

Columbus

One Columbus[®] Egg a day,

**It will not hurt, no matter your
starting health conditions,
And it may help...**

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Belovo SA presents the statistical significant results of the four pilot clinical studies performed with Designer Egg® and Columbus® Egg at four independent laboratories in Alberta (1993), Belgium (2000), Spain (2002) and Iran (2003) by the following groups:

- Jiang, Z. & Sim, J.S. (1993) Consumption of n-3 Polyunsaturated Fatty Acid-Enriched Eggs and Changes in Plasma Lipids of Human Subjects. *Nutrition*, 9(6), 513-518. *Proceedings of the 1st International Congress on the Columbus® Concept, Washington D.C., Sept. 21-25th, 2002, pp.139-155.*
- Watrin, I., Brasseur, D. & Carpentier, Y.A. (2000) Effect of the consumption of ω -3 fatty acid-enriched eggs on the lipid profiles of adolescents with hypercholesterolaemia. *Proceedings of the 1st International Congress on the Columbus® Concept, Washington D.C., Sept. 21-25th, 2002, pp.179-186.*
- Prado Martinez, C., Carmenate Moreno, M., Holts Nielsen Andersen, A., Martinez Martinez, R. & Donoso Melero, C. (2002) Effects of substituting standard eggs for Columbus® eggs in the diet of Spanish postmenopausal female volunteers. *Proceedings of the 1st International Congress on the Columbus® Concept, Washington D.C., Sept. 21-25th, 2002, pp.127-138.*
- Fakhrzadeh, H., Pourebrahim, R. & Taheri, E. (2003) The effects of omega-3 rich eggs (Columbus®) on serum lipid profiles, high sensitivity CRP and fasting insulin levels in healthy volunteers. *Proceedings of the 2nd International Congress on the Columbus® Concept, Athens, Greece, Sept. 25-27th, 2003, to be published.*

Still a long way to go, but so much encouraging...



Designer Egg[®] and Columbus[®] Egg Pilot Clinical Studies

1. Design



2000' Queen Fabiola Study Brussels, Belgium
By Watrin L, Brasseur D, & Carpentier Y, A.
FH-children
between 9 and 14 years of age
n=14
1 group (Columbus[®])
3 to 5 eggs / week
8 weeks
Parameters
- TC, LDL-C, HDL-C, TG
- VLE in Plasma & LDL
- Oxidability of LDL
- FA in LDL-TG, LDL-C
- FA in LDL-PL, RBC-PL

2002' Navalcamero Study Madrid, Spain
By Prado Martinez, C.
(Post)-menopausal women
between 45 and 55 years of age
n=80
2 groups (Columbus[®] & placebo)
1 to 3 eggs a day
8 weeks
Parameters
- Glc, gth, insuline
- TC, LDL-C, HDL-C, TG
- BP, BMI, BF

1993' University Study Alberta, Edmonton, Canada
By Jiang Z. & Sim, L. S.
University students
between 18 and 22 years of age
n=24
2 groups (Designer & Placebo)
2 eggs a day
18 days
Parameters
- TC, LDL-C, HDL-C, TG

2003' Shariati Hospital Study Tehran, Iran
By Fakhzadeh H., Pourbrahim R. & Taheri E.
University students
between 19 and 25 years of age
n=42
2 groups (Columbus[®] & Placebo)
2 eggs a day
6 weeks
Parameters
- TC, LDL-C, HDL-C, TG
- Insulin, C-reactive protein

Wild Food for Health



2. Influence on plasma lipids

<i>Year</i>	<i>1993</i>		<i>2000</i>		<i>2002</i>		<i>2003</i>	
<i>Country</i>	<i>Alberta</i>		<i>Belgium</i>		<i>Spain</i>		<i>Iran</i>	
<i>Egg</i>	<i>S.E.</i>	<i>D.E.</i>	<i>S.E.</i>	<i>C.E.</i>	<i>S.E.</i>	<i>C.E.</i>	<i>S.E.</i>	<i>C.E.</i>
<i># eggs/day</i>	± 2	± 2	0	± 0.5	± 0.5	± 1	± 2	± 2
<i>TC</i>	n.s.	n.s.	-	n.s.	n.s.	n.s.	+12% (0.03)	n.s.
<i>LDL</i>	+12% (0.05)	n.s.	-	n.s.	n.s.	n.s.	+21% (0.01)	n.s.
<i>HDL</i>	n.s.	+8% (0.05)	-	n.s.	n.s.	n.s.	n.s.	+13% (0.03)
<i>TG</i>	n.s.	-40% (0.01)	-	n.s.	n.s.	-9.6% (0.05)	n.s.	-23% (0.04)

S.E.: standard egg; *D.E.*: Designer Egg®; *C.E.*: Columbus® Egg; *n.s.*: no statistical significance; -: not measured.

