

Report on human clinical trials of alginate materials produced by Lascod.

**Clinical trials were conducted at KAREN DENT dental clinic.
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General clinical data

30 patients were randomly selected, 13 men and 17 women. Each patient underwent a routine oral examination, the tooth to be treated was prepared, and the mouth was rinsed with water. Next, registration was carried out. Patients were told that with their consent we needed to make impressions using two materials for clinical trials. In 21 cases an impression was made to work with overdentures, in 9 cases – to work with fixed dentures.

Purpose of the study: to determine the effectiveness and safety of alginate materials manufactured by Lascod.

Working hypothesis: Lascod alginate materials are safe for patients and effective for making precise impressions in dental prostheses clinical cases.

Clinical trial methodology

In each case, two Lascod materials were used.

Impressions and cast models were made.

Test materials: IQ CHROM type 1, IQ CHROM type 2, IQ GREEN type 1, IQ GREEN type 2, IQ TROPICAL type 1, IQ TROPICAL type 2, ALGINELLE type 1, ALGINELLE type 2, MILLENIUM, ALGINORortho, KROMOPAN type 1, KROMOPAN type 2.

Research standards and other rules

In accordance with the Clinical Trial Program evaluation criteria, impressions and cast models were made for each eligible patient to compare the working time, the initial hardening time, and the dimensional stability. The time was recorded using a stopwatch and a watch. These parameters were then divided into two categories: good and bad, depending on compliance with the manufacturer's declared parameters. If the parameters fully corresponded, they were in the good category; if they deviated from the stated parameters by more than 5%, they were in the bad category. In addition, some technical characteristics of the materials were assessed: appearance, color after hardening and taste. Next, they were compared with the declared characteristics. All patients were asked whether there were any side effects when using the material.

Statistical methods: assessment was carried out using the Student's t test.

Clinical trial results

By the criteria: quality of work, precision of the impression, quality of the cast model.

In all 30 cases the test group was in the good category in terms of the working time, the initial hardening time and the dimensional stability.

Table 1 - Clinical characteristics of alginate materials declared by the manufacturer

Indicator	Criteria						
	IQ CHROM	IQ GREEN	IQ TROPICAL	ALGINELLE	MILLENIUM	ALGINOR ortho	KROMOPAN
Working time, sec							
- type 1	110-120	110-120	110-120	105-115	105-115	105-115	105-115
- type 2	170-180	170-180	170-180	165-175	Not applicable	Not applicable	165-175
Initial hardening time, sec							
- type 1	115-130	115-130	115-130	110-135	110-135	110-135	110-135
- type 2	175-190	175-190	175-190	170-190	Not applicable	Not applicable	170-190
Dimensional stability, h	N/A	N/A	N/A	At least 168	At least 168	At least 168	At least 168

Table 2. Results of evaluation of the main parameters of alginate impression materials from Lascod

Indicator	Criteria						
	IQ CHROM	IQ GREEN	IQ TROPICAL	ALGINELLE	MILLENIUM	ALGINOR ortho	KROMOPAN
Working time, sec							
- type 1	113±2,48	114±3,54	118±2,1 4	109,46± 2,18	111,14± 2,46	112,13±2,1 1	109,34±3,4 8
- type 2	174±3,81	175±3,12	175±4,1 8	169,18± 3,38	-	-	168±3,72
Initial hardening time, sec							
- type 1	124,32±3,4 9	126,34±3, 14	126,28± 3,15	131,28± 2,18	124,28± 2,43	131,28±3,2 0	121,46±3,4 6
- type 2	178,18±2,1 2	179±2,18	179,29± 3,16	175±3,1 7	-	-	180,28±3,3 8
Dimensional stability, h	N/A	N/A	N/A	At least 168	At least 168	At least 168	At least 168

When comparing the declared and the obtained parameters using the Student's t test, the result was $P > 0.05$, there was no significant difference.

Table 3 - Technical characteristics of alginate materials

Indicator	Criteria						
	IQ CHROM	IQ GREEN	IQ TROPICAL	ALGINELLE	MILLENIUM	ALGINOR ortho	KROMOPAN
Appearance	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions
Color after hardening	green	green	yellow	orange	pink	green	white
Taste	mint	mint	mango	mint	strawberry	mint	mint

Table 4 - Evaluation of the technical characteristics of alginate materials from Lascod

Indicator	Criteria						
	IQ CHROM	IQ GREEN	IQ TROPICAL	ALGINELLE	MILLENIUM	ALGINOR ortho	KROMOPAN
Appearance	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions	Powder without foreign inclusions
Color after hardening	green	green	yellow	orange	pink	green	white
Taste	mint	mint	mango	mint	strawberry	mint	mint

All declared technical characteristics of materials have been fully confirmed.
None of the 30 patients participating in the study complained about any side effects.

Analysis of clinical trial effects

For 30 patients, impressions were made using Lascod alginate materials according to the instructions. The total working time and the hardening time correspond to the declared time. The dimensional stability of the impression, if stored as recommended, is at least 168 hours. Appearance, color after hardening and taste correspond to the declared parameters. The patients experienced no adverse reactions, the impression is precise, the cast is easily separated, the mass is smooth and clear, the clinical results are good, the same as those of the control group.

Conclusion about the clinical trial

The working hypothesis that alginate materials from Lascod are safe for patients and effective for taking precise impressions in dental prostheses clinical cases was confirmed.

Responsible researcher
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