REFRAME RPD Post-Market Clinical Study

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REFRAME RPD Post-Market Clinical Study

STRICTLY CONFIDENTIAL

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Sponsor:	Solvay Dental 360™
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Protocol Approval Page

REFRAME RPD Post-Market Clinical Study

This protocol has been read and approved by:

Study Sponsor:	Kristy Wynn, Director Quality and Compliance
Signature:	
Date:	

Statistician:	Anna Nordell
Signature:	
Date:	

Principal Investigator – Protocol Approval Page

REFRAME RPD Post-Market Clinical Study

I, the undersigned, have read and understood the Protocol specified above, and agree on the contents. The Protocol and the Clinical Investigation Agreement will serve as a basis for cooperation in the study.

Principal Investigator Name:	
Principal Investigator Title:	
Principal Investigator Address:	
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Principal Investigator E-mail Address:	
Principal Investigator Signature:	
Date of Signature:	

1. Summary

Primary Objective:	To evaluate the change in patient Oral Health-related Quality of Life (OHRQoL) from wearing a cobalt chrome (CoCr) removable partial denture (RPD) to wearing the Solvay Dental 360™ polymer Removable Partial Denture (RPD) for 8 weeks.
Secondary Objectives:	• To investigate the difference in health of the abutment teeth following the use of the polymer Removable Partial Denture (RPD) as compared to the Cobalt chrome (CoCr) Removable Partial Denture (RPD) as assessed by the plaque score and gingival bleeding index • To investigate the difference in whole plaque score following the use of the polymer Removable Partial Denture (RPD) as compared to the Cobalt Chrome (CoCr) Removable Partial Denture (RPD) • To investigate the health of the mucosal bearing areas of the polymer Removable Partial Denture (RPD) as compared to the Cobalt Chrome (CoCr) Removable Partial Denture (RPD) • To investigate framework hygiene (disclosing), probing depths, and abutment tooth mobility • To investigate the professional (operator) based outcomes for the fit, function, occlusion and aesthetics • To investigate the patient assessment of the comfort, aesthetics and chewing ability after the polymer Removable Partial Denture (RPD) and Cobalt Chrome (CoCr) Removable Partial Denture (RPD) • To determine the denture preference of each patient
Indication:	Partial edentulism with no active periodontal disease or caries
Investigational Design:	Cohort study conducted in the United States & United Kingdom to assess Oral Health Related Quality of Life (OHRQoL) in patients receiving the study polymer Removable Partial Denture (RPD) as compared to their baseline Cobalt Chrome (CoCr) Removable Partial Denture (RPD) Oral Health Quality of Life (OHRQoL). Subjects who are current wearers of a Cobalt Chrome (CoCr) Removable Partial Denture (RPD) will complete an Oral Health Related Quality of Life (OHRQoL) instrument, the Oral Health Impact Profile (OHIP) questionnaire, at baseline and again after wearing their prescribed polymer Removable Partial Denture (RPD) for 8 weeks

Inclusion/exclusion criteria:	Inclusion criteria: Adults from age 18 upwards: • With the absence of 4 or less teeth per saddle, excluding third molars • Partial denture in one arch only • With previous denture wearing experience, and Cobalt Chrome (CoCr) Removable Partial Denture (RPD) fitted in the previous 60 months and the patient is currently and routinely wearing the denture • With a stable oral health in terms of absence of disease activity affecting the periodontium, dental hard tissues (caries), pulp and the structural/aesthetic integrity of restored teeth • With at least 1 posterior natural tooth occlusal stop (molar or premolar) • Class I, Class II and Class III (Kennedy's Classification) • Occlusal spacing (static and dynamic) around clasp assembly including the occlusal rest Exclusion criteria: • Patients requiring extensive treatment prior to the provision of a removable partial denture (RPD) • Patients with active primary disease; caries, periodontal disease or symptoms of pulpal or apical pathology to the remaining teeth • Patients with irreversibly compromised structural/aesthetic integrity of restored teeth that cannot be restored as part of the provision of treatment. • Patients with an opposing Removable Partial Denture (RPD). Removable Partial Denture (RPD) to only be in one arch and must oppose a full denture or a dentate arch which provides a stable occlusal relationshipCanines are NOT to be replaced with the Removable Partial Denture's (RPDs). Patients must have their natural canines present
Number of Subjects:	40 subjects Maximum of 3 sites (US and UK)
Target Population:	Patients aged 18 Years and older
Follow-up:	Enrollment, standard of care prosthodontic visits for prescribing Removable Partial Dentures (RPDs), 3 study follow-up visits during 8 week polymer Removable Partial Denture (RPD) wearing period
Length of Investigation:	Up to 6 months

