STUDY REPORT PHASE 1

Study Number: 003/001

Test Item: OSENS device (protection adhesive)

Study Title: Exploratory studies to assess the biological effects of Osens Life devices on *in vitro* models

Phase 1: Study of the cellular organization following exposure to Osens Protection adhésive

Testing Facility

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Version of May, 14th 2018

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1. INTRODUCTION

1.1 Study Dates

This study 003/001 phase 1 comprised one experiment using whole blood drawn from human subjects.

Study plan approval: 02/02/2018

1.2 Responsible Personnel

1.2.1 Testing Facility

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1.3 Study Objectives of phase 1

This phase was undertaken in order to determine the efficacy of OSENS device (protection adhésive) to red blood cell organisation against possible damaging effects of electromagnetism emitted by mobile phones.

2. GUIDELINES

2.1 Quality Assurance

This study phase was conducted in accordance with Axonova standard operating procedures and supervised by the company Quality Management System. The study is not intended to be GLP compliant.

The phase report can be audited. Study-based or process activities can be inspected according to the standard operating procedure at the testing facility.

The complete data can be reviewed to ensure that they describe the methods and procedures and that all the results reflect the raw data.

2.2 Ethics

This protocol was reviewed and accepted by the ethical committee of Axonova Company.

3. TEST MATERIALS

3.1 Test Item 1

Denomination:	Protection adhesive Osens
Supplier:	Osens Life
Storage conditions:	Room temperature

3.2 Test material characterization

The Sponsor assumes responsibility for characterization of the Test Item. The Sponsor will hold information on the composition and method of synthesis of the bulk test item.

The complete description of the test item is under the responsibility of the Sponsor.

The sponsor has certified by signing the study plan that all appropriate data for storage conditions and precautions for handling are available and forwarded to the study director before sending the Test Item.

3.3 Inventory and test material disposition

Test Item was inventoried upon receipt at the Testing Facility, and then stored in accordance with the sponsor's recommendations. A record of all Test Items used was maintained.

4. MATERIALS AND METHODS

4.1 Cell type

Sampling of Human red blood cells was used for this experimentation.

4.2 Subjects

4 blood samples in 4 different human subjects (2 males and 2 females) was performed for this study phase. These 4 subjects was healthy volunteers and they have signed a consent form before starting the study.

4.3 Procedure

Parameters to measure: Observation of cellular organization (agglomeration of red blood cells). Three independent experiments was performed with two parameters; communication only and mobile phone communication with Osens device.

Before each experiment, subjects did not use a mobile phone for a minimum of 8 hours.
A blood sampling was performed on the index finger of each subject before using the phone (pretest). Blood sample was spread on a microscope slide and the cellular organization was observed under an optic microscope (inverted microscope Motic) equipped with a camera system (Moticam 3.0) for image acquisition.
Afterwards, each subject used a Samsung S6 edge mobile phone during 5, 10 and 20 minutes with the same hand. After each communication time, a blood sampling was performed on the same finger. Blood sample was spread on a microscope slide and the cellular organization was observed under an optic microscope equipped with a camera system for image acquisition.
For each slide, 3 pictures was performed. With the 3 independent experiments, a total of 9 pictures per parameter was analyzed.

4.4 Test Item dosing

Test concentration : N/A
Time of exposure/treatment: Varying length of time depending on experimental assay

4.5 Schedule of observations and sampling

Observations by qualitative (microscopic evaluations) and quantitative (scoring of the percentage of red blood cell agglomeration) was carried out as per experimental design and requirements.

4.6 Data collection

Blood samples was performed using a manual finger prick. For each sampling, a volume of 1 µL was collected and spread on a microscope slide. The cellular organization was observed under an optic microscope at x40 magnification. On each slide, 3 pictures was performed in order to scores the red blood cell agglomeration level. The score scale varies between 0 and 4. The score description is presented in the table below. The pictures were acquired in the area between the periphery and the centre where the cell concentration was consistent in all slides.

As a representation, 5 images of the 5 scores are presented in the Figures 1 (A to E) below.

