CLINICAL STUDY

FINAL REPORT

Proven effectiveness of the BICOM Bioresonance Method in the treatment of allergies

- Alleviation of symptoms in all patients
- Significant improvement in quality of life
- Fast recovery time
- Improvement of acute symptoms
- Avoidance of conventional medication
- Without harmful side effects

After many significant results, the study confirms the effectiveness of the BICOM bioresonance method for the treatment of mild to moderate rhino-conjunctivitis. The study was conducted according to the latest standards and demonstrates a strong level of evidence according to current scientific criteria.

Synopsis

This clinical study report describes the design, execution and statistical analysis of the BICOM optima®/Post-Market Clinical Follow-up study on the treatment of allergic rhino-conjunctivitis with BICOM optima® devices. The report covers the period 25.01.2021 until 10.01.2022 (LPLV). This final report is based on the final monitored data of the study after data-analysis.

Final report of the clinical study

Title: Prospective, multi-center, single-arm, open-label, observational study for the evaluation ofperformance and safety of the BICOM optima®/BICOM optima®mobil device for bioresonance treatment in patientswithallergicrhino-conjunctivitis.

Studycenter:9 study sites in Germany,8 collected patient data

Studyperiod: Datefirstpatientenrolled:25.01.2021; date last patient enrolled: 14.10.2021

Registration:DRKS00024523

Phase: Post-market; device is used accordingtoIFU

Investigationaldevice: BICOMoptima®/BICOMoptima®mobil (B32, B34 and BM34)

Patients: 111 (28 children from 4 to 10 years, 14 youth from 12 to 17 years and 69 adults, 18 years and older)

Patient population: Patients 4 years and older diagnosed withallergicrhino-conjunctivitiscausedbypollen (e.g.tree,grass), housedustmite(HDM) and animalhairallergy.

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This study was conducted in accordance with ISO 14155 that ensured adherence to Good Clinical Practices and protection of thesubjects, asrequiredby the directives inoperationatthetime.

1 Rationale for the study

BICOM®Bioresonance therapy isatherapytechniquethat has been part of the fieldofcomplementary medicine for over thirty years. It proposes that low energy electromagnetic waves can be used to treat human illness. The theory is based on established scientific findings of particle physics that each type of matter has its own electromagnetic field.

Well-known medical diagnostic systems like EEG, ECG, EMG, MRT and MEG already use external, technically generated electromagnetic fields for diagnostic and therapeutic purposes.

1.1 Basic functioning

The principle of electromagnetic fields may also be applied to every cell or organ of the human body. The BICOM®device picks up these bioelectromagnetic fields, alters them andreturnsthem to the patientsto achieve a therapeutic effect.

For this purpose, the patient is connected tothe BICOM®device. Patient and device form a so-calledbio-cybernetic control-circuit.The device picks up the patient´s oscillations and processes them: they may beneutralizedaltered, amplified or otherwise conditioned and then returned to the patient.

1.2 Scientific stance

Several clinical studies suggest that bioresonance therapy is particularly effective in the treatment of allergic rhinitis and allergic conjunctivitis (hay fever).Significant treatment success has been demonstrated in these studies using different research approaches. During the therapy, among other things, the electromagnetic fields of the allergens are altered and returned to the patient to achieve therapeutic success.

Results suggest thatbioresonance therapy reducesallergicsymptoms and successfully treats allergies, where “therapy” in this context means:freedom fromallergicsymptomsandnoreoccurrenceofsymptomswithinsixmonths of the end of the treatment.

The treatment is given weekly and takes three to twenty sessions. The best-known other type of treatment for long-term elimination of allergies is allergen immunotherapy (AIT), commonly known as “desensitization”. This usuallytakes three to five years and can be quite costly and restrictivefor the patient. Bioresonance therapy is much faster and cheaper.

In addition, studies have shown that the bioresonance method reducesor even eliminates theneedfor symptom-relieving allergy medications. The elimination of medication often has multiple healthbenefits for the patient.

Several clinical studies have already shown the efficiencyof bioresonance therapy devices and the sustainable success of bioresonance therapy.These studies were however mostly performed outside the EU and at a time where international clinical standards like the GCP (Good Clinical Practice) and ISO 14155 norm did not exist.

This Post-Market Clinical Follow-up study (PMCF), was conducted according to current GCP and ISO 14155 requirements, and is intended to confirm the results of previous studies.