Primary Endpoint:	Change in Patient Oral Health Related Quality of Life (OHRQoL) after wearing the polymer Removable Partial Denture (RPD) and Cobalt Chrome (CoCr) Removable Partial Denture (RPD)
Secondary Outcome	• Comparison of the health of the abutment teeth during/following the use of the polymer Removable Partial Denture (RPD) as compared to Cobalt Chrome (CoCr) Removable Partial Denture (RPD) • Operator assessment of the adaptation of the polymer frame, adaption of the tissue base areas and their relationship to the frame adaptation, functional evaluation, aesthetic assessment and oral health assessment of abutment teeth and the periodontium • Patient-centered assessment of comfort, aesthetics and chewing ability before and after construction of the new denture by a 5 point Likert scale • Oral health parameters associated with the Removable Partial Denture (RPD) abutment teeth (probing depths and mobility) and Removable Partial Denture (RPD) mucosal bearing areas • Evaluation and photographic documentation of the Polymer Removable Partial Denture (RPD) for cracks, fractures, permanent deformation or other signs mechanical failure
Test Device/ Procedure:	Removable partial polymer prosthesis to replace missing teeth
Clinical Performance Assessments:	To investigate patient overall Oral Health Related Quality of Life (OHRQoL) with the polymer Removable Partial Denture (RPD) as compared to the Cobalt Chrome (CoCr) Removable Partial Denture (RPD).
Statistical Analysis:	A one-sample T-test will be used to assess the change in patient overall Oral Health Related Quality of Life (OHRQoL) using the Cobalt Chrome (CoCr) Removable Partial Denture (RPD) and Polymer Removable Partial Denture (RPD). A non-inferiority boundary will be used.

2. Background and Rationale

Partial edentulism is prevalent, especially in adults 65 and older. Periodontal disease is one of the major causes of loss of teeth, along with caries (cavities) and trauma. Tooth loss subsequently affects individual overall oral health and quality of life. Removable partial dentures (RPDs) are commonly made for people with few to several missing teeth as a cost-effective method for replacing teeth. In addition to being more affordable than fixed partials and dental implants, Removable Partial Dentures (RPDs) are a less invasive treatment and may be easier to maintain by the users. Removable partial dentures (RPDs) allow individuals to regain oral function and health and bilateral occlusal support (Wismeijer, 2011). Several factors affect satisfaction and quality of life of those with Removable Partial Dentures (RPDs), including aesthetics, comfort, phonetics, mastication and retention.

The framework of Removable Partial Dentures (RPDs) can be made out of different materials, including metal, acrylic and polymer, all comprised of different properties. A common framework material is cobalt chromium (CoCr), a rigid, nonprecious metal alloy. Other framework materials include titanium and non-metal materials such as medical grade arylketone polymer (AKP). Polymer Removable Partial Dentures (RPDs) provide an alternative to individuals with metal allergies or sensitivity. The plastic replacement teeth and gingival/alveolar complex sit on the framework. The removable partial denture (RPD) stabilises the remaining dentition and unites the entire arch.

Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) is utilised in the fabrication of the polymer Removable Partial Dentures (RPDs). The 3D software provides increased accuracy and faster turn-around time in providing removable dentures to patients.

Careful attention is paid to denture base fit and extensions, functional elements of speech and mastication, occlusion, and appearance/soft tissue support. Post-placement evaluation is done to assess patient comfort, function and aesthetics. Fitting adjustments are made as necessary.

When evaluating or comparing treatment options, variables such as survival rate and longevity of the prostheses, and frequency of complications have been regarded as the most important outcomes for clinicians; however, the social and psychological impacts of treatment, cost effectiveness, benefit, and utility are more important factors from the patient's perspective (Furuyama, 2011).

Patient's satisfaction or dissatisfaction with their partial dentures is an important part of the removable partial denture (RPD) treatment. Patients adapt to partial dentures individually, depending on their prior experience, expectations, emotional and general health status, as well as on the status of the oral cavity. For some patients, satisfaction with partial dentures relates primarily to comfort and ability to masticate, while aesthetics and retention are more important for others (Dubravka, 2000).

In addition, the condition, number, and alignment of the abutment teeth; the gingival, periodontal, and mucosal tissue health; the type of the construction and denture support; and the material and denture base shape are also common reasons for patient dissatisfaction. Other factors dependent on the patient may be the quality of the denture-supporting area and oral mucosa, influence of the surrounding muscles on the denture flanges, viscosity of saliva, patient's age and ability to get used to the denture, state of the abutments, condition of the other teeth in the mouth, relation between the horizontal and vertical dimensions of occlusion, hygiene habits, diet, presence of chronic diseases, position of the patient's teeth in the mouth, and quality of the removable appliance. (Reference: Treatment Outcomes with Removable Partial Dentures: A Comparison

Between Patient and Prosthodontist Assessments). Therefore, a thorough initial oral exam is a critical step in the preparation for the insertion of the Removable Partial Denture (RPD).

