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Randomised Controlled Clinical Trial Evaluating a Novel Dentine Hypersensitivity Relieve Gel

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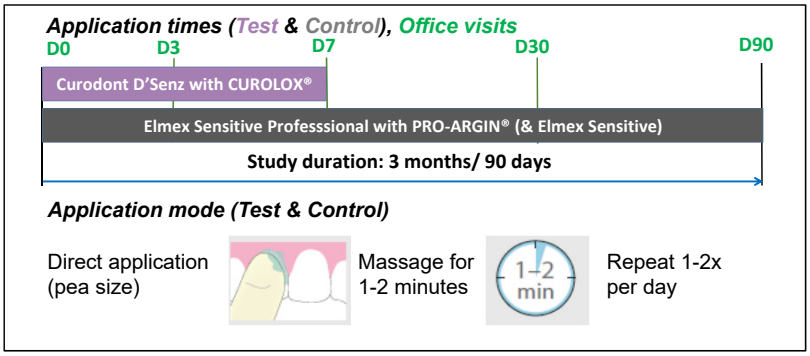
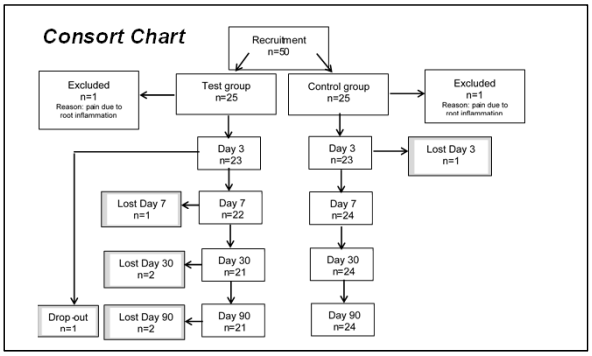
1 Objective

This clinical investigation evaluated the post-treatment pain reduction of a novel dentine hypersensitivity relieve gel (CURODONT™ D'Senz with CUROLOX™ TECHNOLOGY, credentis ag) applied in an intensive treatment regimen of 7 days compared to an established dentifrice for dentine hypersensitivity (Elmex Sensitive Professional with PRO-ARGIN™, GABA Colgate-Palmolive) with daily treatment for 90 days.

2 Material and Method

Clinical effectiveness of the treatment was evaluated both by patient response via VAS and VRS scales after applying stimuli (dental explorer, cold water, air blast) as well as by patient questionnaire. The interview assessed pain frequency, pain intensity, Global Impression of Change, and subjective success of treatment. Safety and efficacy was evaluated at days 3, 7, 30, 90. Study approval by ethical committee (FEKI, Freiburg, GER).





3 Results*

A total of 50 subjects were included in the study, with 25 in each group. Overall, patients had significantly ($p<0.05$) reduced sensitivity at the end of the study D90 (Fig 1). Pain relief was evident for a majority of subjects, with median improvements on the VAS scale of 90% for the test group compared to 54% of the control group after D90 (Fig 2). A difference was recorded for pain relief on D7 with 59% mean reduction on VAS scale for the test group and 37% mean reduction for the control ($p<0.05$). Visual Response Scale indicated superior pain relieve on D7 and D90 for the test group (Fig 3&4) ($p<0.05$). Patients regarded the success of treatment as comparable on D30 and D90, but different on D3 and D7, where 73% respective 80% of the test group stated that they were pain free or felt noticeable relieve at D3 and D7, whereas 22% (D3) and 31% (D7) of control group did (Fig 5; $p<0.05$)

** Note: Data at abstract submission might minimally differ from data after complete statistical analysis*

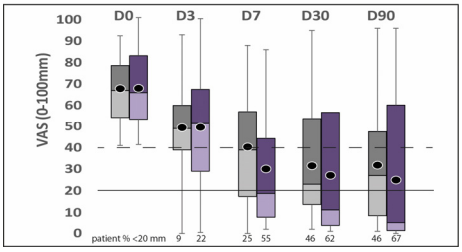


Figure 1:
Boxplot: VAS for pain at Baseline (D0) and after 3, 7, 30 and 90 days. Mean value (●). Control group (■), test group (■). Dotted line «40mm – inclusion criteria»; 20mm line & numbers: %ige of patients with value <20mm.

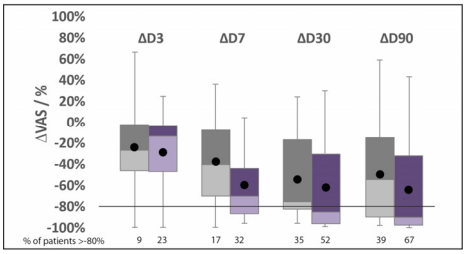


Figure 2:
Boxplot: ΔVAS for pain intensity (in %) vs Baseline (D0) at 3, 7, 30 and 90 days. Mean value (●). Control group (■), test group (■). Line at «-80%»; numbers: %ige of patients >80% pain reduction.

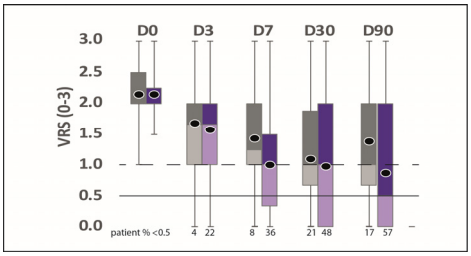


Figure 3:
Boxplot: VRS for pain intensity at Baseline (D0) and after 3, 7, 30 and 90 days. «0» no pain; «3» worst pain. Mean value (●). Control group (■), test group (■). Dotted line «1.0»: minimum response at D0; 0.5 line & numbers: %ige of patients with VRS <0.5.

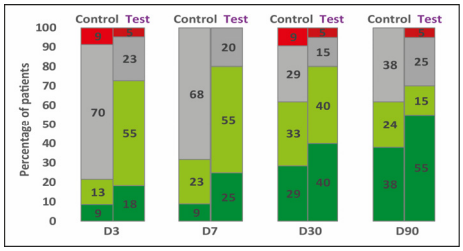
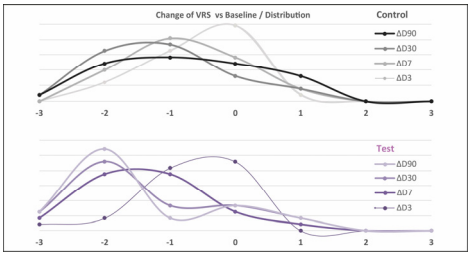


Figure 5: Question: ***Was the treatment successful?***
Barchart with %ige within the boxes.
Left: Control group; Right; Test Group:
(■) Yes, pain is gone
(■) Yes, ease of pain a noticable improvement
(■) No, no difference
(■) No, pain has increased

Figure 4: **Change of VRS for pain intensity vs D0**
Top: Test group: Bottom : Control group.
D7 and D90 ($p<0.05$)



4 Conclusion

The clinical study indicates successful pain relieve for both CUROLOX™ TECHNOLOGY and PRO-ARGIN™, with **faster pain relieve and higher patient satisfaction** for the test group early in the treatment regimen.