

Treatment of Sports Injuries with Traumeel Ointment

A Controlled Double-Blind Study

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Abstract

A controlled double-blind study was conducted on outpatients with sports injuries, to compare with a placebo the effectiveness of Traumeel ointment in its normal commercially available form (Traumeel S), and in a form of this preparation containing only six constituents (Traumeel Sine). The primary criteria employed to assess medication effectiveness were regression of swelling and reduction in skin temperature. Secondary criteria for effectiveness were the following: increase in maximum muscle force, reduction of pain intensity (pain index), time until resumption of training, and overall evaluation of effectiveness by patient and physician.

A total of 102 patients was included in this study, with breakdown into groups of 34 patients each. It was possible to evaluate data for all patients except one (who was disqualified for not satisfying criteria for acceptance into the study). All other patients completed the study in compliance with the criteria for conduct of the study.

With respect to the main criteria of skin temperature, no differences became apparent among the three treatment groups; variance was determined, however, for swelling. Convincing evidence has been obtained

that there is no difference between the effectiveness of Traumeel S and Traumeel Sine, but that the effectiveness of both differs from that of the placebo. Purely formally, however, in the sense of control of multiple-level alpha, only the difference between Traumeel Sine and the placebo was able to be verified.

All secondary criteria such as maximum muscle force, pain index, resumption of training, and overall evaluation confirm without exception, and with low *P* values, that there is no difference in effectiveness between the two Traumeel preparations, but that a great difference does exist between these preparations and the placebo. The values of *P* on the 15th day were smaller than 0.001 for the pain index and the overall evaluation. In addition, the Mann-Whitney characteristic $P(X < Y)$ reveals that these differences are of considerable clinical significance. At the end of the study, the patients and the physician evaluated the tolerance of the tested substances as good to very good. No undesired side effects were observed in any of the three treatment groups.

Introduction

In amateur and professional areas

of athletics in Germany, the number of sports injuries has shown progressive increase over the recent past: the level is now at approximately 1.6 million sports injuries per year in Germany. These injuries primarily involve injuries by blunt force in the form of contusions and sprains, accompanied by subcutaneous rupture of tissue in the afflicted area. Edemas (permeability alteration) and vascular injuries (hemorrhages) are the consequence. The majority of these injuries are minor in nature and will as a rule heal within two to six weeks. Such injuries, however, do have the initial effect of terminating athletic activity, and they do in certain cases attain considerable significance as illnesses in their own right. An essential therapeutic objective is therefore the elimination of primary symptoms such as swelling, inflammation, and pain, as well as the ability to completely resume sports activities as soon as possible. This objective is possible through interruption of the mutual dependence of inflammatory and traumatic disorders: i.e., pain, muscle stiffness, and restriction of mobility.

A series of studies conducted over the past years has investigated the ef-

festiveness of Traumeel ointment for the therapy of such sports injuries. Post-marketing drug surveillance conducted with 3,422 patients using Traumeel S revealed good to very good therapeutic results with respect to treatment of first- and second-degree sprains and contusions, and to reduction of the term of therapy [St. Zenner and H. Metelmann, 1991]. In their 1988 clinical tests conducted to compare the effectiveness of Traumeel ointment with that of a placebo in the therapy of ankle sprains, J. Zen, W.D. Connert, J. Mau, and G. Feuerstake verified that Traumeel ointment was superior to the placebo with respect to the primary objective criterion of "restoration of complete ankle mobility," and for the secondary comparison criterion "pain upon movement and inversion." Planning is for the results of this study to be validated in a further investigation.

Methodology of testing

Purpose of the study and testing criteria

The objective of this controlled double-blind study was evaluation of the effectiveness of Traumeel ointment in conjunction with regression of the main consequences of sports injuries: first- and second-degree sprains and contusions. The parameters of testing were:

- Swelling
- Skin temperature
- Maximum muscle force
- Pain intensity
- Time elapsed until resumption of training without complaints.

The specific purpose of the study was verification of the superior effectiveness of Traumeel over the placebo. In addition to the well-known preparation Traumeel ointment, the study also included verification of the effectiveness of a new preparation containing only six of the constituents of Traumeel ointment.

Measurement of the effectiveness criteria took place on the injured as well as on the uninjured contralateral extremity.

The primary criteria for effectiveness were the following:

- Abatement of swelling (i.e., of the measured circumference).
- Normalization of skin temperature.

