

# Assessment of Incorporated Fabric with MIG3® Invel® Bioceramics Effects in Generating the Gasotransmitter NO

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## Introduction

The studies' onset with nitrogen oxide started in the 80s. In this period, the discovery of the nitric oxide (NO) as a molecular messenger for several mammalians systems revolutionized researches about its biological activity. This small and simple gaseous molecule, the NO, showed a crucial rule in early life-maintenance, the control of circulating platelets.

IGNARRO et al., 1987, also studied NO's function. In his Nobel prize winner's study, he found out how the NO, the endothelium-derived relaxing factor (EDRF) released by endothelium cells from aorta artery, would respond along with hemoglobin to form the nitrosylhemoglobin.

FURCHGOTT researched the vasodilator factor associated to endothelium (EDRF), concluding years later that the NO is the responsible for its biological activity. He was awarded the Nobel Prize in Physiology and Medicine because of this research.

Vasodilators effects, produced by NO, are caused by its interaction with soluble guanylate cyclase enzyme (sGC). The guanylate cyclase is a hemeprotein that catalyzes the conversion of guanosine triphosphate (GTP) to the second cyclic guanosine monophosphate (cGMP) messenger, and it is the action of such compound that leads to the relaxation the relaxation of the smooth muscle.

# **Objective**

# Primary objective:

To assess whether fabrics containing MIG3® Invel® Bioceramics have the ability to produce the gasotransmitter NO via the nitrite quantification in the saliva in the BioC group compared to C group.

#### Secondary objective:

Discuss the action of the gasotransmitter NO in the human system, its benefits and its use in therapies with the support of indexed publications.

## Methodology

# Study Design:

An open-label, randomized, crossover study with two treatments, two periods (2 sequences), with a 7-days window between the periods, in which the research subjects received in each period treatment with BioC and C. 30 healthy male volunteers aged between 21 and 40 years old and with weight range of  $\pm 15\%$  considering BMI between 19 and 25 Kg/m2 were included. The volunteer was required to present VO2max above 30mL.kg.min.

Investigational products: BioC Group - Invel® Actiive Shirt and Invel® Actiive Shorts.

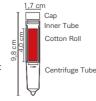
C Group - "Hering®" cotton t-shirt and 100% Polyester shorts.

#### Samples Collection Time:



## Saliva collection:

Collection was performed using "Salivette" " collector: Figure 3 – Illustration of "Salivette" collector.



# **Dose of Salivary Nitric Oxide**

Nitrite levels in saliva were measured by Griess colorimetric assay (TSIKAS, 2005) and it was calculated from linear regression calculation, based on the values obtained from nitrite standard curve (NaNO2) with increasing concentrations ranging from 0.003 to 0.4  $\mu\text{M}$ , where 50  $\mu\text{L}$  of saliva were processed and incubated into 50  $\mu\text{L}$  of Griess reagent. Reading was performed in a spectrophotometer at 570nm.

#### Results

NO significant superiority of baseline BioC was seen compared to C. **Estimation were**: BioC:  $(71.65 \pm 5.77)$  and C:  $(47.76 \pm 5.77)$ .

It was seen inferiority of baseline NO from period 1 compared to period 2. Estimations were P1: (51  $\pm$ 5.77) and P2: (68.42 $\pm$ 5.77).

Baseline NO means from sequence 1 and 2 were not significant. This indicates that research subjects randomization to sequences S1 (58.53  $\pm$  8.66) and S2 (60.88 $\pm$  8.66) were properly performed.

Fixed factors		Mean	Standard Error	P-value	Difference	CI (9	9 <b>5%)</b> SL
TRT	BioC C	71.65 47.76	5.77 5.77	0.0067	23.89	7.17	40.61
Period	P1 P2	51.00 68.42	5.77 5.77	0.0418	-17.42	-34.14	-0.70
Sequence	S1 S2	58.53 60.88	8.66 8.66	0.8494	-2.35	-27.45	22.75

Table 1. Estimations (Ism) and standard-error, P-value and CI (95%) from means differences of treatments at T0.



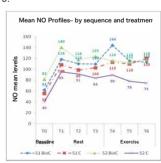


Chart 1: Nitric Oxide (NO) summary statistics, by sequence, period, Activity (Rest=R and Exercise=E), in each measurement timepoint.

### Conclusion

Fabrics with MIG® Invel® Bioceramic have the ability to promote production of gasotransmitter NO. These fabrics are secure and effective. Thus, indications for the products manufactured with these fabrics are the following: Coadjuvant treatments in the maintenance of blood flow, peripheral vasodilation and regulation of local microcisculation.

All these effects and their respective mechanisms of action were described by the authors and winners of Nobel prizes, Furchgott, 1999 and Ignarro et al., 1987. ANVISA, National Health Surveillance Agency, recognized the efficacy and safety of this product and granted on 13/JUN/2011 the registration ANVISA/MS No. 80104760007.

#### References

- 1. FURCHGOTT, R. F. Endothelium-derived relaxing factor: discovery, early studies, and identification as nitric oxide. Biosci. Rep. v19, n.4, p. 235-251, Aug 1999.
- 2. IGNARRO, L. J.; BUGA, G. M.; WOOD, K. S.; BYRNS, R. E.; CHAUDHURI, G. Endothelium-derived relaxing factor produced and released from artery and vein is nitric oxide. Proc. Natl. Acad. Sci. USA. v.84, n.24, p.9265-9269, Dec 1987.
- 3. TSIKAS, D. Methods of quantitative analysis of the nitric oxide metabolites nitrite and nitrate in human biological fluids. Free Radic. Res. V.38, n.8, p.797-815, 2005.