

Report on human clinical trials of silicone impression materials manufactured by Lascod.
Clinical trials were conducted at KAREN DENT dental clinic.
Responsible executor Dr. Hrant Martirosyan

General clinical data

36 patients were randomly selected, 18 men and 18 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 for clinical trials with their consent we needed to make impressions using two materials with a two-layer method. In 26 cases, an impression was made to work with overdentures, in 10 cases – to work with fixed dentures.

Purpose of the study: to determine the effectiveness and safety of silicone impression materials produced by Lascod.

Working hypothesis: Lascod silicone impression materials are safe for patients and effective for making precise impressions when manufacturing dental prostheses.

Clinical trial methodology

In each case, two Lascod materials were used.
Impressions and cast models were made.

Test materials:

1. KROMOPAN SIL silicone putty soft NORMAL SET
2. KROMOPAN SIL silicone putty soft FAST SET
3. KROMOPAN SIL silicone putty hard NORMAL SET
4. KROMOPAN SIL silicone putty hard FAST SET
5. KROMOPAN SIL silicone super lightbody NORMAL SET (2 x 50 ml cartridges)
6. KROMOPAN SIL silicone super lightbody NORMAL SET (4 x 50 ml cartridges)
7. KROMOPAN SIL silicone super lightbody FAST SET (2 x 50 ml cartridges)
8. KROMOPAN SIL silicone super lightbody FAST SET (4 x 50 ml cartridges)
9. KROMOPAN SIL silicone light body NORMAL SET (2 x 50 ml cartridges)
10. KROMOPAN SIL silicone light body NORMAL SET (4 x 50 ml cartridges)
11. KROMOPAN SIL silicone light body FAST SET (2 x 50 ml cartridges)
12. KROMOPAN SIL silicone light body FAST SET (4 x 50 ml cartridges)
13. KROMOPAN SIL silicone regular body NORMAL SET (2 x 50 ml cartridges)
14. KROMOPAN SIL silicone regular body NORMAL SET (4 x 50 ml cartridges)
15. KROMOPAN SIL silicone regular body FAST SET (2 x 50 ml cartridges)
16. KROMOPAN SIL silicone regular body FAST SET (4 x 50 ml cartridges)
17. KROMOPAN SIL silicone heavy body NORMAL SET (2 x 50 ml cartridges)
18. KROMOPAN SIL silicone heavy body NORMAL SET (4 x 50 ml cartridges)
19. KROMOPAN SIL silicone heavy body FAST SET (2 x 50 ml cartridges)
20. KROMOPAN SIL silicone heavy body FAST SET (4 x 50 ml cartridges)
21. KROMOPAN SIL BITE silicone (2 x 50 ml cartridges)
22. KROMOPAN SIL BITE silicone (4 x 50 ml cartridges)
23. KROMOPAN SIL MONO silicone (2 x 50 ml cartridges)
24. KROMOPAN SIL MONO silicone (4 x 50 ml cartridges)
25. ENERSYL catalyst
26. SILAXIL silicone putty
27. SILAXIL silicone light body
28. SILAXIL silicone regular body

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 following parameters: working time and minimum time spent in the mouth. 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

The 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 36 cases, the test group was in good category in terms of the working time, the initial hardening time and the dimensional stability.

Table 1 – Declared characteristics of A-silicones KROMOPAN SIL silicone putty

Characteristics	soft NORMAL SET	soft FAST SET	hard NORMAL SET	hard FAST SET
Color after mixing	purple	purple	purple	purple
Odor	mint	mint	mint	mint
Working time	from 2'30'' to 3'00''	from 1'15'' to 1'45''	from 2'30'' to 3'00''	from 1'15'' to 1'45''
Minimum time in mouth	2'15''	1'30''	2'15''	1'30''

Table 2 – Obtained clinical characteristics of A-silicones KROMOPAN SIL silicone putty

Characteristics	soft NORMAL SET	soft FAST SET	hard NORMAL SET	hard FAST SET
Color after mixing	purple	purple	purple	purple
Odor	mint	mint	mint	mint
Working time	2'42''±5''	1'19''±4''	2'42'' ±3''	1'25'' ±5''
Minimum time in mouth	2'15''	1'30''	2'15''	1'30''

Table 3 – Declared characteristics of A-silicones KROMOPAN SIL silicone body

Characteristic	superlight NORMAL SET	superlight FAST SET	light NORMAL SET	light FAST SET	regular NORMAL SET	regular FAST SET	heavy NORMAL SET	heavy FAST SET
Color after mixing	pink	pink	pink	pink	pink	pink	pink	pink
Working time	from 2'00'' to 2'30''	from 1'20'' to 1'50''	from 2'00'' to 2'30''	from 1'20'' to 1'50''	from 2'00'' to 2'30''	from 1'20'' to 1'50''	from 2'00'' to 2'30''	from 1'20'' to 1'50''

Minimum time in mouth	1'30''	60''	1'30''	60''	1'30''	60''	1'30''	60''
-----------------------	--------	------	--------	------	--------	------	--------	------

Table 4 – Obtained characteristics of A-silicones KROMOPAN SIL silicone body

Characteristics	superlight NORMAL SET	superlight FAST SET	light NORMAL SET	light FAST SET	regular NORMAL SET	regular FAST SET	heavy NORMAL SET	heavy FAST SET
Color after mixing	pink	pink	pink	pink	pink	pink	pink	pink
Working time	2'13''±5''	from 1'34'' ±5''	2'19'' ±6''	1'33'' ±5''	2'05'' ±4''	from 1'35'' 7''	2'19'' ±4''	1'31'' ±6''
Minimum time in mouth	1'30''	60''	1'30''	60''	1'30''	60''	1'30''	60''

Table 5 – Declared characteristics of KROMOPAN SIL MONO

Color after mixing	purple
Odor	mint
Working time	from 2'00'' to 2'30''
Minimum time in mouth	1'30''

Table 6 – Obtained characteristics of KROMOPAN SIL MONO

Color after mixing	purple
Odor	mint
Working time	2'22''±4''
Minimum time in mouth	1'30''

Table 7 – Declared characteristics of C-silicones SILAXIL

	SILAXIL silicone putty	SILAXIL silicone light body	SILAXIL silicone regular body
Color after mixing	red	purple	green
Odor	mint	orange	orange
Working time	from 1'20'' to 1'50''	from 2'00'' to 2'30''	from 2'00'' to 2'30''
Minimum time in mouth	3'	3'30''	3'30''

Table 8 – Obtained characteristics of C-silicones SILAXIL

	SILAXIL silicone putty	SILAXIL silicone lightbody	SILAXIL silicone regular body
Color after mixing	red	purple	green
Odor	mint	orange	orange
Working time	1'32''±4''	2'25''±5''	2'24''±4''
Minimum time in mouth	3'	3'30''	3'30''

All of the declared technical characteristics of materials have been fully confirmed.

None of the 36 patients participating in the study complained of any side effects.

Analysis of clinical trial effects

For 36 patients, impressions were made using Lascod silicone impression materials according to the instructions, as stated. 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 Lascod silicone impression materials are safe for patients and effective for taking precise impressions when manufacturing dental prostheses was confirmed.

Responsible researcher Hrant Martirosyan