Circumference of the injured extremity (in cm):

The circumference of the injured extremity was measured by means of a flexible tape measure before treatment on the first day, as well as on the fifth and fifteenth days. Measurement took place on all days at the same, initially marked point. On the contralateral, uninjured side, comparative measurements took place during each of the examinations.

Measurement of the skin temperature (in °C):

The skin temperature was measured with a proximity thermometer: a radiation thermometer of type KT41, made by the company Heimann GmbH of Wiesbaden, Germany. At the first measurement, the point of greatest pressure sensitivity was taken as registration point and was marked for the following examinations. Skin temperature measurements were performed according to the identical procedure on the contralateral, uninjured side.

Secondary criteria for therapeutic effectiveness:

Maximum muscle force, measured in kg by a dynamometer-type device.

Abatement of the pain intensity, expressed as a pain index - a cumulative index value composed of summed values for pain experienced at rest, in motion, and under pressure (each valued on a scale of 0 to 2: 0 = no pain; 1 = slight pain; 2 = severe pain).

Time elapsed until resumption of sports activities without complaints.

Number of therapy interruptions.

Evaluation of the effectiveness of treatment by the patients and the physician at the end of therapy (on a valuation scale from 1 to 4, with 1 = very good results; 2 = good; 3 = mod-

erate; 4 = poor).

Maximum muscle force as well as pain experienced at rest, in motion, and under pressure were measured or evaluated and recorded before the beginning of therapy, and upon each of the following examinations, on the fifth and fifteenth days.

Testing procedure

The testing procedure was a randomized parallel group test earned out under double-blind conditions. The entire patient population was broken down into the following three therapy groups:

- One group treated with Traumeel S;
- One group treated with Traumeel Sine;
- One group treated with a placebo (Traumeel ointment base).

Thirty patients were initially selected for each group, which ensured a sufficient number of independent observations for evaluation of distribution models. In order to compensate for interruptions in therapy or possible nonuniformities in the treatment groups, four additional patients were accepted into each group i.e., a total of 34 was selected for each therapy group. The number of cases was not determined in accordance with specific calculations, since information on the primary criteria was not yet available at the time involved.

Randomizing took place according to the principle of random-permuted blocks, with each block consisting of six patients each. We employed the PC program RANCODE developed by the company IDV (located in Gauting, near Munich) for this work.

The study was conducted under strict double-blind conditions. The three ointments applied could not be distinguished by outward observation. They were identified by consecutive numbers.

Biometric evaluation procedures

In the plan of testing, the objectives of the study were primarily formulated in an exploratory sense. Swelling and skin temperature were, however, de-

patient would therefore require 30 x 10 = 300 g of ointment. We consequently dispensed to each patient three tubes of ointment, each containing 100 g of the tested preparation and the comparison preparation. The therapeutic procedure was identical for all three test groups.

Content of medication:

The following were contained in 100 g of the ointment with medicinally active agents:

Traumeel ointment 1 (Traumeel S):

Aconitum 1X 0.05 g; Arnica 3X 1.50 g; Belladonna 1X 0.05 g; Bellis perennis, mother tincture, 0.10 g; Calendula, mother tincture, 0.45 g; Chamomilla, mother tincture, 0.15 g; Echinacea angustifolia, mother tincture, 0.15 g; Echinacea purpurea, mother tincture, 0.15 g; Hamamelis, mother tincture, 0.45 g; Hepar sulfuris 6X 0.025 g; Hypericum 6X 0.09 g; Mercurius solubilis Hahnemanni 6X 0.04 g; Millefolium, mother tincture, 0.09 g; Symphytum 4X 0.10 g.

Traumeel ointment 2 (Traumeel Sine):

Arnica 3X 1.50 g; Calendula, mother tincture, 0.45 g; Hamamelis, mother tincture, 0.45 g; Millefolium, mother tincture, 0.09 g; Mercurius solubilis Hahnemanni 6X 0.04 g; Hypericum 6X 0.09 g.

Note: 1X= the first decimal attenuation, etc.

Placebo:

The control group received 100 g of Traumeel ointment base, without the medicinally active agents.