Tentative conclusions:

- 1• One egg a day is OK (McNamara, 2000) is confirmed. Up to that level (Belgium, Spain), standard egg does not affect blood lipids significantly. Above that daily rate (Alberta, Iran), standard egg starts to negatively influence classical blood lipid parameters (TC, LDL-C) - in red in the table.
- 2• Columbus® Egg positively influences classical blood lipid parameters (TG, HDL-C) and the beneficial influence is dose-dependent: the effects are already seen at a daily ingestion rate of one egg a day (Spain) and are amplified at that of two eggs a day (Alberta, Iran) - in green in the table.



3. Influence on glycemia

<i>Year</i>	<i>1993</i>		<i>2000</i>		<i>2002</i>		<i>2003</i>	
<i>Country</i>	Alberta		Belgium		Spain		Iran	
<i>Egg</i>	S.E.	D.E.	S.E.	C.E.	S.E.	C.E.	S.E.	C.E.
<i># eggs/day</i>	± 2	± 2	0	± 0.5	± 0.5	± 1	± 2	± 2
<i>Glucose</i>	-	-	-	-	n.s.	n.s.	n.s.	n.s.
<i>Insulin</i>	-	-	-	-	n.s.	-20% (0.001)	n.s.	-28% (0.01)
<i>gHb</i>	-	-	-	-	n.s.	+5% (0.01)	n.s.	n.s.

S.E.: standard egg; *D.E.:* Designer Egg®; *C.E.:* Columbus® Egg; *gHb:* glycosylated hemoglobin; *n.s.:* no statistical significance; - : not measured.

Tentative conclusions:

- 1 • Standard egg (S.E.) does not influence glycemia up to an ingestion rate of two eggs a day.
- 2 • Columbus® Egg positively influences glycemia through its potent effect on fasting insulin, as seen in post-menopausal women (Spain) and in young university students (Iran). The effect is clearly observed as starting at an ingestion rate of one egg a day - in green in the table. This beneficial effect on circulating insulin has no influence on glucose, but has a minor, but significant, effect on glycosylated hemoglobin (gHb) in post-menopausal women after 8-weeks on the 'one Columbus® Egg a day' diet.



4. Influence on secondary cardio-vascular parameters

<i>Year</i>	<i>1993</i>		<i>2000</i>		<i>2002</i>		<i>2003</i>	
<i>Country</i>	Alberta		Belgium		Spain		Iran	
<i>Egg</i>	S.E.	D.E.	S.E.	C.E.	S.E.	C.E.	S.E.	C.E.
<i># eggs/day</i>	± 2	± 2	0	± 0.5	± 0.5	± 1	± 2	± 2
<i>Weight</i>	-	-	-	-	n.s.	-1% (0.01)	-	-
<i>Waist</i>	-	-	-	-	n.s.	+2.5% (0.01)	-	-
<i>Hip</i>	-	-	-	-	n.s.	-3% (0.001)	-	-
<i>SBP</i>	-	-	-	-	n.s.	-6% (0.01)	n.s.	-3% (0.03)
<i>CRP</i>	-	-	-	-	-	-	n.s.	-13% (0.01)

S.E.: standard egg; *D.E.:* Designer Egg®; *C.E.:* Columbus® Egg; *SBP:* systolic blood pressure; *CRP:* C-reactive protein; *n.s.:* no statistical significance; *-:* not measured.

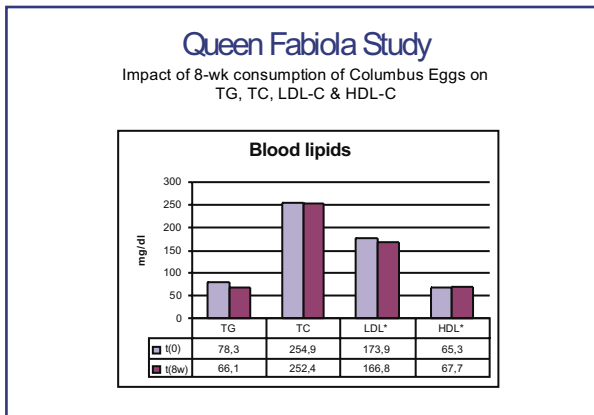
Tentative conclusions:

- 1 • Standard egg (S.E.) does not influence secondary CVD-risks up to an ingestion rate of two eggs a day.
- 2 • Columbus® Egg positively influences secondary CVD-risks through its positive effect on systolic blood pressure (no effect on the diastolic counterpart), as seen in post-menopausal women (Spain) and in young university students (Iran). The effect is clearly observed as starting at an ingestion rate of one egg a day - in green in the table. This beneficial effect on systolic blood pressure is accompanied by minor, but significant, positive anthropometric changes (weight, waist and hip perimeters) in post-menopausal women after 8-weeks on the 'one Columbus® Egg at day' diet and by a substantial drop in CRP pro-inflammatory parameters in young university students on the 'two Columbus® Egg a day' diet.



5. No statistically significant results

Although a number of observations could not reach statistical significance in these pilot clinical studies – especially in the 2000’ Belgian study involving family-inherited hypercholestaemic children for whom the small number of patients and eggs tested as well as the absence of control-groups were obvious ethical requirements – their close analyses reveal similar positive trends. In this particular group of FH-children, a synergistic Columbus® Egg - Statin effect was also observed.



