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REPORT

on

Clinical (medical) trials of the Aires matrix applicator developed by the Aires New Medical Technologies Foundation (St. Petersburg, Russia) and intended for providing treatment using BAPs and BAZs

1. The medical trials of the prototypes of the Aires matrix applicator developed by the AIRES New Medical Technologies Foundation (St. Petersburg, Russia) were instituted according to the resolution of the Commission on Devices and Apparatus for Performing Quick Diagnostics of the Human Organism's Functional State by Physiological Indices of Its Reflective Zones (RZs) and Biologically Active Points (BAPs) and for Conducting Reflexotherapy Using RZs and BAPs, of the Committee on New Medical Equipment of the Russian Federation Ministry of Public Health (Protocol #3, July 14, 2000). They were performed at the Center for Treatment for Surgical Infections and at the clinical base of the St. Petersburg Medical Academy of Postgraduate Education in the period of August 22, 2000, till October 31, 2000.

2. To perform the medical trials, the following items were used:

- a) prototype samples of the applicator
- b) the certificate of engineering tests #ATHJI 0.009.2081 as of August 21, 2000
- c) the report on toxicological tests #63-2000 as of February 17, 2000
- d) user's instruction

3. Brief Description of the Applicator

The Aires matrix applicator (further referred to as just applicator) presents a 0.1-mm-thick polyester (self-adhesive) film carrying on its outside a symmetric pattern composed of graphite lines of 50 mics in width. The unit module is 26.4 by 26.4 mm in size. The modules are combined into block-lists of 138 by 138 mm in size. One block-list includes 25 applicators. To

use the applicator, it is applied to skin projections of biologically active points, to painful points and/or to lesion sites. The medical effect of the Aires applicator is due to its ability to normalize subtle information-energetic processes going on in the human organism, so the applicator is classified as a traditional (alternative) medical remedy. According to the user instruction, the applicators can be used in medical treatment and prevention institutions as well as in household environment.

4. The clinical trials were conducted according to the program and procedure of the medical trials. Patients with acute and chronic pyoinflammatory diseases of fingers and the hand, that is, such complicated forms of panaritium as thecal whitlow, articular panaritium, bony panaritium, osteoarticular panaritium, and pandactylitis, were chosen as subjects of the investigation. The trials of the Aires applicators were performed in a group of 30 patients of both sexes aged between 18 and 35. The duration of having had the disease by the time the therapy was started ranged between one week and two and a half months. Most of the patients had undergone multiple surgical operations provided in both ambulatory and inpatient environments. In 11 of the patients, the disease developed together with Raynaud's disease. The control group consisted of 15 patients with analogous diseases. These patients received treatment according to the standard surgical technique, without the use of the Aires applicators. The patients underwent antibacterial therapy, were administered with rheovasotropic remedies, and regularly had their injured limbs dressed with an antiseptic bandage.

The Aires applicators were prescribed to the patients with the following aims:

- 1) To study the therapeutic effect of the applicator as a component of a complex therapy for a suppurative pathology of fingers and the hand.
- 2) To evaluate the safeness of the use of the applicator.
- 3) To evaluate the usability properties of the applicator.

The applicators were used in all phases of inflammation. The period during which the patients wore the applicators ranged between eight and 20 days. The applicators were affixed over the gauze bandage, on the projection of an injured site. The clinical examination of the patients was performed each day (at the inpatient stage of the treatment). At the same time, the patients from the control group were also examined.

All patients endured the application therapy course well, without any negative or side reactions. The most prominent effect of the applicators was their analgesic properties which helped arrest the pronounced pain syndrome manifested in the early postoperative period. The arresting or considerable reducing of pains was accompanied by rapid abatement of edema and

hyperemia (as soon as the second and third day after the surgical operation). In the control group, patients continued to complain about pains in an injured site as long as up to five days after the operation.

In the main group of patients, the first phase of inflammation was observed to be shorter than in the control group. Moreover, with suppurative cavities and swelling, the applicator brought about an earlier rejection of necrotic masses and the reduction of exudation, whereas three patients in the control group needed to undergo extra drainage operations in the first-phase inflammation process because of an inexorable expansion of the suppurative process and the depressed resistibility of the patients' organisms.

