

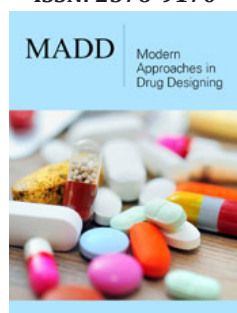
Influence of Consciousness Energy Healing Treatment on the Properties of Poly(lactic-co-glycolic) Acid (PLGA)

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ISSN: 2576-9170



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Submission:  October 18, 2019

Published:  November 04, 2019

Volume 2 - Issue 4

How to cite this article: Dahryn T, Mahendra KT, Alice B, Gopal N, Snehasis J. Influence of Consciousness Energy Healing Treatment on the Properties of Poly(lactic-co-glycolic) Acid (PLGA). *Mod Appro Drug Des.* 2(4). MADD.000544.2019. DOI: [10.31031/MADD.2019.02.000544](https://doi.org/10.31031/MADD.2019.02.000544).

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Abstract

Poly(lactic-co-glycolic) acid (PLGA) is the most popular biodegradable copolymers have several applications in the pharmaceuticals and biomedical industries, but degradation and stability of PLGA are major apprehensions. The aim of this study was to evaluate the impact of the Trivedi Effect[®] on the physicochemical and thermal properties of PLGA using a number of analytical techniques. The PLGA powder sample was divided into two parts, one part of the test samples was considered as a control sample, whereas the other part of PLGA samples received the Trivedi Effect[®]-Consciousness Energy Healing Treatment remotely by a well-known Biofield Energy Healer, Dahryn Trivedi and termed as a Biofield Energy Treated sample. The particle size values of the treated PLGA powder were significantly decreased by 48.08% (d_{10}), 40.08% (d_{50}), 33.78% (d_{90}), and 37.17% {D (4,3)} compared to the control sample. Hence, the specific surface area of the treated PLGA powder sample was significantly increased by 72.57% compared to the control sample. The PXRD diffractograms of the control and treated PLGA powder sample did not show sharp and intense peaks, indicated that both the samples were amorphous. The evaporation and melting temperature of the treated sample were slightly altered by 1.31% and -0.94%, respectively compared with the control sample. But, the latent heat of evaporation and latent heat of fusion of the treated PLGA sample were significantly increased by 6.91% and 116.91%, respectively compared with the control sample. The total weight loss was significantly decreased by 4.1%; however, the residue amount was 21.99% more in the treated PLGA sample compared to the control sample. The maximum thermal degradation temperature of the treated PLGA was altered by 2.37% compared with the control sample. From the results, it was established that the Trivedi Effect[®]-Consciousness Energy Healing Treatment might introduce a new form of PLGA, which would show better solubility, dissolution rate, absorption, bioavailability, and thermal stability compared with the control PLGA. This the Trivedi Effect[®]-Consciousness Energy Healing Treated PLGA would be a better choice for the pharmaceutical formulations, i.e., the drug like amoxicillin, simvastatin, minocycline, and vancomycin loaded PLGA nanoparticles and manufacturing of biomedical devices, i.e., grafts, surgical sealant films, sutures, prosthetic devices, implants, micro, and nanoparticles.

Keywords: The Trivedi Effect[®]; Consciousness energy healing treatment; Poly(lactic-co-glycolic) acid; Particle size; Surface area; DSC; TGA/DTG

Introduction

Poly(lactic-co-glycolic) acid (PLGA) is most popular among the several available biodegradable polymers with long clinical experience [1]. It is a synthetic copolymer of polylactic acid and glycolic acid (Figure 1). On hydrolysis in the presence of water release the monomers. The monomers, i.e., polylactic acid and glycolic acid are the by-products of various metabolic pathways in the body, hence exhibit minimum systemic toxicity. The higher the content of glycolide units in the PLGA lower the time for degradation. PLGA gained importance in the research and development due to its mechanical resistance, constant biodegradation rate, and regular individual chain geometry [2]. It is very much important for the manufacturing of biomedical devices, i.e., grafts, sutures, surgical sealant films, prosthetic devices, implants, micro, and nanoparticles [3]. It is among the FDA-approved polymers that have been extensively studied as delivery vehicles for drugs, proteins, and other macromolecules such as peptides, RNA, and DNA [1]. Specifically, PLGA is useful for the

designing of better pharmaceutical formulations, i.e., the drug like simvastatin, vancomycin, amoxicillin, and minocycline loaded PLGA nanoparticles could be effective in sustain drug release [4-6]. PLGA contains less than 50% glycolic acid units is easily soluble in most common organic solvents. But, PLGA rich in glycolyl units more than 50% is insoluble in most organic solvents [7,8]. Anhydride form of PLGA has adequate heat stability [9]. The stability is a major concern for PLGA, which completely depends upon the monomer percentage, chain-ends chemical composition, porosity, size, shape, and presence of additives, moisture, and temperature [10-12].

