Objective: A 42-day prospective clinical trial was conducted to compare clinical gingivitis evaluation and non-invasive intraoral digital photography analysis (gingivitis image analysis) for the detection of gingivitis natural history. Methods: After institutional review and informed consent, healthy adults were enrolled in a 3-phase induced (experimental) gingivitis clinical trial. From Day -14 to Day 0, oral health was promoted with dental prophylaxes and daily supervised brushing. At Day 0, oral hygiene was suspended, and gingivitis was induced over 21 days. Oral hygiene was resumed, a prophylaxis was administered, and subjects were evaluated at Day 28. Anterior facial gingivitis was measured every 7 days using two methods: clinical examination by a trained examiner using the Modified Gingivitis Index (MGI), and non-invasive instrumental examination using gingivitis image analysis (GIA). The latter method used standardized digital photography and lighting, and image analysis software to assess red-green-blue (RGB) values on the marginal gingiva, with the primary response parameter being ΔG. Results: Mean (SD) age of the 16 enrolled subjects was 21.6 (4.4) years, with 15 completing the study. During the 14 day hygiene period, mean change in MGI was -0.86. During gingivitis induction, mean MGI increased by 1.69 units. With the reinstitution of hygiene during Days 21-28, mean change in MGI was -0.72. Similar responses were measured with GIA. ΔG increased by 6.2 units from Day -14 to Day 0; decreased by 15.2 units from Day 0 to Day 21; and increased by 12.6 units from Day 21 to Day 28. These differences between visits, as evaluated using both the clinical and instrumental methods, were statistically significant (p<0.001). Conclusion: In a 42-day induced gingivitis study, clinical and instrumental gingivitis image analysis methods showed gingivitis natural history including treatment and progression, consistent with established disease processes.

RESULTS

Mean (SD) ΔG was 118.2 (9.1) at baseline. ΔG increased by 6.2 units from Day -14 to Day 0; decreased by 15.2 units from Day 0 to Day 21; and increased by 12.6 units from Day 21 to Day 28, differing significantly (p<0.013) from the preceding period at each phase. Mean (SD) MGI was 2.1(0.59) at baseline. MGI decreased by 0.9 units from Day -14 to Day 0; increased by 1.7 units from Day 0 to Day 21; and decreased by 0.7 units from Day 21 to Day 28, differing significantly (p<0.01) from the preceding period at each phase.

Conclusions: In a 42-day induced gingivitis study, clinical and instrumental gingivitis image analysis methods showed gingivitis natural history including treatment and progression, consistent with established disease processes.