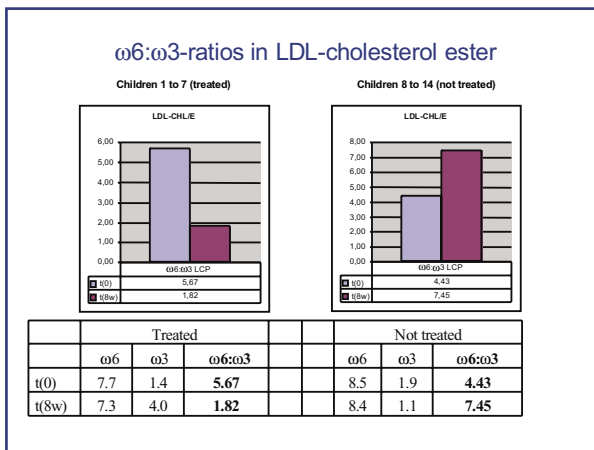
Triglycerides were not high in the first place (std values are around 100 mg%), but did show a 15% reduction (without reaching statistical significance), TC and HDL-C were both high, but the ratio between the two remains within std values (< 5) and showed a trend downwards at the end of the experiment, LDL-C is quite high (note that the LDL-C/HDL-C ratio < 2.88 is still within norms), and the consumption of 3-5 Columbus eggs weekly also resulted in a trend towards a promising blood cholesterol redistribution within this group of patients. For the great majority of the FH-children, there actually was a net positive effect on the lipid profile – reduction or no effect on TC and LDL-C, neutral effect on HDL-C, with corresponding changes reflected in apo-B and apo-A1.

Queen Fabiola Study
Fatty acid composition of LDL after 8-wk consumption of Columbus Eggs

LDL	SAFA		MUFA		PUFA		LCP		ω6 LCP		ω3 LCP	
	0	8	0	8	0	8	0	8	0	8	0	8
PL	47.7	49.0	7.9	7.7	24.5	21.5	20.0	21.8	15.5	16.0	5.1	5.8
TG	31.2	42.6	48.1	39.8	19.3	16.3	1.5	1.3	1.5	0.9	0	0.6
CHL/E	12.3	13.2	18.6	17.0	59.4	59.4	9.8	10.4	8.1	7.9	1.6	2.6

}	5.06
}	3.04

The whole group of children taken in average for their LDL lipid fractions (PLs, TGs, CHL/Es) presents some striking changes after 8-wk on Columbus® Egg. PLs and CHL/Es benefit from a slight increase in ω3 LCPs and therefore from a reduction in the w6:w3 ratio (from 5.06 to 3.04 in CHL/Es), TG see their SAFA and MUFA increased (31.2 to 42.6%) and decreased (48.1 to 39.8%), respectively, by about 10%. Another observation that emerges from this study is the difference in response between those FH-children treated with lipid-lowering therapy (statins) and those FH-children untreated.



The w6:w3 ratio in LDL-cholesteryl ester did improve substantially in those children under statin-treatment due to a significant rise in omega-3 LCPs after 8-wk on Columbus® Egg (1.4% to 4.0%) with no change in omega-6, while this was clearly not the case within the group of untreated children (1.9% to 1.0%). The w6:w3 ratio in the LDL-phospholipids showed similar trends although less obvious, with a reduction in the group of statin-treated children and no change in the untreated children. Again, given the numbers of eggs ingested (3 to 5 in a week), one would expect LDL-C/E and LDL-PL not to be affected in terms of their fatty acid composition. The amazingly beneficial effect seen in the statin-treated children is again unexpected and requires further investigation. This behaviour presumably reflects a drug-diet interaction, whose mechanism remains unclear.



6. Conclusions

Gold standard clinical trials are on-going to confirm the results accumulated during the four pilot clinical studies carried out so far. This is a requirement to further progress in the field. However, one has to recognize that Columbus® Egg outperforms expectations in a number of clinical parameters classically presented as dietary cardiovascular risks, i.e., it seems to:

- not affect plasma total cholesterol (TC),
- trigger a beneficial redistribution between LDL- and HDL-cholesterol,
- significantly reduce blood triglycerides,
- substantially reduce fasting insulin and glycemia,
- effectively reduce systolic blood pressure,
- improve anthropometric parameters (weight, waist and hip perimeters),
- reduce pro-inflammatory indexes (CRP, LDL-CHL/ $\omega 6:\omega 3$ ratio), and
- help FH-children with their statin treatment.

When tested for, these effects were observed for so widely different groups of patients (phenotypes) as FH-children (between 9 and 15 years of age), healthy university students (between 18 and 32 years of age), and postmenopausal women (between 45 and 55 years of age).

It may therefore be concluded that Columbus® Egg is a safe staple food for the greatest majority of people and that it may help in many circumstances to improve health conditions. It just belongs to man's genetic heritage.