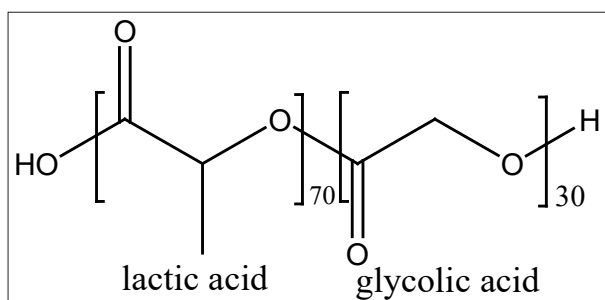


Figure 1: Poly(lactide-co-glycolide) (PLGA, 70:30).

The Trivedi Effect®-Consciousness Energy Healing treatment has been scientifically studied and claimed to have a significant influence on altering the crystallite size, particle size, surface area, solubility, melting point, latent heat, etc. of the object(s) [13-15]. The Trivedi Effect® is a natural and scientifically proven phenomenon in which a skilled person can harness this inherently intelligent energy from the “Universe” and transfer it anywhere on the planet via the possible mediation of neutrinos [16]. Due to the continuous movement of the charged particles, i.e., ions, cells, etc. inside the body, a unique para-dimensional electromagnetic field generated inside the body is called “Biofield” (A putative energy field). Biofield Energy Healers can harness the energy from the Universe and can transmit into any living or non-living object(s) around the earth. Biofield Energy Healing therapy has been recognized as a Complementary and Alternative Medicine (CAM) health care approach by the National Center of Complementary and Integrative Health (NCCIH) with other therapies and accepted by most of the world population [17,18]. The Biofield Energy Healing Therapies have been accepted worldwide and reported in many scientific journals with significant outcomes against various diseases and improved quality of life [19,20]. Similarly, the Trivedi Effect®-Consciousness Energy Healing Treatment also reported with the significant outcomes in different field of sciences, i.e., organic chemistry [21], material science [22], nutraceutical/pharmaceutical sciences [23,24], microbiology [25,26], agriculture [27], biotechnology [28], and medical science [29]. All these study results encouraged to evaluate the influence of the Trivedi Effect®-Consciousness Energy Healing Treatment on most popular polymer PLGA using particle size analysis (PSA), powder X-ray diffraction (PXRD), differential scanning calorimetry (DSC) analytical techniques, and thermogravimetric analysis (TGA)/ Differential thermogravimetric analysis (DTG).

Materials and Methods

Chemicals and reagents

The test sample polylactic-co-glycolic acid (PLGA, 70:30; CAS registry number 30846-39-0) powder was purchased from Changchun Hang Gai Biological Technology Co., Ltd., China. The sunflower oil used for particle size analysis was of analytical grade purchased in India.

Consciousness energy healing treatment strategies

PLGA powder sample was considered as the test sample, which divided into two parts. One part of the test samples was received the Trivedi Effect®-Consciousness Energy Healing Treatment remotely under standard laboratory conditions for 3 minutes by the renowned Biofield Energy Healer, Dahryn Trivedi (USA), known as the Biofield Energy Treated sample. The other part of the test sample was considered as a control sample, which was not received with Biofield Energy Treatment. But the control sample was treated with a “sham” healer who did not have any knowledge about the Biofield Energy Treatment. After all the treatment, the treated and untreated PLGA powder samples were kept in the sealed conditions and characterized using sophisticated analytical techniques.

Characterization

The PSA was performed with the help of Malvern Mastersizer 2000, from the UK using the wet method [30,31]. The PXRD analysis of PLGA powder sample was performed with the help of Rigaku MiniFlex-II Desktop X-ray diffractometer (Japan) [32,33]. The average size of crystallites was calculated using the Scherrer’s formula (1)

$$G = k\lambda / \beta \cos\theta \quad (1)$$

Where G = crystallite size (nm), k = equipment constant (0.94), λ = radiation wavelength (0.154056nm for $K\alpha_1$ emission), β = full width at half maximum, and θ = Bragg angle [34].

