater or less extent after accidents, with and without fractures, keep on posing new therapeutic problems to the hospital surgeon since these traumatic swellings frequently make impossible and very often delay considerably rapid and final correct immobilization of the traumatized limbs in a plastic cast or through surgical treatment. On the other hand, swelling of a traumatized extremity after fitting an immobilizing plaster cast is an unpleasant and usually unavoidable complication, which frequently necessitates modifying the plaster cast, (e.g. recasting, splitting the plaster etc.) with the known risks of the set fracture slipping and which is always connected with a considerable extra amount of work and with unpleasantness and pain for the patient.

Local treatment with swelling reducing medicines or with other local measures can practically never be performed or only in the rarest cases, since an absolutely necessary immobilizing plaster cast or other immovable bandage makes such treatment impossible.

In our search for a pharmaceutical which accelerates detumescence orally or parenterally, we in the Quierschied/Saar clinic, which admits very many accident patients with considerable soft tissue swellings, came upon the preparation Traumeel, which is available as ointment, drops, ampoules and tablets.

Traumeel is a phytotherapeutic agent composed of 12 individual plant constituents which contains in addition calci-

um sulphide and polysulphide as well as mercurius amidonitrate and mercuric oxide, the mercurial compounds being present in a non-toxic dosage beneath the physiological threshold, so that even a highly dosed longterm therapy with this preparation is tolerated free of side effects. (1)

The action mechanism of the individual constituents contained in Traumeel is sketched briefly as follows with regard to the traumatology or the swelling reducing properties of this preparation:

Mercurius amidonitrate and mercuric oxide

Detumescent action on edematous conditions; i.e. the pathological soluble condition of the tissue colloids is brought back into the physiological gel condition by the mercurial compounds.

Calcium sulphide and polysulphide

Vessel-sealing action; support and improvement of vesicular respiration and oxidation processes in the traumatized tissue.

Millefolium

Hemostatic action, especially in arterial (micro) hemorrhages.

Arnica montana and Aconitum

Action on the arterial vascular system, reduction of the vascular micro-ruptures and of the emergence of erythrocytes as well as avoiding the formation of erythromas [according to Doring (2)].

Belladonna

Congestions of every type, rubor, tumor, calor, dolor.

Bellis perennis

Exudative processes, resorption of edemas.

Echinacea angustifolia and purpurea

Hyaluronidase inhibiting and antiphlogistic action

Hamamelis

Eliminating venous stases and antithrombotic effect; further inflammation inhibiting and analgesic action. (The constituents chamomilla, hypericum, arnica and aconitum contained in Traumeel also act analgesically).

Symphytum, calendula

Acceleration of callus formation in fractures, stimulation of wound healing.

As has been known for many years, symphytum and calendula together with hamamelis have been the constituents of many well proven "plant sports ointments" because of the properties briefly sketched above and are also contained in preparations for the internal treatment of sports and accident injuries.

It must be obvious that the therapeutic properties of these three proven therapeutic agents are effectively supplemented and extended by the further individual constituents contained in Traumeel and characterized above briefly, so that Traumeel represents a valuable therapeutic agent in all traumatic processes accompanied by swellings and edemas. On the other hand, this preparation is also indicated in degenerative chronic-inflammatory diseases connected with exudative irritations. Publications have been made on the successful application of Traumeel in these two indication groups also from the clinic (i.v. and i.m. application of Traumeel in acute concussion of the brain (1), intraarticular application of Traumeel in chronic osteoarthritis (3) in conjunction with local Traumeel ointment application).

In orienting examinations and treatments with Traumeel (drops, ampoules, ointment*) stretching over several months on approximately 100 in-patients and out-patients with traumatic and post-operative soft tissue swellings, we convinced ourselves in the Miner's Provident Fund Hospital of the detumescent action of this preparation.

*In the case of Traumeel ointment it must be specially emphasized that this is indicated not only in contused injuries such as in soft tissue swellings, hematomas and distortions but also in open wounds. This reference appears to us to be particularly important, since indeed experience shows that both types of injury are frequently present simultaneously at the same part of the body.

We then decided, for the objectification of our favourable findings, to perform an accurate clinical trial (4) with this preparation in the shape of a random test (5) or a controlled study (5).

Observations were made on 34 in-patients, all male, aged from 18 to 84 years with an average age of 41 years, in which the detumescent action of Traumeel in post-traumatic

soft tissue swellings of widely differing localization with and without fractures was to be tested. Out of these 34 patients, 24 were treated with Traumeel whereas 10 patients were included in this examination series as controls without Traumeel therapy and also without any other detumescent medicinal measures whatever.

The methodical procedure took place in this case in a somewhat modified form of unselected alternating series according to Martini (6), in that:

cases 1, 2, 4, 5, 7, 8 etc. received Traumeel

cases 3, 6, 9 etc. received no medication whatever.

The selection was therefore made neither according to the extent nor according to the localization of the soft tissue swelling.

The distribution of the cases under diagnosis and therapy groups can be seen in table 1.