2 Legal framework

This study gathered clinical data on BICOM®devicesmanufactured by REGUMED®, Regulative Medizintechnik GmbH. The aim was to test the performance and safety of the BICOM optima®/BICOM optima®mobil devices (B32, B34 and BM34).

The devicescarrieda CE-mark and were used according to the instructions for use (IFU). The study aimed to collect clinical data for the BICOM® devices in use.

The devices are medical devices (risk class IIa) for professional use. They were developed exclusively for use by trained, licensed doctors, state-approved naturopaths or trained medical professionals under their supervision.

The commissioned research institute conducted the study in accordance with the professional code of conduct for doctors in Germany and was advised by the Ethics Committee of the North Rhine Medical Association (EthikkommissionÄrztekammerNordrhein).

2.1 Information and data protection

All patients consented to participate in writingbefore the start of the study. Among other things, the patients were informed about data protection, the use of their medical data and their right to withdraw from the study at any time without specification of reasons.

In addition, the applicable data protection regulations, in particular the EU General Data Protection Regulation (GDPR) was applied.

2.2 Monitoring

The study was monitored in accordancewith the Declaration of Helsinki, ISO 14155:2020, the Clinical Investigational Protocol (CIP), the signed agreement between REGUMED® and the research institute as well as national regulations.

2.3 Adaptation for general publication

The study has been summarized by REGUMED®for the purpose of general publication in this document.

3 BICOM®bioresonancetherapy

BICOM®bioresonance therapy isa method from the fieldofcomplementary medicine.

Electromagnetic interactions play as much a role in cell communication and the transmission of information, as electrical processes at the receptor proteins and bio membranes. Specific electromagnetic wave patterns act as carriers of information. These wave patterns can be modulated by the BICOM® devices to eliminate disturbing or stressful information in the body.

The aimis to restorethe free flow of healing information (cell-communication) and thus to stimulate the organism's self-regulation and the self-healing powers of the body. The therapyuses individual patient-information as well as the information of native and digitalized substances.

Discrepancies with findings from conventional medicine arise from these different points of view. While BICOM®bioresonance therapy focuses on information and principles from quantum-physics, the approachof conventional medicine is still based on the mechanistic-deterministic worldview (Newton).

BICOM®devices are recommended for the treatmentofmildtomoderateallergiesandallergy-relateddiseasesorcomplications. They focus on allergicrhino-conjunctivitis and are suitable for treatingchildren and adults alike.

3.1 Allergies in Germany

Allergic rhinitis is a chronic inflammation of the nasal mucosa triggeredby an immune response of the body as a result of a hypersensitive allergic reaction. Symptoms of allergic rhinitis include a runny nose, nasal congestion, nasal itching, and repeatedsneezing. It is often accompanied by allergic conjunctivitis with symptoms that can include itchy, red, watery, and/or swollen eyes.

Studies suggest a wide prevalence of allergies within the German population. According to research, nearly every third adult will bediagnosed with an allergy by a doctor at some point in their lives. The most common diseases are rhino-conjunctivitis (around15%), followed by asthma and contact eczema (around 8%), food allergies (around 5%) and atopic dermatitis, urticaria as well as insect venom allergies (around 3% each). Studies for children find a prevalence of neurodermatitis (almost 13%), hay fever (11%), bronchial asthma (6%), and allergic contact dermatitis (nearly 3%).

Due to the non-life-threatening nature of symptoms,allergiesare often considered to beunimportant or minordiseases. They are, however, increasingly recognized as having a major effect on quality of life, emotional well-being, sleep, daily activities and productivity when poorly controlled.Restrictions are often severe, with patients unable to find a basic therapy.

3.2 Treatment prospects

The first form of treatment for allergies is typically allergen avoidance. Patients are advisedto limit exposure to the relevant allergens. After that allergies are usually treated with antihistamines, corticosteroids, leukotriene antagonists and inhaled beta-blockers.

Allergen immunotherapy, commonly known as “desensitization”, is the best-known other treatment method for eliminating allergies. Desensitization is the practice of gradually introducing allergens to the patient in larger and larger amounts in order to gradually accustom the body to the allergen and reduce the allergic symptoms.

Treatmenttakes three to five years and can be verycostly. It also involves a lot of effort on the part of the patient. Therefore, only a few patients turn to this treatment option. In addition, patients are at risk of suffering severe side effects, including anaphylaxis.The treatment is raising concerns over safety and limiting its widespread use.