Medication

All the patients in the three therapy groups observed the instructions as stipulated in the test protocol, until the study was completed. Therapy with the ointment dressing took place according to the following plan:

No patient received medicamentous therapy before or during the study. In a number of cases, the patients received

adjuvant physical therapy before this study began: this therapy ended, at the latest, at the first day of the study.

and localization,

Primary criteria for effectiveness

For the two primary criteria for ef-

Therapy Group	1st day	2nd . . . 15th day
Traumeel S (Traumeel Ointment 1)	1x 10g	2 x 10 g / day
Traumeel Sine (Traumeel Ointment 2)	1x 10g	2 x 10 g / day
Placebo (Traumeel ointment base)	1x 10g	2 x 10 g / day

Conduct of the study

This study was conducted according to the Declarations of Helsinki and Venice, or according to the relevant guidelines of the German Drug Law (*Arzneimittelgesetz*).

Results of the study

Quality of the data

All patients satisfied the selection criteria, with the exception of one polytraumatic patient for whom double data were submitted (for thigh and calf). Continuously conducted quality control enabled complete acquisition of all findings data.

Patient characteristics

Of the 102 patients originally available for the study, it was possible to analyze the findings from 101 (as stated, one patient did not satisfy the selection criteria). Of these 101 patients, 34 received Traumeel S, 33 obtained Traumeel Sine, and 34 were treated with the placebo. Table 1 shows a compilation of the collected data.

The data on the next page in Table 1 reveal that the three therapy groups are eminently comparable with respect to age, sex, height, and weight. Even with the Lorenz Index which was calculated in order to compensate for any potential influencing factors such as body weight only slight differences were apparent. The three therapy groups were furthermore comparable to a great degree with regard to diagnosis, intensity of the injury, case his-

festiveness i.e., abatement of swelling and normalization of skin temperature confirmatory analysis of the two points in time of patient examination was conducted in the sense of verification of effectiveness. As stipulated by the provisions set forth with the statistical methods, the four values of P were required to be smaller than 0.012, 0.017, 0.025, and 0.05. As Table 2 shows, this provision was satisfied only for the percent of abatement of swelling on the 15th day (P= 0.0067). In the individual comparisons of the three therapy groups, application of the Shaffer Method revealed superiority of Traumeel Sine over the placebo (P = 0.0028). In the strict sense of confirmatory testing, these data therefore verify superiority of Traumeel Sine over the placebo only for the measurement of circumference on the fifteenth day of therapy. Differences in the primary criteria are indeed apparent on the fifth day of therapy although they do not achieve the level of significance stipulated for this study. There is practically no difference between the two Traumeel formulations. With respect to skin temperature, no differences became apparent among the three therapy groups. On the fifth day, however, the Mann-Whitney characteristic P(X<Y) reveals slight differences in favor of the two Traumeel groups, over the placebo.

The mean abatement of swelling was approximately the same for the two Traumeel groups, both on the fifth and on the fifteenth days (see Table 3 below).

Entirely analogous results were ob-

tained for the reduction of skin-temperature difference between injured and contralateral uninjured sides: i.e., approximately the same reduction in the two Traumeel groups, and less reduction in the placebo group (see Table 4 below).

Figs. 1 and 2 graphically represent plots of the two primary criteria.

Secondary criteria for effectiveness

The results of test statistics have been compiled in Table 5. Comparisons among the individual groups for maximum muscle force revealed that the two Traumeel groups were notably superior to the placebo only as verified on the 15th-day examination (global test: $P = 0.0052$; individual comparisons: $P = 0.0070$ and 0.0062). The 5th-day test, however, did not manifest advantages for the Traumeel groups (global test: $P = 0.2469$; individual comparisons: $P = 0.3361$ and 0.1158). The individual comparisons for the pain index demonstrated definite superiority of the two Traumeel groups over the placebo: both on the 5th-day examination (global test: $P = 0.0016$; individual comparisons: $P = 0.0005$ and 0.0082) as well as on the 15th-day examination (global test: $P = 0.0002$; individual comparisons: $P = 0.0004$ and 0.0002). The individual comparisons showed marked superiority of the two Traumeel groups over the placebo group with respect to the length of time required until resumption of athletic training (global test: $P = 0.0004$; individual comparisons: $P = 0.0002$ and 0.0006). Individual group comparisons among the three different therapy groups further revealed the following: no difference between the effects of Traumeel S versus Traumeel Sine ($P = 0.789$), very good effectiveness for Traumeel S with respect to the placebo ($P = 0.002$), and very good effectiveness for Traumeel Sine with respect to the placebo ($P = 0.006$). Both the assessments of the patients as well as those of the physician for therapeutic effectiveness disclosed definite advantages for the two Traumeel groups over the placebo group (global test: $P = 0.0002$ for patient evaluation and $P =$