Diagnosis	Number of patients		
	Traumeel	Control	Total
a) Lower leg contusion	4	1	5
b) Lower leg fracture	3	5	8
c) Foot contusion	4	3	7
d) Foot fracture	7	1	8
e) Thigh contusion	1		1
f) Thigh fracture	1		1
g) Patellar fracture	1		1
h) Upper arm fracture	1		1
i) Lower arm fracture	1		1
j) Metacarpal fracture	1		1
Total	24	10	34

Table 1

Traumeel was given in 11 cases in drop form in a dosage of 15 drops 3 times daily. In 11 patients this oral Traumeel medication was combined with intramuscular application of 1 ampoule of Traumeel daily.

In one case a Traumeel ointment application performed twice daily was made in addition to the oral Traumeel drop medication (15 drops 3 times daily), which could not be performed for the other 23 patients since in their cases the injured limb was immobilized with a plaster splint immediately after the accident. A further case was eliminated for external reasons from the comparative investigation of Traumeel oral and Traumeel oral plus parenteral.

Before immobilization of the traumatized swollen part of the body, the circumference of the injured extremity was measured and for purposes of control, that of the uninjured extremity, with certain measuring points (MI-MIII or MIV) being laid down for the individual limbs, as indicated below:

Lower leg:	MI = 15 cm	} beneath the upper ridge of the patella
	MII = 20 cm	
	MIII = 25 cm	

- Foot:
- MI = instep circumference 10 cm distant from the tip of the big toe
 - MII = instep circumference at the insertion of the tibialis anterior muscle
 - MIII = heel-ankle circumference.

Only in four cases with injuries to the lower leg or the foot had the above standardized measuring scheme to be deviated from by determining an additional measuring point, since the maximum of the swelling lay outside these measuring points.

- Thigh
- MI = 15 cm
 - MII = 20 cm
 - MIII = 25 cm
 - MVI = 30 cm
- } above the lower ridge of the patella

- Elbows
- MI = 5 cm below the olecranon tip
 - MII = elbow joint circumference
 - MIII = 5 cm above the olecranon tip

In one case with injuries of the upper limb (subcapital upper arm dislocation fracture) it was also necessary to deviate from this measuring scheme, since the maximum of the swelling lay outside these measuring points.

Traumeel was administered immediately in the above described manner, (oral or oral plus intramuscular) for several days after the first measurement had been made immediately after hospital admission or immediately after surgery (marrow nailing, screw connection etc.). Administration continued up to the time at which the reduction in swelling of the traumatized extremity had advanced to such an extent that

immobilization on a plaster splint could be replaced by a regular plaster cast or by another form of recasting. A second measurement was performed at the measuring points stated above prior to this.

In the case of 6 patients treated with Traumeel, in whose case because of the primary extent of the soft tissue swellings a lengthy period of detumescence had to be reckoned with clinically from the start, orientating intermediate measurements were performed between the third and the twelfth day after commencement of treatment. However, since these circumference measurements were performed at non-pre-determined intervals, the time for the maximum detumescent action of Traumeel cannot be determined from these intermediate measurements.

The period of detumescence (i.e. the time expressed in days between the first and the second or last measurement before changing the plaster cast - both days included) was subject to accurate analysis*.

Here it resulted that in the 24 cases which were treated with Traumeel, the period of detumescence lay between 4 and 20 days with an average detumescence period of 10 days. In the control cases, the detumescence period was between 5 and 20 days. However in these cases the average detumescence period amounted to 13 days.

*We wish to express at this point our special gratitude to Dr. med. habil. H.-J. Lange of the Institute for Medical Statistics and Documentation of the University of Mainz (Director: Prof. Dr. Dr. S. Koller) for the medicinal statistical evaluation.

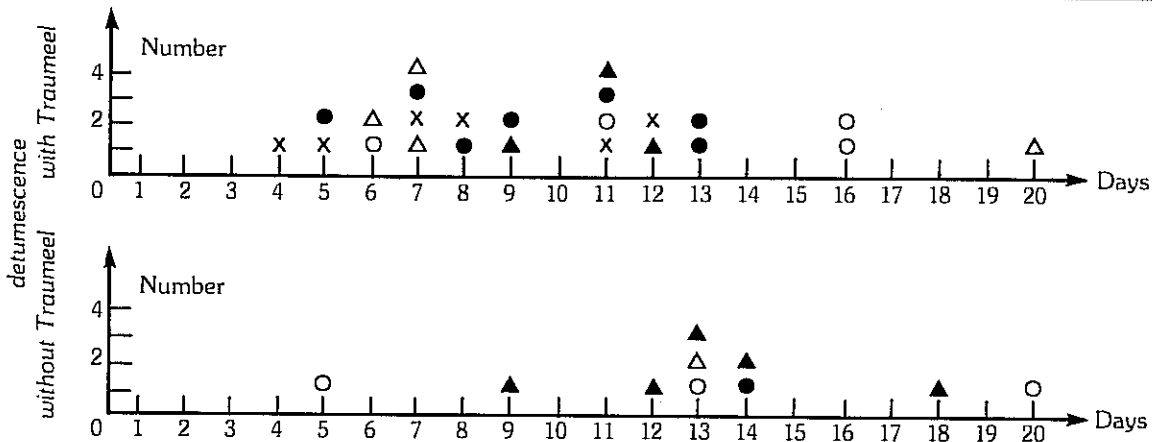


Diagram: comparative graphical display of the detumescence times for the 24 patients treated with Traumeel and for the 10 untreated patients of the control group.