Figure 1: Picture example scoring (A to E)

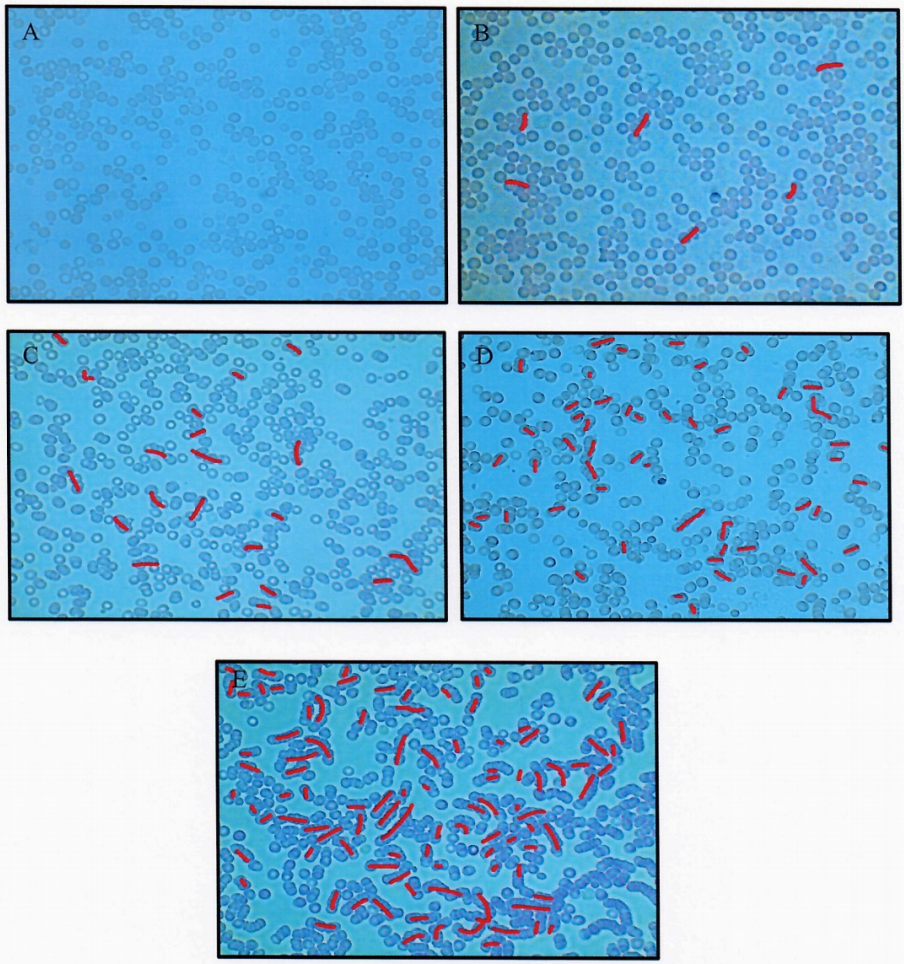


Table 1: Table of correspondence of the scores with the number of cell agglomerations

Score	Score 0	Score 1	Score 2	Score 3	Score 4
Number of agglomerations	No agglomeration of a minimum of 3 cells	1 to 19 cell agglomerations	20 to 39 cell agglomerations	40 to 59 cell agglomerations	more than 60 cell agglomerations
Picture	A	B	C	D	E

On each slide, cellular organization was different according to the areas observed. On the periphery of the slide, cell concentration was too high. This region was disregarded during data acquisition as it would not have been feasible to count the cellular organisations. At the center of the slide, the cell concentration was too low. Therefore pictures were acquired in the area between the periphery and the centre where the cell concentration was consistent in all slides. It is important to note that the red blood cell organization of the same slide could vary according to the area visualised. The results may be dependent on the field of view chosen and the analyst taking the picture. The scoring system may also be an analyst-dependent parameter.

4.7 Statistical tests

Statistical test was performed with the mean of the 9 pictures for each subjects for each time point. Statistical tests and graphs were obtained with the software GraphPad Prism 7.00. Data was analyzed with the two way repeated measures ANOVA Test (factor device and factor time). Significant results were analyzed via post-hoc Bonferroni's multiple comparisons test. Results are considered significant when $p<0.05$ and confidence intervals were set at 95%.