Criteria	Traumeel S		Traumeel Sine		placebo	
	N	(in %)	N	(in %)	N	(in %)
Number of patients (N)	34		33		34	
Age (in years):						
Mean (S. D.)	31.1	(9.83)	31.3	(9.88)	29.5	(11.17)
Min.-Max.	19.0	-50.0	18.0	-50.0	18.0	-50.0
Median	27.0		30.0		24.5	
Sex:						
Male	21	(61.8)	22	(66.7)	23	(67.6)
Female	13	(38.2)	11	(33.3)	11	(32.4)
Height (in cm):						
Mean (S. D.)	177.4	(10.24)	175.7	(10.05)	177.8	(8.71)
Min.-Max.	163.0	-208.0	152.0	-194.0	160.0	-193.0
Median	175.0		175.0		178.0	
Weight (in kg):						
Mean (S. D.)	75.7	(13.75)	71.9	(11.19)	72.7	(11.03)
Min.-Max.	55.0	-110.0	50.0	-92.0	48.0	-96.0
Median	72.5		73.0		73.0	
Lorenz index (in %):						
Mean (S. D.)	8.04	(13.38)	4.22	(8.89)	3.24	(9.94)
Min.-Max.	-13.00	-60.80	-13.80	-24.30	-17.20	-22.30
Median	6.95		3.60		2.10	
Diagnosis:						
Contusions	20	(58.8)	16	(48.5)	11	(32.4)
Sprains	14	(41.2)	17	(51.5)	23	(67.6)
Pain intensity:						
Slight	1	(2.9)	0	(0.0)	1	(2.9)
Moderate	33	(97.1)	33	(100.0)	33	(97.1)
Case history:						
Sports injury	31	(91.2)	32	(97.0)	34	(100.0)
Other cause	3	(8.8)	1	(3.0)	0	(0.0)
Prior treatment:						
Medicamentous	0	(0.0)	0	(0.0)	0	(0.0)
Phys. therapy	7	(20.6)	6	(18.8)	8	(23.5)

Table 1: Compilation of demographic and case-study data

0.002 for physician's evaluation; individual comparisons: $P = 0.0014$ and 0.0001 for patients' assessments, and $P = 0.0003$ and $P = 0.0007$ for physician's assessment).

Maximum muscle force

In the two Traumeel groups, the maximum muscle force capable of being exerted by the injured side has, after Traumeel therapy, approached the

muscle force of the contralateral, noninjured side to a definitely greater degree than the improvement in the placebo group. See Table 6 below.

Pain index

Data on pain were acquired in the form of a cumulative index value consisting of individual evaluation for the following types of pain: pain at rest, pain upon movement, and pain upon

Criterion	Test	Data from examination on the 5th day		Data from examination on the 5th day	
		P	P (X < Y)	P	P (X < Y)
Abatement of swelling (in cm of circumference)	Overall	0.0252		0.0067	
	Traumeel S vs. Traumeel Sine	0.3929	0.56	0.4147	0.56
	Traumeel S vs. placebo	0.0440	0.36	0.0214	0.34
	Traumeel Sine vs. placebo	0.0129	0.32	0.0028	0.29
Skin temp. in °C	Overall	0.4301		0.8453	
	Traumeel S vs. Traumeel Sine	0.5539	0.54	0.7477	0.48
	Traumeel S vs. placebo	0.3548	0.43	0.5586	0.46
	Traumeel Sine vs. placebo	0.2480	0.41	0.8369	0.48

Table 2: Compilation of test statistics for the two primary criteria used to evaluate effectiveness (percent change with respect to baseline data).

Therapy		Baseline	3rd . . . 5th day	13th . . . 15th day
Traumeel S	N	34	34	34
	Mean (StD)	34.12 (7.339)	-1.94 (1.242)	-4.38 (1.810)
Traumeel Sine	N	33	33	33
	Mean (StD)	33.22 (7.697)	-2.16 (1.483)	-4.68 (1.776)
Placebo	N	34	34	34
	Mean (StD)	32.50 (7.220)	-1.44 (1.136)	-3.46 (1.540)

Table 3. Abatement in swelling - reduction in circumference (in cm), with percent change with respect to baseline.

