Cosmetic Dentistry Prospective Protocol Verification Study
Principal Investigator: Lawrence E. Brooks DDS
Sponsor: Smile-Vision Inc.

The purpose of this study is to determine the value of using digital cosmetic simulations followed-up by the Template Technique Protocol as a tool in planning and executing cosmetic dental procedures.

Objectives:
Primary: To determine the value of using digital cosmetic simulation and the Template Technique Protocol as tools in planning and executing cosmetic dental procedures to dental practitioners.

Secondary: To determine the value of using digital cosmetic simulation and the Template Technique Protocol as tools in planning and executing cosmetic dental procedures to patients.

Population: Dentists will accept candidates for study from their patient population. Candidates may be of any age, gender, demographic group or health status they feel appropriate for the performance of cosmetic procedures.

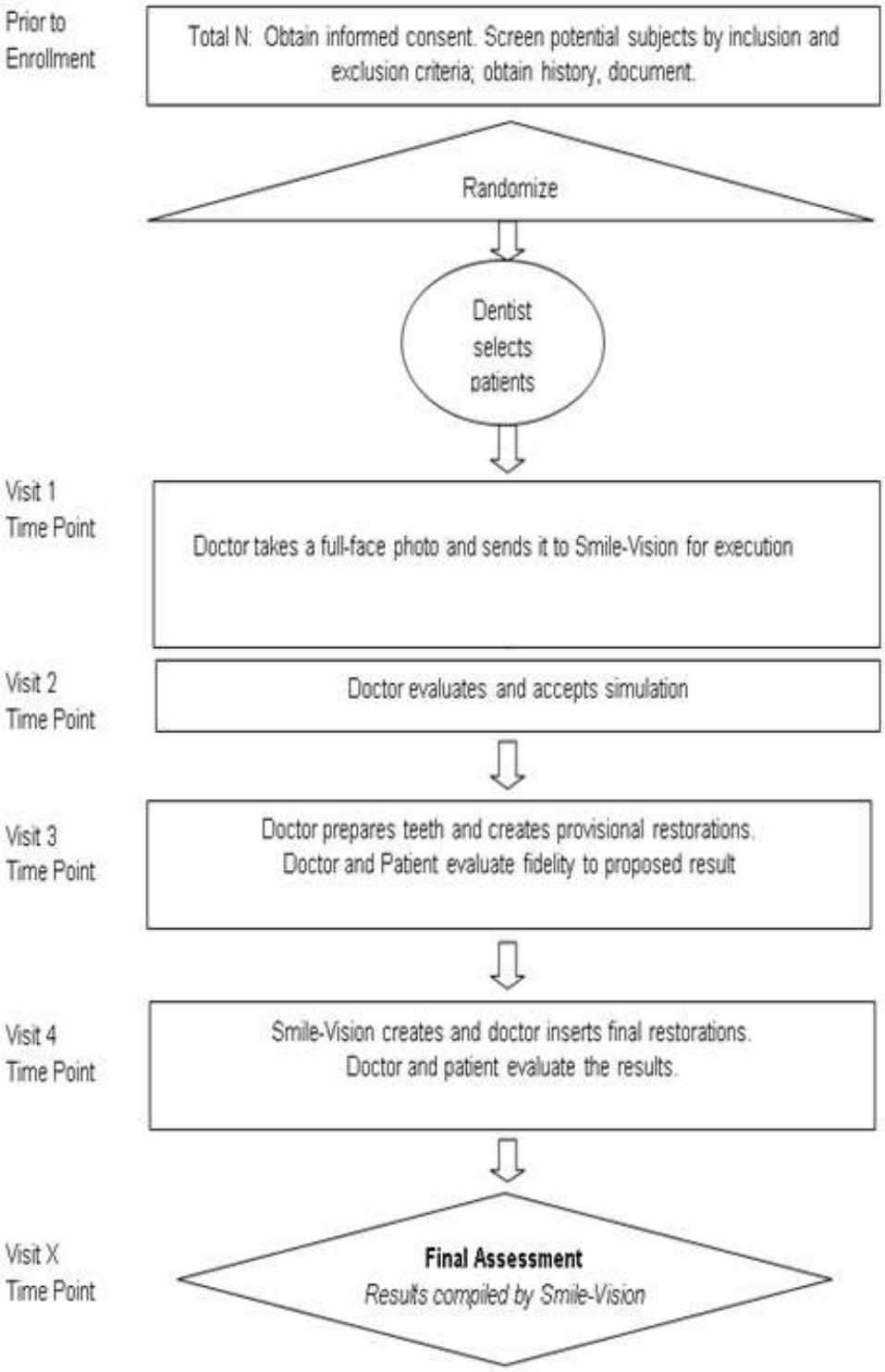
Number of Sites:
1: The office of the participating dentist may be located anywhere in the USA or Canada.

2. Smile-Vision will create the digital cosmetic simulations and perform the laboratory phases of the treatment.

Description of Intervention:
Dentists will promote the study to their patient demographic and offer them cosmetic enhancement of their smiles. They will take a full-face image of the patient with a natural smile and submit it to Smile-Vision for a digital cosmetic simulation. The doctor and Smile-Vision will co-operate in delivering temporary restorations and final restorations that meet the criteria established in the cosmetic simulation

Study Duration:
36 Months or 100 cases completed
Subject Participation Duration: 3 months
Estimated Time to Complete Enrollment: 12 Months

Schematic of Study Design:



1 KEY ROLES AND CONTACT INFORMATION

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Clinical Site Investigators:
Doctors will register for the study. All properly licensed dentists will be allowed into the study on a first-come-first-served basis. Only one office per 100,000 population will be allowed to enter the study.

