ASSESSMENT OF INCORPORATED FABRIC WITH MIG3® INVEL® BIOCERAMICS EFFECTSIN 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 nitro hemoglobin.

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

Vasodilators effects, produced by NO, are prevenient of its interaction with the 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 addresses the relaxation of the smooth muscle.

Objective

Primary objective:

To assess the ability of whether fabrics containing MIG3® Invel® Bioceramics produce the NO's gasotransmitter through the nitrite quantification in the saliva in the BioC group, compared to C group.

Secondary objective:

Supported by indexed publications, discuss about the action of the NO's gasotransmitter in the human system, its' benefits and its' use in therapies.

Methodology

Study Design:

An open-label, randomized, cross over 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 ±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:

		BASELINE	WORE	REST			EXERCISE After reaching maximum 65% VO2		
Arrive	Body Temperature Stabilization	T0		T1	T2	T3	T4	T5	T6
At least 03h of fasting	10 MIN	DRAW		10 MIN	10 MIN	10 MIN	10 MIN	10 MIN	10 MIN
Drank a isotonic Performed oral hygiene	Room at 24°C and 55% RU, orthostatic position								

Saliva collection: Collection was performed using "Salivette®" collector:

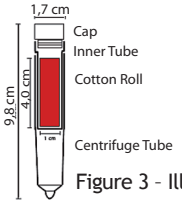


Figure 3 – Illustration of "Salivette" collector.

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 µM, where 50 µL of saliva were processed and incubated into 50 µL of Griess reagent. Reading was performed in a spectrophotometer at 570nm.

Results

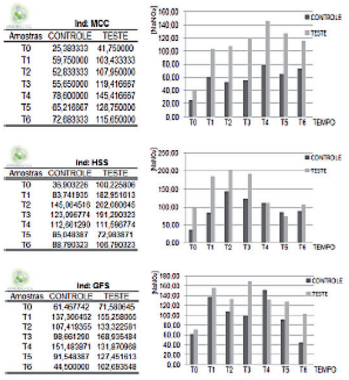
NO significant superiority of baseline BioC was seen compared to C. Estimation were: BioC: (71.65 ±5.77) and C: (47.76± 5.77).

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

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

Fixed factors		Mean	Standard Error	P-value	Difference	CI (95%)	
TRT	BioC	71.65	5.77	0.0067	23.89	IL 7.17	SL 40.61
	C	47.76	5.77				
Period	P1	51.00	5.77	0.0418	-17.42	-34.14	-0.70
	P2	68.42	5.77				
Sequence	S1	58.53	8.66	0.8494	-2.35	-27.45	22.75
	S2	60.88	8.66				

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



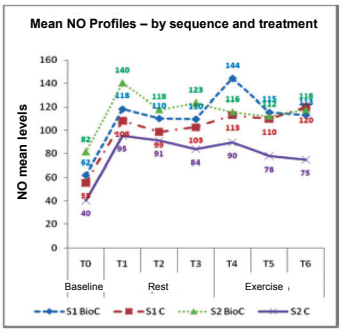


Chart 1: Nitric Oxide (NO) summary statistics, by sequence, period, Activity (Rest=R and Exercise=E), in each measurement timepoint.

Conclusion

Fabrics of MIG3® Invel® Bioceramics have the ability to promote NO's gasotransmitter production and these are secure and effective fabrics. Thus, indications for the products manufactured with these fabrics are: Coadjutant treatments in the maintenance of blood flow, peripheral vasodilatation and regulation of local microcirculation. All these effects and its respective action mechanisms were well 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 register ANVISA/MS No. 80104760007.

References

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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.
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