In the second phase of inflammation, no pathologic hypergranulations developed in the wounds in most of the patients of the main group in contrast to the control group. Moreover, the defects were observed to be made up with granular tissues, and edge epithelization was noted to proceed more rapidly. Cicatrices were distinguished by elasticity and good skin pigmentation. The functions of the patients' fingers and hands were recovered by 80-96%. Three patients of the main group, who were unsuccessfully treated for a long time before they were received in the hospital, had depression, a state of aggressiveness, and psychosomatic disorders. As early as in two days after starting using the applicators, these patients were noted to have their mood improved, and by the day of their discharge from the hospital, a remission of chronic internal diseases was noted in those patients. Furthermore, the duration of treatment with the use of the applicators was 1.3-1.8 times shorter as compared to the control group.

The clinical examinations were combined with special laboratory and instrumental examinations. All patients underwent thermography of the injured limbs, the blood coagulation system analysis, and the estimation of the perspiration ability of the hand and fingers by Moberg's technique. These examinations were performed in the first and the second phases of inflammation, and after some period of time after that, and indices of both injured and good limbs were compared.

The infra-red picture revealed an improvement in the patients' state manifested by a temperature increase in the proximal and distal parts of the limbs. The temperature gradient was 1.3 degrees Celsius on average. In the group of patients who received the applications, a positive effect was noted to appear as early as on the second or third day, and the therapy gave the most lasting results. In eight of the patients of the main group, the temperature gradient ranged within 1.4 and 1.7 degrees Celsius and remained at this level till the patients were discharged from the hospital. The patients in the control group displayed similar, but less pronounced changes. Their thermographic indices were nonuniform. The temperature gradient ranged within 0.4 and 1.2

degrees Celsius, and the effect of the therapy was noted to appear as late as on the forth or fifth day or even later.

With respect to the blood coagulation system, the applicator was noted to produce a moderate anticoagulant effect on sixteen patients of the main group (see Table below).

Table

Blood Coagulation System Dynamics* in Both Main and Control Groups of Patients

Indices of Blood Coagulation System	Examination Results		
	Before Therapy	After Therapy	
		Standard Procedure (n=15)	Standard Procedure Combined with Applicators (n=30)
Prothrombin Index (%)	100.0±0.6	98.0±2.0	93.0±0.5
Thrombin Test (sec)	13.0±0.7	15.0±0.8	17.0±0.2
Fibrinogen (g/l)	3.2±0.6	2.8±0.5	2.6±0.1
APTT (sec)	38.0±0.6	37.5±6.0	40.0±1.0
VIII Factor Activity (%)	108.0±0.5	98.0±1.0	94.0±0.3
XIIa-dependent Fibrinolysis (min)	20.0±0.8	16.0±2.0	12.0±0.6

* The examinations were performed with the use of the Thrombotimer device, and reagents manufactured by Renam company.

In the control group, four patients who displayed signs of trombophilia developed extensive necrotic changes in the tissues of the injured fingers, so they had to undergo mutilating operations, such as exarticulations of the phalanges, and amputations of the fingers. Most of the operative interventions performed in the main group were of organ-saving character, and only one operation for amputation of a finger had to be performed.

The examination of the perspiration ability of the patients' hands and fingers skin revealed dyshidrosis (with predominating hyperhidrosis) in 38% of the cases in both of the groups. In eight patients of the main group, the perspiration ability became normal in four or five days after the start of the therapy, whereas in the control group, eleven patients displayed normalization of the perspiration ability in seven to 15 days.

5. Results of the Medical Trials

All of the patients tolerated the complex application therapy well. No negative nor side effects were noted. The therapeutic efficiency of the Aires applicators is due to rapid wound repair, rapid convalescence of patients, positive dynamics of patients' clinical and laboratory indices and good tolerance of the therapy. The applicators meet their medical purpose in terms of their functional and service qualities, are handy in use, meet modern design requirements and are intended for personal use only. The applicators can be used for arresting pain syndromes and treating for vegetative and vascular disturbance in patients of surgical profile. It should be pointed out that the applicators are most useful in cases of patients with background psychosomatic diseases. Due to the fact that the applicators are tolerated well by patients and produce no adverse effects, they may be indicated for patients with pronounced allergic reactions to medical preparations. The application therapy can well be combined with traditional, i.e. drug, therapy.

Conclusion

The Aires applicators may be recommended to the commission of the Committee on New Medical Equipment of the Russian Federation Ministry of Public Health as to the issue of their serial production.

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