Similarly, the DSC of PLGA was performed with the help of DSC Q200, TA instruments. The TGA/DTG of PLGA was performed with the help of TGA Q50 TA instruments [30,31].

The % change in the Biofield Energy Treated sample was calculated compared with the control sample using the following equation 2:

$$\% \text{ Change} = \frac{[\text{Treated} - \text{Control}]}{\text{Control}} \times 100 \quad (2)$$

Results and Discussion

Particle Size Analysis (PSA)

The particle size distribution analysis of both the control and Biofield Energy Treated PLGA powder sample were performed, and the results are presented in Table 1. The particle size values in the Biofield Energy Treated PLGA powder sample was significantly decreased by 48.08%, 40.08%, 33.78%, and 37.17% at d_{10} , d_{50} , d_{90} , and D (4,3), respectively compared to the control sample (Table 1). The specific surface area (SSA) of the Biofield Energy Treated

PLGA powder sample ($0.0302\text{m}^2/\text{g}$) was significantly increased by 72.57% compared with the control sample ($0.0175\text{m}^2/\text{g}$). The Trivedi Effect®-Consciousness Energy Healing Treatment might have fractured the larger particles into smaller ones, hence increased the surface area of the PLGA particle. The particle size of a compound has a significant effect on the solubility, dissolution,

absorption, and bioavailability of it [35,36]. Thus, the Biofield Energy Treated PLGA would show more solubility, dissolution, absorption, and bioavailability compared to the control sample. This treated PLGA would be better for the pharmaceutical formulations and biomedical devices manufacturing industry using it as a raw material.

Table 1: The particle size distribution of the control and treated PLGA.

Parameter	d_{10} (μm)	d_{50} (μm)	d_{90} (μm)	D (4,3) (μm)	SSA (m^2/g)
Control	200.935	577.416	1227.608	653.678	0.0175
Biofield Treated	104.316	346.014	812.953	410.693	0.0302
Percent change* (%)	-48.08	-40.08	-33.78	-37.17	72.57

d_{10} , d_{50} , and d_{90} are particle diameter corresponding to 10%, 50%, and 90%, respectively of the cumulative distribution. D(4,3) is the average mass-volume diameter. SSA is the specific surface area. *denotes the percentage change in the particle size distribution of the treated sample with respect to the control sample.

Powder X-ray Diffraction (PXRD) analysis

The PXRD diffractograms of the control and Biofield Energy Treated PLGA samples did not show sharp and intense peaks (Figure 2), indicated that both samples were amorphous in nature. The Biofield Energy Treatment did not affect the crystallinity and pattern of the PLGA.

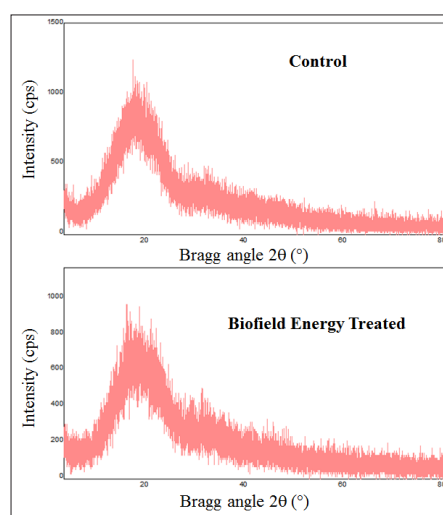


Figure 2: PXRD diffractograms of the control and treated PLGA.

Differential Scanning Calorimetry (DSC) analysis

The thermal analysis of both the control and Biofield Energy Treated samples showed two endothermic peaks. The control PLGA sample showed the sharp endothermic peaks at 61.11°C and 329.01°C in the thermogram (Figure 3). Similarly, the Biofield Energy Treated PLGA sample showed the sharp endothermic peaks at 61.91°C and 325.91°C in the thermogram (Figure 3). The 1st endothermic peak was due to the evaporation of absorbed water molecule from the sample, whereas the 2nd large endothermic pick was due to the melting of PLGA compounds. The observed thermogram patterns were well matched with the reported data [1]. The evaporation and melting temperature of the Biofield Energy Treated PLGA sample were slightly altered by 1.31% and -0.94%, respectively compared

to the control sample (Table 2). But, the latent heat of evaporation ($\Delta H_{\text{evaporation}}$) and latent heat of fusion (ΔH_{fusion}) of the Biofield Energy Treated PLGA sample were significantly increased by 6.91% and 116.91%, respectively compared with the control sample (Table 2). The evaporation and melting temperature were slightly altered, but the heat energy required by the Biofield Energy Treated sample for the evaporation and melting was significantly increased compared to the control sample. Any change in the molecular chains, and the crystal structure influence the thermal stability [37]. Hence, Dahryn's Biofield Energy Treatment could have disturbed the molecular chains and crystal structure of PLGA, which lead to the increased thermal stability of the treated PLGA sample compared to the control sample.