5. RESULTS

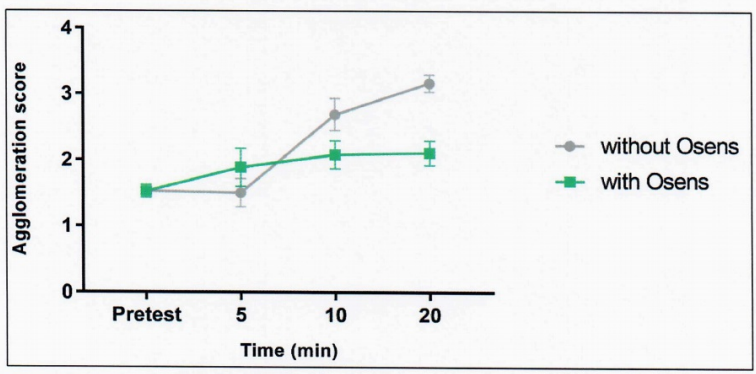
5.1 Red blood cell agglomeration scoring

Table 2: Table of the mean scoring results

	Pretest	5min	10min	20min	5min Osens	10min Osens	20min Osens
S1	1.56	0.89	3.11	3.33	1.22	2.56	1.56
S2	1.44	1.89	3.11	3.44	2.56	1.56	2.33
S3	1.78	1.56	2.22	2.89	2.11	2.22	2.22
S4	1.33	1.67	2.33	3.00	1.67	2.00	2.33
Mean	1.53	1.50	2.69	3.17	1.89	2.08	2.11

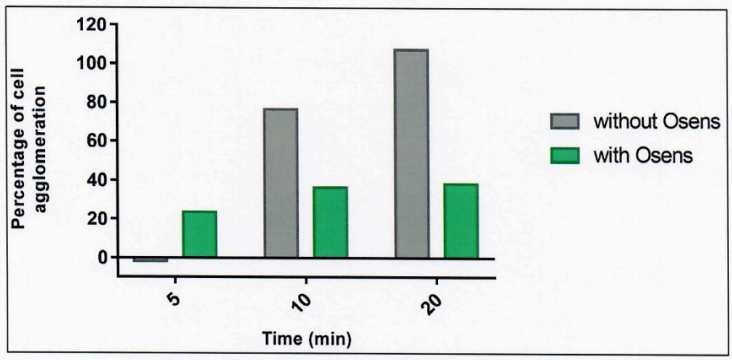
Above are the results of scoring averages. These averages are based on the results of the 9 pictures acquired for each of the 4 subjects (S1 to S4).

Figure 2: Red blood cell agglomeration monitoring



The graph presented in the Figure 6 shows the Mean Aggregation Level (with Standard Mean of Error [SEM]) over time during a call with a mobile phone. Without Osens device, an increase of red blood cell aggregation at 10 minutes and 20 minutes was observed. After 5 minutes, no significant difference was observed.

Figure 3: Evolution of the percentage of agglomeration compared to the pretest



After 5 minutes of telephone conversation, there was no significant difference between the two conditions tested. After 10 minutes of call, a 76% increase in cell agglomeration was observed without the Osens device. In the presence of the Osens device, this increase was 36%. After 20 minutes of call, an increase of more than 107% in cell agglomeration was observed without the Osens device. In the presence of the Osens device, this increase was only 38%.
There is therefore a decrease of aproximately 40% and 69% in the percentage of agglomeration after 10 minutes and 20 minutes of call respectively in the presence of the Osens adhesive protection.

5.2 Statistical test

Statistical test was performed with the mean of the 9 pictures for each points.

Table 3: Table of the statistical tests

Two-way RM ANOVA	Matching: Both factors			
Source of Variation	% of total variation	P value	P value summary	Significance
Device	5,926	0,0673	ns	No
Time	49,95	0,003	**	Yes
Interaction: Device x Time	17,87	0,0062	**	Yes

ns: non significant

As described in the Table 2, data was analyzed with the two way repeated measures ANOVA Test. The two factors were the deivce and the time. This test failed to show a significant difference on the device parameter only. However a significant difference was highlighted for the time parameter only and for the interaction of device/time factor.