Therapy		Baseline	3rd . . . 5th day	13th . . . 15th day
Traumeel S	N	34	34	33
	Mean (StD)	1.21 (0.403)	0.75 (0.331)	0.25 (0.235)
Traumeel Sine	N	33	33	33
	Mean (StD)	1.24 (0.419)	0.87 (0.468)	0.40 (0.482)
Placebo	N	34	33	33
	Mean (StD)	1.27 (0.410)	1.12 (1.250)	0.75 (1.035)

Table 4: Difference in skin temperature (in °C) between injured and contralateral, non injured side.

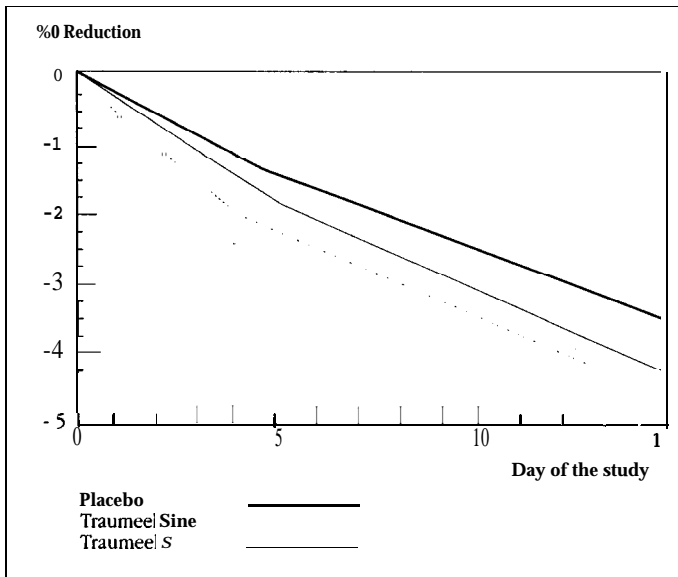


Figure 1: Réduction du sweating as percent of decrease from baseline value

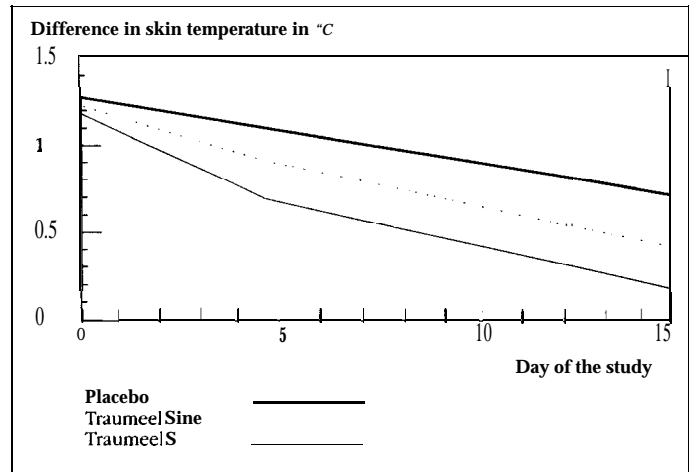


Figure 2: Difference in skin temperature (in °C) between injured and noninjured (contralateral) side.

Criterion	Test	Data from examination on the 5th day		Data from examination on the 5th day	
		P	P (X < Y)	P	P (X < Y)
Maximum muscle force in kg	Overall	0.2469		0.0052	
	Traumeel S vs. Traumeel Sine	0.3805	0.44	0.4404	0.45
	Traumeel S vs. placebo	0.3361	0.57	0.0070	0.69
	Traumeel Sine vs. placebo	0.1158	0.61	0.0062	0.69
Pain Index	Overall	0.0016		0.0002	
	Traumeel S vs. Traumeel Sine	0.4137	0.45	0.6132	0.53
	Traumeel S vs. placebo	0.0007	0.28	0.0005	0.27
	Traumeel Sine vs. placebo	0.0089	0.33	0.0003	0.26
Resumption of training	Overall			End of therapy P = 0.004	
	Traumeel S vs. Traumeel Sine	0.789			P (X < Y) 0.49
	Traumeel S vs. placebo	0.002			0.31
	Traumeel Sine vs. placebo	0.006			0.32
Overall assessment of effectiveness	Overall	0.0002		0.0002	
	Traumeel S vs. Traumeel Sine	0.6571	0.53	0.9462	0.50
	Traumeel S vs. placebo	0.0010	0.28	0.0003	0.25
	Traumeel Sine vs. placebo	0.0001	0.24	0.0007	0.27

Table 5: Compilation of test statistics for the secondary criteria for therapeutic effectiveness.

pressure. Each of these three types of pain received a grade from the following scale: 0 = no pain; 1 = slight pain; 2 = severe pain.