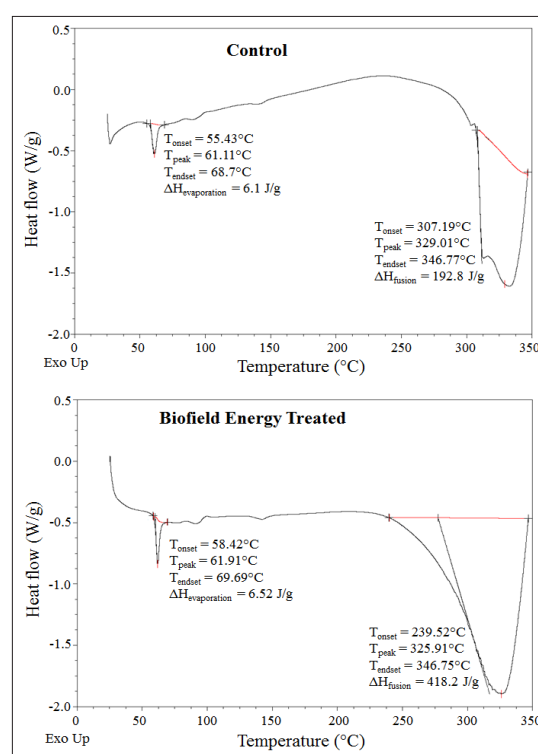


Figure 3: DSC thermograms of the control and treated PLGA.

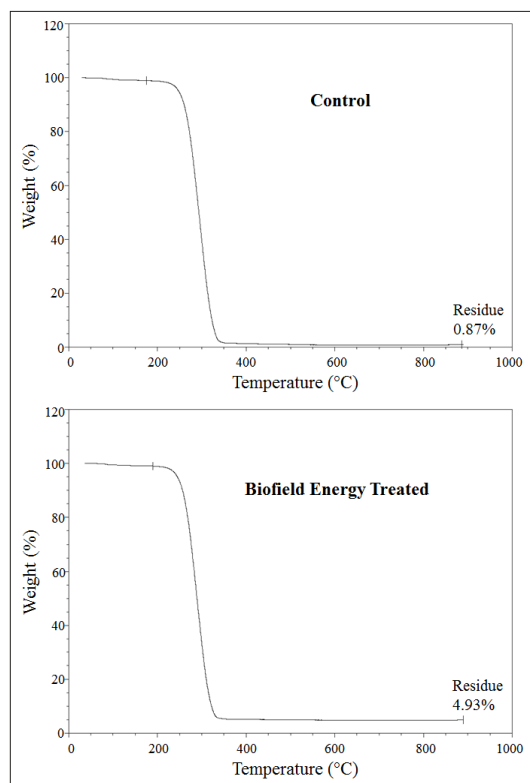
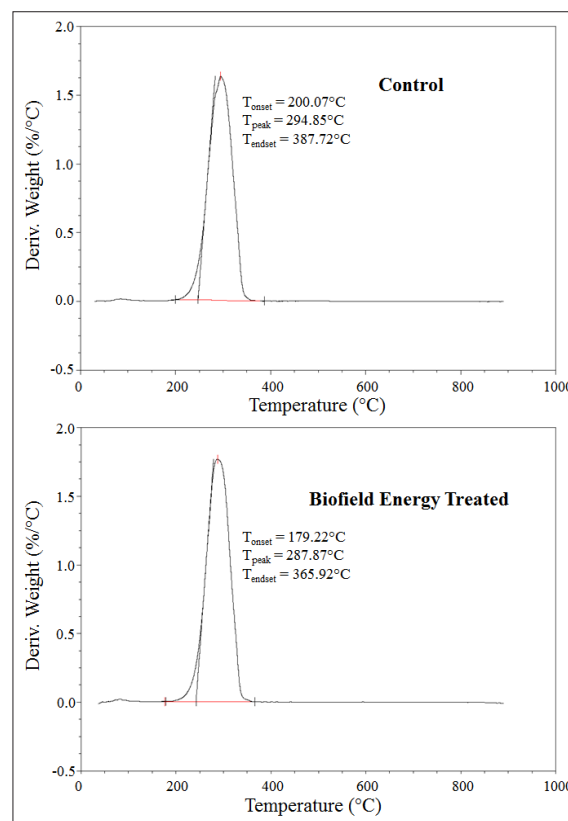
Table 2: DSC data for both control and treated PLGA.