△ = lower leg contusion ▲ = lower leg fracture ○ = foot contusion ● = foot fracture x = miscellaneous

The graphical representation coded according to diagnosis shows clearly the detumescent action of Traumeel compared with the untreated control group (see illustration).

A further statistical analysis produced the following results:

Apart from the different frequency of the diagnosis, (cf table 1 a to d), both groups were comparable amongst one another with regard to the severity, i.e. the appearance and the extent of the post-traumatic swelling conditions.

In particular both groups coincided completely with regard to sex distribution (all men) and with regard to the age distribution (average age of the Traumeel group 41 years, average age of the control group also 41 years).

Even if the medicinal statistical evaluation of the findings brought about no statistical significance because of the relatively small number of cases, this excludes in no way that on repetition of the test on a more extensive number of patients, the detumescent action of Traumeel indicated in this exam-

ination series can be verified with statistical significance as well.

The following partial results from the detailed analysis of the numerically very accurately recorded observations were interesting: in two cases absolutely no effect of the Traumeel was detectable, i.e. there was no difference between the measurement before and after removal of the plaster splint.

Out of the remaining 22 cases treated with Traumeel, complete detumescence occurred in 11 cases inside the observation period, as could be easily ascertained from the comparative measurements with the sections of the nontraumatized extremities in each case.

In 11 cases slight residual swelling still existed even after conclusion of Traumeel medication.

Out of the 10 control cases, complete detumescence occurred in 4 cases during the observation period, whereas in 6 cases residual swelling was present even after conclusion of the observation period.

The average detumescence period in the 11 cases which received Traumeel only orally (15 drops 3 times daily) was 9.7 days, whereas the average detumescence period in the 11 cases which received Traumeel orally (15 drops 3 times daily) and parenterally (1 ampoule intramuscularly daily) amounted to 10.4 days.

The fact that in the combined (oral + parenteral) application of Traumeel the detumescence period was somewhat longer is due to the fact that in principle in primarily considerable soft tissue swellings the combined Traumeel application was performed while we were satisfied with oral medication in the cases of less massive swellings.

In 6 cases of the combined series, parenteral Traumeel medication was discontinued and Traumeel was administered only orally on incidence of detumescence after 1 to 12 days (on average after 4 days).

The compatibility of the preparation was excellent. Side effects of a local or general nature were not seen.

Summary

In a clinical examination series of 24 male in-patients with traumatic soft tissue swellings of the limbs with and without fractures, a detumescent action of Traumeel (15 drops 3 times daily** or 15 drops 3 times daily** in combination with 1 ampoule intramuscularly daily) could be verified in comparison to a control group of 10 male patients congruent with regard to severity and extent of the swellings as well as

with regard to age, based on the accurate evaluation of extremity circumference measurements at certain predetermined measuring points.

The good therapeutic experiences with Traumeel in traumatic and post-operative soft tissue swellings made during several months previously with a large number of patients were confirmed by this accurately performed and evaluated examination series in the shape of a random sample test or a controlled study.

**Further treatment with Traumeel performed after conclusion of this clinical trial has shown that at a significantly higher dosage of orally administered Traumeel - namely 30 drops 3 times daily - even better therapeutic results could be achieved. Neither were any incompatibility symptoms or side effects seen at this dosage, this being so even if at the same time 1 ampoule Traumeel daily was administered intramuscularly in addition.

References:

- (1) Kunt, T.: Über die Anwendung von Vertigoheel und Traumeel bei der Commotio cerebri acuta; *Hom.-Journal*, 5 : 25-28 (1966)
- (2) Doring, G.: *Mtschr. Unfallhk.*, 55 : 134 (1952)
- (3) Hieber, F.: Therapie der Knie- und Hüftgelenksarthralgie durch intraartikuläre Injektion einer neuen pflanzlichen Wirkstoffkombination; *Hippokrates* 38 : 206-207 (1967)
- (4) John, J.: Zur Problematik der Auswertung von Therapieergebnissen und Untersuchungsreihen; *Hom.-Journal* 6 : 181-191 (1967)
- (5) Haberland, G. L.: Ärztliche und methodische Problematik bei der klinischen Prüfung; *Therapeutische Berichte Bayer*, 37 : 155-156 (1965)
- (6) Martini, P.: *Methodenlehre der therapeutisch-klinischen Forschung*; 3. Auflage, Springer-Verlag, Berlin-Göttingen-Heidelberg (1953)

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