In the two Traumeel groups, the mean value for pain index demonstrated definitely greater reduction both at the 5th-day examination, as well as at the 15th-day checkup than did the reduction in the placebo group. See Table 7.

Resumption of training

On the average, the patients in the two Traumeel groups were able to resume athletic training sooner than the patients in the placebo group. See Table 8.

Assessment of therapeutic effectiveness

At the end of therapy, the patients and the treating physician separately evaluated the therapeutic effectiveness for each case. The following four-point scale of grading was used: 1 = very good; 2 = good; 3 = moderate; 4 = poor. In this evaluation, both patients and physician judged the two Traumeel preparations to be more effective than the placebo. See Table 9.

Figures 3,4,5, and 6 are graphical representations of data results in conjunction with the secondary criteria. Figures 3 and 4 show the plots of mean values. Fig. 5 is a graphical depiction in the form of a Kaplan-Meier Function Plot, and Fig. 6 is a vertical bar graph of the mean values.

Criteria for tolerance and side effects

Assessment of patient tolerance to the preparations:

At the end of the therapeutic phase, the patients and the physician rated tolerance to the ointment by a number from the following scale: 1 = very good; 2 = good; 3 = moderate; 4 = poor.

In all three therapy groups, both the patients as well as the physician rated tolerance to the ointment as either good or very good. See the data in

Table 10.

Undesired side effects

During the entire course of the study, no undesired side effects were observed for any of the patients in any of the three therapy groups.

Interpretation of results

The parameters used in this study in the recording of swelling reduction, muscle force, and pain proved to be sufficiently sensitive and reliable in revealing developments in a patient's condition. The pain index proved to be an extraordinarily good measure of such conditions, as revealed by the small values of P and by the Mann-Whitney characteristic $P(X < Y)$ as indicator of relevance.

The time required until resumption of training also proved highly appropriate to indicate the positive or negative success of a medication. The data obtained for this criterion likewise yielded small values of P. On the other hand, skin temperature proved ineffective as an indicator of therapeutic success.

The following may be summarized from the results of this study: the pain index proved to be the most suitable indicator of therapeutic effectiveness. In addition, muscle force, time until resumption of training, and degree of reduction in swelling all similarly proved to be good criteria. These indicators all revealed practically identical therapeutic effects through application of the preparations Traumeel S and Traumeel Sine. Both of these preparations were superior to the placebo. Only the criterion of skin temperature revealed no difference.

Marked differences also resulted from the overall assessment of effectiveness: as a rule, a criterion with a quite sensitive response. Very small values of P resulted here for the distinction with respect to the placebo. The Mann-Whitney characteristics were all less than 0.28, which indicates significant differences.

If a final assessment is made in accordance with a decision model based

on strict statistical principles, it is true that superiority is evidenced only for Traumeel Sine in comparison to the placebo for circumference of the injured point on the 15th day. Indeed, confirmatory testing was successful only in that context. A decision strictly on this basis, however, appears excessively narrow, particularly in light of the significant differences revealed for the other criteria above all, pain index and overall assessment of effectiveness. Under consideration of all data, evidence is indeed convincing for the equivalence of the preparations with active constituents, and for their difference with respect to the placebo group. As the Mann-Whitney characteristics reveal, the differences of the Traumeel preparations with respect to the placebo group are indeed very considerable.

The fact that the data in the study evidenced great differences for both forms of administration of the Traumeel preparation (Traumeel S and Traumeel Sine) over the placebo is also a finding which speaks eloquently for the effectiveness of the preparation: in this way, confirmation of effectiveness of the one preparation supports that of the other. Our one single study, therefore, provides both verification of effectiveness as well as validation for the medication.

