Lokosana® Observational Study by Josef A. Wirth, MD





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Lokosana® (SAMINA) observational study

Observation period: 10/01/2003 through 01/31/2004

Patient number: 15 (8 male/7 female)

Patient age: 52 + 20 years

Indication: Insomnia (Sleep disorders/sleeplessness)

Study profile: The test subjects were observed polysomnographically over two

nights. During one of these nights, the subjects were sleeping on a Lokosana® sleeping pad. Neither the patient nor the researcher

knew when they slept on Lokosana® (double-blind trial).

The studies were recorded according to the following derivatives:

EEG, EOG, EMG submandibular, EMG pretibial, ECG, chest movements, abdominal movements, airflow at the nose and mouth, oxygen saturation, snoring sounds, videometry.

The following parameters were determined:

Sleep efficiency (Scheff %)

Sleep time (Schzeit in min)

Micro-arousel throughout the sleep time (MAr)

Respiratory Disorders = Respiratoy Disease Index (RDI /h)

REM sleep (REM %)

Deep sleep stages (S1 %; S2 %; S3 %, S4 %)

Results:

| : Lokosana® | With Lokosana® | |
|-------------|---|--|
| n values): | (median values) | |
| 83,03 % | Scheff: | 96,36 % |
| 286,5 min | Schzeit: | 382,6 min |
| 201,2 | MAr: | 219,0 |
| 6,3 / h | RDI: | 5,6 / h |
| 14,42 % | REM: | 16,06 % |
| 21,25 % | S1: | 19,95 % |
| 50,88 % | S2: | 50,20 % |
| 14,03 % | S3: | 12,07 % |
| 0,85 % | S4: | 0,97 % |
| | 286,5 min 201,2 6,3 / h 14,42 % 21,25 % 50,88 % 14,03 % | values): (median 83,03 % Scheff: 286,5 min Schzeit: 201,2 MAr: 6,3 / h RDI: 14,42 % REM: 21,25 % S1: 50,88 % S2: 14,03 % S3: |

Discussion of the results:

Under the influence of Lokosana®, there was a significant improvement in sleep efficiency by 13.32%, as well as an increase in sleep time by an average of 98.7 minutes. An average increase of 18 in microarousal over the entire sleep time was remarkable, which could be seen as a reaction of the body to the Lokosana® sleeping pad.

A positive effect was also reflected in the overall sleep architecture, which is closely approximating that of a healthy sleeper.

January 31, 2004 Josef A. Wirth, MD / Internist and somnologist