Sample	Melting Point (°C)		ΔH (J/g)	
	1 st Peak	2 nd Peak	Evaporation	Melting
Control Sample	61.11	329.01	6.1	192.8
Biofield Energy Treated	61.91	325.91	6.52	418.2
% Change*	1.31	-0.94	6.91	116.91

ΔH : Latent heat of evaporation/fusion, *denotes the percentage change of the treated PLGA with respect to the control sample.

Thermal Gravimetric Analysis (TGA) / Differential Thermogravimetric Analysis (DTG)

The TGA/DTG thermograms of the control and Biofield Treated PLGA are displayed in Figure 4 and Figure 5. Both the sample showed one step of the thermal degradation process. The total weight loss in Biofield Energy Treated PLGA (95.07%) was significantly decreased by 4.1% compared with the control sample (99.13%). Therefore, the residue amount was 468.24% more in the Biofield Energy Treated sample compared to the control sample (Table 3). The thermograms of the control and Biofield Energy Treated PLGA exhibited one sharp peak (Figure 5). The maximum thermal degradation temperature (T_{max}) of the Biofield Energy Treated sample was decreased by 2.37% compared with the control sample. Overall, TGA/DTG thermal analytical results concluded that the thermal stability of the Biofield Energy Treated sample was increased compared with the control sample.

**Figure 4:** TGA thermograms of the control and treated PLGA.**Figure 5:** DTG thermograms of the control and treated PLGA.

Conclusion

The experimental results established that the Trivedi Effect®-Consciousness Energy Healing Treatment has a significant impact on the particle size, surface area, and thermal behaviors of the PLGA powder sample. The particle size values of the Biofield Energy Treated PLGA powder were significantly decreased by 48.08%, 40.08%, 33.78%, and 37.17% at d_{10} , d_{50} , d_{90} , and D (4,3), respectively compared to the control sample. Hence, the specific surface area of the Biofield Energy Treated PLGA powder sample was significantly increased by 72.57% compared to the control sample. The evaporation and melting temperature of the Biofield Energy Treated sample were slightly altered by 1.31% and -0.94%, respectively compared with the control sample. But, the latent heat of $\Delta H_{evaporation}$ and ΔH_{fusion} of the Biofield Energy Treated PLGA sample were significantly increased by 6.91% and 116.91%, respectively

compared with the control sample. The total weight loss was significantly decreased by 4.1%; however, the residue amount was 21.99% more in the Biofield Energy Treated PLGA sample compared to the control sample. The T_{max} of the treated PLGA was altered by 2.37% compared with the control sample. From the results, it was established that the Trivedi Effect®-Consciousness Energy Healing Treatment might introduce a new form of PLGA, which would show better solubility, dissolution rate, absorption, bioavailability, and

thermal stability compared with the control PLGA. This the Trivedi Effect®-Consciousness Energy Healing Treated PLGA would be a better choice for the pharmaceutical formulations, i.e., the drug-like amoxicillin, simvastatin, minocycline, and vancomycin loaded PLGA nanoparticles and manufacturing of biomedical devices, i.e., grafts, surgical sealant films, sutures, prosthetic devices, implants, micro, and nanoparticles.

Table 3: TGA/DTG data of the control and treated samples of PLGA.

Sample	TGA		DTG
	Total weight loss (%)	Residue %	T_{max} (°C)
Control	99.13	0.87	294.85
Biofield Energy Treated	95.07	4.93	287.87
% Change*	-4.1	468.25	-2.37

*denotes the percentage change of the treated sample with respect to the control sample,

T_{max} = the temperature at which maximum weight loss takes place in TG or peak temperature in DTG.

Acknowledgement

The authors are grateful to Central Leather Research Institute, SIPRA Lab. Ltd., Trivedi Science, Trivedi Global, Inc., and Trivedi Master Wellness for their assistance and support during this work.

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