Figure 4: Evolution of the percentage of red blood cell agglomeration

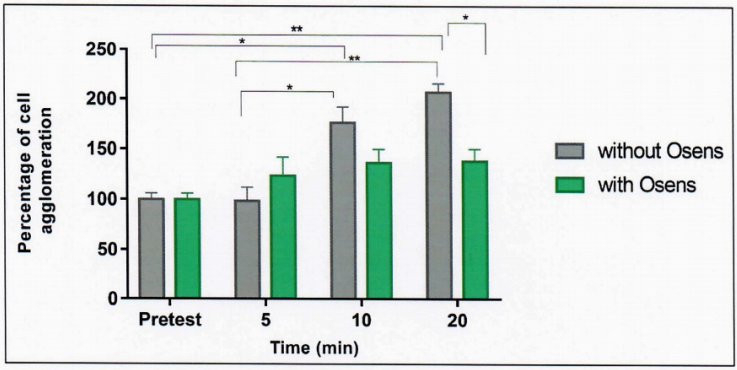


Table 4: Table of the statistical tests

Bonferroni's multiple comparisons test	Mean Diff.	95,00% CI of diff.	Significant?	Summary	Adjusted P Value
Without Osens:Pretest vs. Without Osens:10 min	-1,167	-2,148 to -0,1853	Yes	*	0,0158
Without Osens:Pretest vs. Without Osens:20 min	-1,639	-2,62 to -0,6576	Yes	**	0,0013
Without Osens:5 min vs. Without Osens:10 min	-1,194	-2,176 to -0,2131	Yes	*	0,0134
Without Osens:5 min vs. Without Osens:20 min	-1,667	-2,648 to -0,6853	Yes	**	0,0011
Without Osens:20 min vs. With Osens:20 min	1,056	0,07424 to 2,037	Yes	*	0,0311

As described in the Figure 8 and the Table 3, a very significant difference of the red blood cell agglomeration rate was highlighted between:

- pretest data and 20 minutes phone communication without Osens device.
- 5 and 20 minutes phone communication without Osens device.

Furthermore, a significant difference of the red blood cell agglomeration rate was highlighted between:

- a 20 minutes phone comunication with and without Osens device.
- Pretest data and 10 minutes phone comunication without Osens device.
- 5 and 10 minutes phone comunication without Osens device.

No difference could be found by comparing the pretests and the 5 minutes of telephone communication with or without osens device.

5.3 Conclusion

This phase of study has made it possible to demonstrate that the extent of red blood cell agglomeration varies according to the duration of mobile phone comunication. After 5 minutes of telephone conversation, there was no significant difference between the two conditions tested. However, there is a decrease of approximately 40% and 69% in the percentage of agglomeration after 10 minutes and 20 minutes of call respectively in the presence of the Osens adhesive protection.

This data seems to validate the experimental model. Subsequently, it was possible to establish a interaction between the time parameter and the presence or absence of the Osens device. With these results, it was possible to conclude that the Osens adhesive protection reduced the influence of a 20-minute phone conversation on red blood cell agglomeration.

6. AMENDMENTS

No amendment was performed during this study phase.

7. DEVIATIONS

No deviation was performed during this study phase.

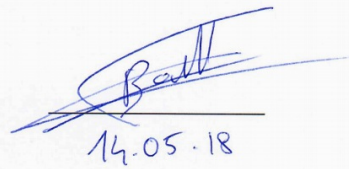
8. ARCHIVES

After finalization of the study report, the records will be archived for a minimum period of 5 years or eventually transferred to the Sponsor's facility or to another location approved by the Sponsor.

9. PHASE REPORT APPROVAL

Testing Facility Manager:

Fabien BOULLE, PhD, CEO
Axonova Ltd



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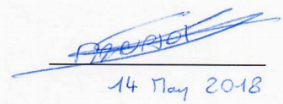

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