BICOM®bioresonance therapy proposes a better method of treatment. The method has been used for decades to treat allergies and theirassociated symptomsand has fewer risks and side effects. In addition, studies have shown that the use of allergy medications can be reduced or even stopped through the use of bioresonance therapy.

The required number of treatment-sessions depends on the severity of the allergy and generally ranges between three to twenty sessions at weekly intervals. Thus, the duration of treatment is significantly shorter than with desensitization.A session lasts no longer than an hour and is administered automatically by the BICOM®bioresonance device after having been programmed by a doctor, practitioner or medical trained personnel.

Good education of the doctor ornaturopathic practitioner is crucial for the success of the treatment. The BICOM® devices may only be operated by medically trained personnel.

4 The Post-Market Clinical Follow-up study

The study investigated whether the symptoms of rhino-conjunctivitis improved with routine treatment using the BICOM® method.

The patient sample was representative of the average patient population, including children from the age of 4 years. There were only a few exclusion criteria.

4.1 Evaluation of the decrease in symptoms

The main objective was to measure the change in the patients´ weekly symptoms. For this purpose, the patients received a questionnaire with six listed symptoms. They were asked to choose a score ranging from zero (no symptoms at all) to three. The symptoms were nasal irritation, sneezing, runny nose, stuffy nose,itchy/red eyes and watery/swollen eyes. An improvement of one point was considered to be a success of the treatment.

In addition, data was collected on quality of life, need for medication and acute symptoms. This was measured by three additional scores.

4.2 Evaluation of adverse effects

To evaluate the safety of BICOM® bioresonance therapy, patients were asked about any adverse effects. These could be triggered either by the device or the treatment. Adverse effects and serious adverse effects were included in the questionnaire from the beginning as part of the study. In the case of serious adverse effects the treatment was discontinued and the incident was noted.

Doctorsand therapists working with the BICOM® bioresonancemethod have long been familiar with the phenomenon of a short-term worsening of symptoms during treatment, the so called initial aggravation. This is a known effect of the therapy and these symptoms are considered desirable as they are an indicator that the therapy is beginning to work. They represent activation of the immune system and should not be suppressed. They can however be alleviated by medication.

Severe cases of initial aggravation are an exception. In these cases, the decision is at the discretion of the doctor or naturopathic practitioner. The severity of the initial reaction depends on the severity and type of disease being treated.

Initial worseningwas included in the questionnaire as an adverse effect.

For general information on contraindications, warnings and sideeffects, consult a doctoror naturopathic practitionerorrefer to the instructions for use (IFU) of the BICOM® devices.

4.3 Method of collecting data

Patient data was always collected before the start of every treatment session, including the first. An additional questionnaire was conducted within two weeks after the end of the last treatment (follow-up).

Only treatments that lasted three sessions or longer were included in this study. If a patient required more than eight treatment sessions, only the first eight sessions were included, or the first fifteen weeks of treatment, whichever came first.

4.4 The study at a glance

	Visit 1(optional)	Visit 2(optional)	Visit3tovisitmax 10, if applicable	EOS for eachpatient
	Preparationtreatment Session 1	Preparationtreatment Session2	Allergytreatment Session 3 up toSession10	One weekfollow upafterthelast allergy treatment
Informedconsent[a)]	X			
Anamnesis[a)]	X			
Demographicdata[a)]	X			
Symptom Score [a),b)]	X	X	X	X
MedicationScore[a),b)]	X	X	X	X
ActualSymptom Score byinvestigator[a)]	X	X	X	X
QualityofLife Questionnaire[a),c)]	X	X	X	X
Energetictesting [d)]	X	X	X	
Basictreatment[e)]	X	X		
Blockage-releasing treatment[f)]	X	X	X	
Eliminationtreatment[g)]	X	X	X	
Allergytreatment[h)]			X	
ADE/SADErecording [i)]	X	X	X	