Background information and scientific rationale: Currently, cosmetic dentistry is primarily an art form without a pre-procedure evaluation protocol allowing patients, labs and doctors to communicate effectively. Therefore, cases are started and evaluated as they develop. This process often leads to unnecessary anxiety and indecision for dentists, laboratory partners and doctors.

This study is intended to demonstrate that the use of digital full-face cosmetic simulations plus The Template Technique Laboratory Protocol are an effective way of setting procedure goals, ensuring patient satisfaction right from the start and making the entire cosmetic process more predictable for both doctors and patients.

The procedures being evaluated have been under development at Smile-Vision beginning in 1987 with over ten thousand simulations and 3,000 physical cases competed. Results appear to have been outstanding, but the dental profession is slow to adopt the protocol. This study is an attempt to document results using digital cosmetic simulations and the Template Technique and have them gain wider acceptance within the dental community.

Hypothesis: Restorative dental cosmetic cases involving more than two teeth are executed with precision and confidence when using the Template Technique Protocol of digital cosmetic simulation followed by corresponding laboratory and clinical steps. This study will solicit feedback from both doctors and patients on 100 cases.

Method: Dentists will gain patient acceptance for restorative cosmetic procedures involving more than two teeth. They will submit a full-face image to Smile-Vision for digital cosmetic simulation. Once the proposed outcome (as depicted in the simulation is accepted by the patient) the dentist will proceed to follow the Template Technique Protocol to case conclusion.

{Include a description of, and justification for, the route of administration, dosage, dosing regimen, intervention periods, or behavioral intervention methods and selection of study population. Include a statement of the hypothesis.}

Potential Risks: Patient will not approve of the final result even though they approved it in the digital simulation format. There are no additional risks generated by this study other than those inherent in ANY restorative cosmetic process.

Potential Benefits:

1. Patients will exhibit confidence in the cosmetic process when they have an end result they have approved prior to starting treatment.

2. Doctors will spend less time in completing each case due to reduced carving in the mouth and patient compliance.

3. The interim provisional restorations give patient and doctor a second opportunity to make changes in the restorations, enhancing the opportunity for a predictable outcome and less time spent than with more conventional planning methods.

4. Patients will be pleased with the final result as they have had a hand in approving it.

Objectives: To determine if the effectiveness of restorative cosmetic procedures of more than two teeth planned and executed with the aid of digital cosmetic simulations and the Template Technique Protocol deliver satisfaction to patients and doctors.

The Study Outcome measures doctor and patient satisfaction with the results of restorative cosmetic procedures of more than two teeth planned and executed with the aid of digital cosmetic simulations and the Template Technique Protocol.

Study Design: Restorative cosmetic dental treatment for more than 6 teeth will be carried out in the offices of participating licensed dentists. Each doctor will deliver treatment using digital cosmetic simulations and the Template Technique Protocol with Smile-Vision providing the simulations and lab support for the Template Technique.

The study population will be determined by each dentist/participant in the study in order to get a random sample of patients for this initial study. Further studies may be implemented later to gain more specific demographic and patient selection information.

Dentist Participants may enroll in the study at any time. Hopefully, most or all will be enrolled within 12 months. Individual patient treatment should take no longer than three months. It may take as long as 36 months to gain all 100 cases deemed sufficient for data analysis and publication.

In this is a study there will be no control cases.

Participating doctors and patients will be required to complete a short questionnaire relating to satisfaction with the process. Results will be tabulated by Smile-Vision and made available to the dental public.

Study Enrollment and Withdrawal:

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

-Provide signed and dated informed consent form

-Comply with all study procedures and be available for the duration of the study
-Be in good general health

Subject Exclusion Criteria:

An individual who meets any of the following criteria will be excluded from participation in this study:
-Heavy smoker or drinker or substance abuser
-Severe gingival inflammation
-Severe dental or periodontal disease mandating extraction of more than 6 teeth
-Uncooperative or abusive behavior

Strategies for Recruitment and Retention:

The study will accept cases as they are accepted and paid for by patients.

Subject Withdrawal:

Doctors and/or patients may withdraw voluntarily from the study or the investigator may terminate a subject's participation at any time and without cause.

Screening Visit: Obtain and document consent from potential subject on screening consent form.

* Review medical/dental history to determine eligibility based on inclusion/exclusion criteria.

* Review medications history to determine eligibility based on inclusion/exclusion criteria.

* Perform medical/dental examinations needed to determine eligibility.

* Schedule study visits for individuals who are eligible and available for the duration of the study.

* Provide potential subjects with instructions needed to prepare for first study visit.

* Obtain and document consent from subject on study consent form.

* Verify inclusion/exclusion criteria.

* Obtain medical/dental history, medication history, alcohol, and tobacco use history.

* Record results of dental examination.

Final Study Visit: Participating doctor will request patient to complete post-op questionnaire at the first post-op visit.

Ethics/protection of human subjects: The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection

of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

Informed Consent Process: Patients will be provided with an Informed Consent Document. IA consent form describing in detail the study procedures and risks will be given to the subject. The subject is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the subject and answer any questions that may arise. The subject will sign the informed consent document prior to any study-related assessments or procedures. Subjects will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study.

The consent process will be documented in the clinical or research record. Subject confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the patient.

Data Handling and record keeping: The participating dentists are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The participating dentists will maintain adequate case histories of study subjects, including accurate case report forms (CRFs), and source documentation.

Data Management Responsibilities: Data collection and accurate documentation are the responsibility of the study staff under the supervision of Dr. Lawrence Brooks. All source documents and laboratory reports must be reviewed by the study team and data entry staff who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the investigator or designee.

Types of Data: Data will be maintained on-line on a HIPPA compliant web site.