It is also interesting to compare the results of this study with those obtained in an earlier investigation conducted by Zen et al. In the Zen study as well, the criterion of skin temperature revealed no therapeutic effects. In Zen, the criterion of swelling was relatively unresponsive; in our study, on the other hand, this criterion was in fact eloquent with respect to therapy, although not as conclusively as the others. In the earlier Zen study, pain upon movement proved to be highly suitable as evidence of effectiveness. In our study as well, pain data in the form of the index value highly effectively revealed the differences between the forms of treatment. Angular measurements of joint articulation, which showed good differentiation in the earlier study, was

Therapy		Baseline	3rd . . . 5th day	13th . . . 15th day
Traumeel S	N Mean (StD)	34 - 30.12 (9.868)	34 -16.15 (8.958)	34 - 2.32 (4.374)
Traumeel Sine	N Mean (StD)	33 -27.27 (11.281)	33 -14.55 (8.832)	33 - 2.15 (5.864)
Placebo	N Mean (StD)	34 -28.69 (9.350)	34 -18.26 (9.643)	34 - 7.94 (8.866)

Table 6: Reduction in the difference between the maximum muscle force capable of being exerted by the injured side, and the muscle force exerted by the contralateral noninjured side.

Therapy		Baseline	3rd . . . 5th day	13th . . . 15th day
Traumeel S	N Mean (StD)	34 4.7 (0.68)	34 2.6 (0.81)	34 1.0 (0.67)
Traumeel Sine	N Mean (StD)	33 4.8 (0.61)	33 2.8 (0.83)	33 0.9 (0.77)
Placebo	N Mean (StD)	34 4.9 (0.33)	34 3.4 (0.95)	34 1.8 (0.96)

Table 7: Pain Index.

Therapy		Date of final examination	Day of resumption of training
Traumeel S	N Mean (StD)	34 14.6 (0.61)	34 12.1 (2.56)
Traumeel Sine	N Mean (StD)	33 14.4 (0.74)	33 12.2 (2.46)
Placebo	N Mean (StD)	34 14.6 (0.55)	34 13.5 (2.25)

Table 8: Date of final examination and date of resumption of athletic training

Effectiveness	Traumeel S Assessment by		Traumeel Sine Assessment by		Placebo Assessment by	
	Patient (%)	Physician (%)	Patient (%)	Physician (%)	Patient (%)	Physician (Ye)
Very good	16 (47.1)	8 (23.5)	16 (48.5)	9 (27.3)	6 (17.6)	3 (8.8)
Good	13 (38.2)	17 (50.0)	15 (45.5)	14 (42.4)	11 (32.4)	9 (26.5)
Moderate	5 (14.7)	9 (26.5)	2 (6.1)	9 (27.3)	17 (50.0)	10 (29.4)
Poor	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	12 (35.3)
N	34	34	33	33	34	34

Table 9: Assessment of therapeutic effectiveness by patients and physician.

Tolerance	Traumeel S Assessment by		Traumeel Sine Assessment by		Placebo Assessment by	
	Patient	Physician	Patient	Physician	Patient	Physician
very good	22	21	21	21	11	11
Good	12	13	12	12	23	23
Moderate	0	0	0	0	0	0
Poor	0	0	0	0	0	0
N	34	34	33	33	34	34

Table 10: Assessment of tolerance to the ointment by patient and physician

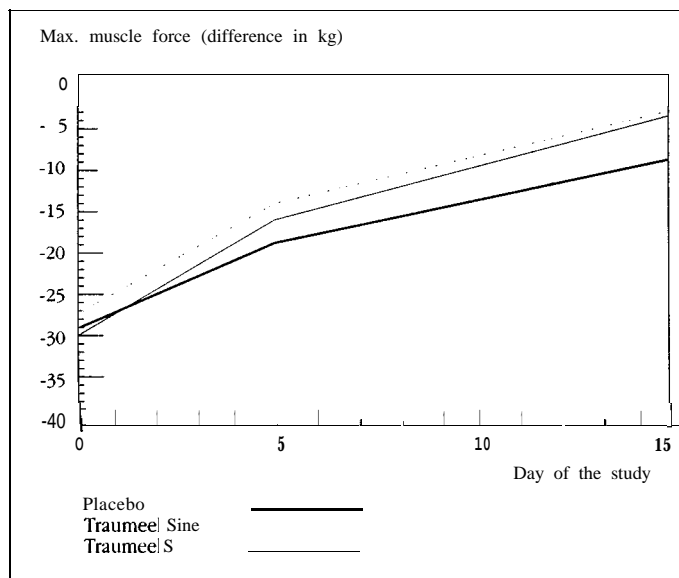


Figure 3. Maximum muscle force in kg reduction in the difference between injured and non injured (contralateral) side