Note: *Before each treatment session, the symptoms, the medication, and the quality of lifescores wererecorded. This also applied to the two preparation treatments withbasic*treatment**,** *blockage-releasingtreatment and elimination treatment.*

a) Data from patients who did not receive preparation-treatment was collected from the firstallergytreatment session

b) Thisscore asked about the most severesymptoms and their duration in days, as well as medication includingthe durationofmedicationindays

c) Thisscore assessedthe impactof rhino-conjunctivitis on quality of life

d) This test is part of the standard procedure when using BICOM®bioresonancedevices

e) A basic therapy program or sequence aims to prepare the patient for allergytreatment

f) Up to three blockage-releasing programs or sequences could be used after bioenergetic testing

g) Up to three elimination programs or sequences could be used afterbioenergetic testing

h) Allergy treatment involved the use of allergy therapy programs as well as supportive symptom-relatedprograms or sequences

i) Adverse device effects (ADE) and serious adverse device effects (SADE) were recorded from the firsttreatmentsession

5 Results

Data from eight study-sites was used in the evaluation. 111 patients were part of the study.The first subject was surveyed on January 25th 2021 and the last patient was surveyed onJanuary 10th 2022.

Distribution of patients	Value
Number of patients for the final evaluation	111
Adults ≥ 18 years	69
Patients ≥ 12 years	83
Youth, aged 12 to 17 years	14
Children, 4 to 11 years	28

On average, patients had suffered from rhino-conjunctivitis for 13.8 years.The maintriggerswerepollen,followedbyhousedustmiteandanimalhair.Themajority ofpatientshadacombinationoftriggers.

5.1 Alleviation of symptoms

The main objective of the evaluation was to note changes in symptoms. Patients regularly completed a questionnaire. They were asked about nasal irritation, sneezing, runny nose, nasal congestion,itchy/red eyes and watery/swollen eyes. The patients could choose between a severity of 0 (no symptoms) to 3.

The weekly Symptom Score (wSS)represents the severity of symptoms during the previous week. The lower the wSS-value, the lesser the patient's symptoms were.The lower the score, the lower were the symptoms. The maximum symptom-score was 18 (six times three). The minimum symptom-score was 0.

The baselinesymptom score was recordedat the start of the therapy. Data was also collected during treatment sessions and once after the end of the last session (follow-up). From this, an average value was calculated from the weekly Symptom Scores and measured against the starting baseline score.The endpoint of the treatmentwas reached on average after 4.4 sessions.

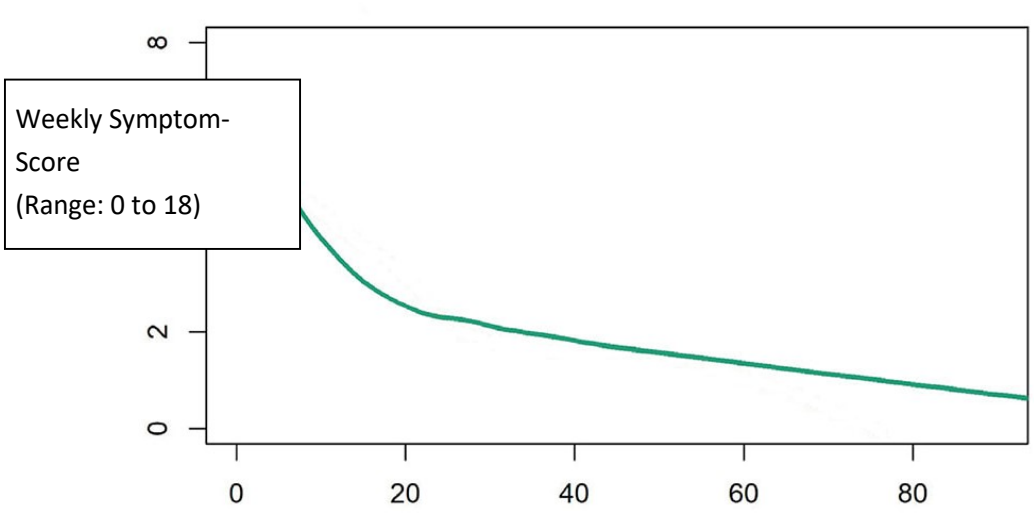
Weekly Symptom Score: baseline,average during the treatment and difference

	All N = 111	Children 4-11 N = 28	Youths 12-17 N = 14	Patients ≥ 12 N = 83	Adults ≥ 18 N = 69
Baseline Mean:	7	6.3	7.3	7.2	7.2
During treatment Mean:	2.1	2	2.6	2.1	2
Difference Mean:	4.9	4.3	4.8	5.1	5.1

The symptoms decreased on average from 7 to 2.1 points in all patients, reflecting a clinically and statistically significant improvement for the whole sample.The absolute change in score, which is 4.9, is clearly above the target reduction of 1 point, which was set at the beginning of the study to measure efficacy of the treatment.