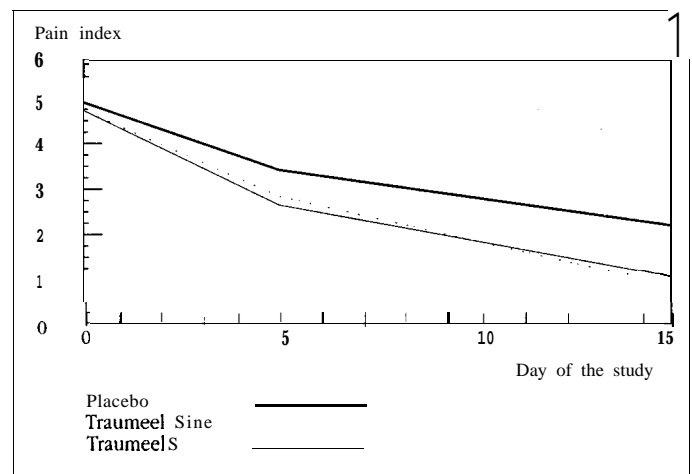


Figure 4: Pain index (cumulative score.)

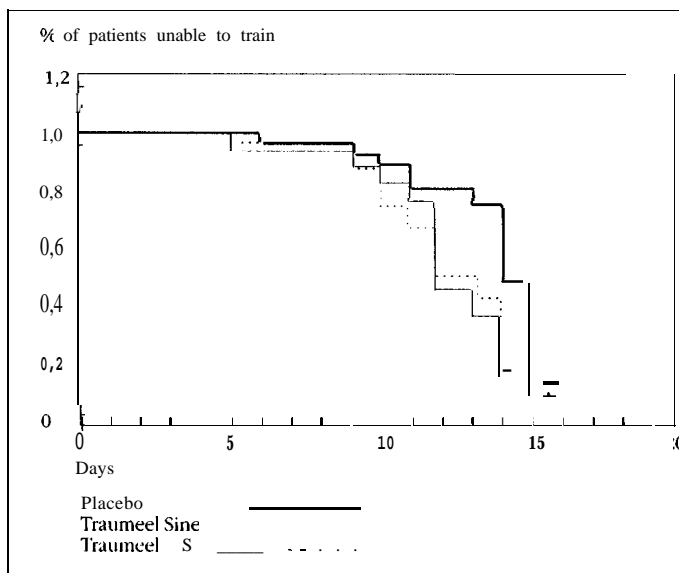


Figure 5: Kaplan -Meier function plot: no. of days until resumption of training

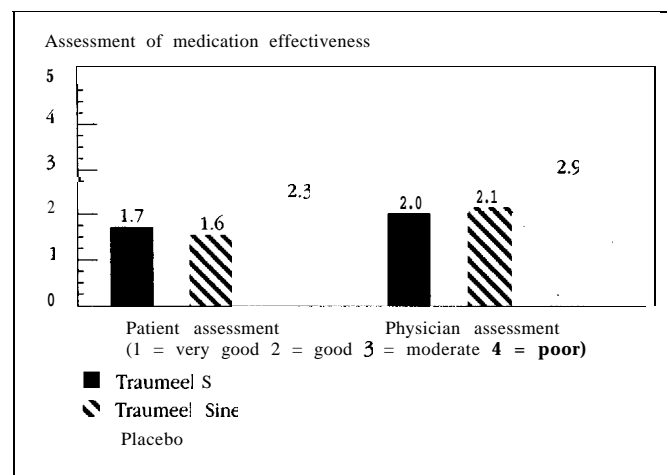


Figure 6: Assessment of effectiveness by patients and the physician (mean values)

not used in our work.

On the whole, our study provided highly congruous findings when compared to the earlier, comparable investigation, in confirmation of the effectiveness of the preparations Traumeel S and Traumeel Sine. The conclusions which we reached with respect to the effectiveness of Traumeel S confirm the findings of the earlier study, with good

agreement obtained in the conclusions reached for the comparable individual criteria.

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