For all age groups, the results are clinically and statistically highly significant independently of each other. Reductions in symptoms are similarly independently highly statistically significant. The study thus clearly demonstrates the reduction of symptoms through treatment with BICOM® bioresonance.

Mean course of weekly symptoms



5.2 Improvement in quality of life

The study also evaluated the change in quality of life as perceived by the patient. Thequestionnairefor this wascomposed of sixitems: patients were asked to fill in scoresabout their restrictions in wellbeing, sleep, everyday activities, sports activities, school or professional activities and social contacts.

A scale ranging from 0 to 4 was used for this, with 0 meaningno limitations.In this way, the gravest of limitations would be a score of 24.

Duration of treatment (days)

Quality of Life Score: baseline,average during the treatment and difference

	All N = 111	Children 4-11 N = 28	Youths 12-17 N = 14	Patients ≥ 12 N = 83	Adults ≥ 18 N = 69
Baseline Mean:	9.4	7.1	8.7	10.2	10.3
During treatment Mean:	2.5	1.8	1.7	2.7	3
Difference Mean:	6.9	5.3	7	7.5	7.6

The score shows a significant decreasein restrictions on the quality of life from a score of 9.4 to 2.5 points for all age groups. The difference of 6.9 points represents an improvement of almost 75 percent compared to the baseline. Improvements are seen in all age groups. The study thus demonstrates a significant increase in the quality of life for patients with rhino-conjunctivitis when treated with BICOM® bioresonance.

5.3 Changesinthe need for medication

The need for symptom easing medication was another point of analysis in this study. For this purpose, the patients filled out a questionnaire on their need for medicationas a score on a weekly basis. A decrease in the need for medication is consider a success of BICOM® bioresonance therapy.

The medication score assessed the use of antihistamines for ingestion or in the form of eye drops, nasal sprays, intranasal glucocorticoids with/without antihistamines and glucocorticoids with/without intranasal glucocorticoids or with/without antihistamines.

The study showed that most patients did not use conventional medications before the start of the first session and that this did not change during treatment. According to the research institute commissioned, the data on a possible reduction in the need for medication is therefore not conclusive. Further evaluation, for example by reviewing the mean values with regard to possible improvements, must therefore be omitted.

5.4 Improvement of acute symptoms

Before every treatment session and one week after the last allergy treatment (follow up),theacutesymptomswere surveyed by the examining doctor or therapist. Lowvaluesrepresentfewerandorweakersymptoms.

Acute symptoms: baseline, averageduring the treatment and difference

	All N = 111	Children 4-11 N = 28	Youth 12-17 N = 14	Patients ≥ 12 N = 83	Adults ≥ 18 N = 69
Baseline Mean:	1.2	1	1	1.3	1.3
During treatment Mean:	0.4	0.3	0.4	0.4	0.4
Difference Mean:	0.8	0.7	0.6	0.9	0.9

The study shows a significant improvement in acute symptoms across all age groups during BICOM® bioresonance treatment. On average, symptoms improved 66 percent from the baseline score, from 1.2 to 0.4. The results were similar for all age groups.

The study thus demonstrates the improvement of acute symptoms for patients with rhino-conjunctivitis when treated with BICOM® bioresonance therapy.

5.5 Adverse effects

Six patients experienced adverse effects. There were however no seriouscomplications and no serious adverse effects. All cases were mild to moderate and all patients recovered.

One patient, in consultation with the doctor, decided not to continue treatment due to the side effects. The study found no indications in which to change theexisting positiverisk-benefit assessment.

5.6 Final conclusion

The result of this study shows that the treatmentof mild to moderate rhino-conjunctivitis with BICOM®bioresonance therapy leads to a significant improvement in symptoms and quality of life. The study demonstrates the efficacy of the treatment and the benefit to the patient.

In addition, BICOM® devicesare very safe. No serious adverse effects occurred during the course of the study, which ran for more than a year.

Imprint

Post Market Clinical follow-up study on the performance and safety of BICOM optima®/BICOM optima® mobil devices for bioresonance treatment in patients with allergic rhino-conjunctivitis.

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