There is a need to assess the impact of polymer removable partial dentures (RPDs) on overall patient oral health and quality of life. Based on previous studies and literature, Removable Partial Denture (RPD) alternatives, such as polymer Removable Partial Dentures (RPDs), should be considered and assessed, with Oral Health Related Quality of Life (OHRQoL) validated instruments and patient satisfaction surveys.

2.1. Background

Background of Polymers and use in Denture Frames

The family of polymers known as arylketone polymers (AKP) are high performance polymers that have proven useful in a variety of demanding engineering applications, often as a lightweight alternative to metals. Because of their physical and chemical properties, Arylketone is considered a high-performance polymer with utility in fabrication via traditional melt processing and used successfully in the aerospace, chemical processing, and medical devices markets. Arylketone Polymers (AKP) also exhibit biocompatibility and have been used successfully in a variety of medical applications, including orthopaedic implants and instrumentation. The arylketone polymers have long been considered viable replacements for metals in medical applications as demonstrated by numerous global regulatory approvals. Arylketones offer weight reduction over metals for devices such as surgical retractors and orthopaedic implants. Polymers such as PEEK have been used extensively to replace cobalt chrome and titanium in orthopaedic implants to reduce the effects of stress shielding (Najeeb S., 2015). These polymers are also radio-lucent, thereby eliminating the possibility of imaging artifacts. Polymers may also offer significant cost savings and eliminate the risk of metal sensitivity.

Due to these combinations of properties, arylketones represent promising alternatives for metals in denture frames. Their customisation to patient needs, via either conventional melt processing or machining of fabricated forms, enables dentists and dental labs to optimally customise each frame to the patient with a material that has a safe history in medical devices. There are currently several polymeric products on the market in the United States and Europe which are thermoplastic materials used for the manufacture of full and partial removable dentures and implant overdentures. Many of these are formed into milling blanks which enable the dentist and dental labs to customise the design of the denture frame for each patient using standard CAD/CAM milling techniques.

They have also been tested and evaluated for biocompatibility and strength according to internationally recognised standards. These include ISO 7405:2008 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry and ISO 20795-1:2013 Dentistry – Base polymers – Part 1: Denture base polymers.

2.2. Risk/Benefit Analysis

Arylketone polymers provide an alternative to metal and acrylic denture frames that have previously been used in various medical device applications and have completed full biocompatibility testing.

There are no additional risks to the patient for participating in the study that he/she would not otherwise encounter with standard denture frame assessment and fitting. Standard procedures for

a removable partial denture includes an oral exam, impressions of the jaws, wax bite block, trial insertion of the framework and teeth, fitting and placement of the denture frame, followed by a final review visit.

The public will benefit from the study results that will help to refine the use of polymer removable partial dentures. This will help aid clinicians in the selection of materials to optimise their clinical outcomes of treatment. Data acquisition includes non-invasive collection methods before and after the fitting of the polymer denture frame. The goal of this study is to obtain data on patient centered outcomes on the Oral Health Related Quality of Life (OHRQoL) in patients wearing arylketone polymer (AKP) Removable Partial Dentures (RPDs). The results of this study will advance the design, fabrication and fitting of the polymer Removable Partial Denture (RPD) to further benefit the partially edentulous population. This will help aid clinicians in the selection of materials to optimise their clinical outcomes of treatment.

3. Objectives

3.1. Hypothesis

Patient Oral Health-related Quality of Life (OHRQoL) after wearing the Solvay Dental 360™ polymer Removable Partial Denture (RPD) is non-inferior to patient Oral Health-related Quality of Life (OHRQoL) after wearing a cobalt chrome (CoCr) Removable Partial Denture (RPD).

3.2. Primary Objective

To evaluate the change in patient Oral Health-related Quality of Life (OHRQoL) from wearing a cobalt chrome (CoCr) removable partial denture (RPD) to wearing the Solvay Dental 360™ polymer Removable Partial Denture (RPD) for 8 weeks.

3.3. Secondary Objectives

The secondary objectives are:

- To investigate the difference in health of the abutment teeth following the use of the polymer Removable Partial Denture (RPD) as compared to the Cobalt chrome (CoCr) Removable Partial Denture (RPD) as assessed by the plaque score and gingival bleeding index.

- To investigate the difference in whole plaque score following the use of the polymer Removable Partial Denture (RPD) as compared to the cobalt chrome (CoCr) Removable Partial Denture (RPD).

- To investigate the health of the mucosal bearing areas of the polymer Removable Partial Denture (RPD) as compared to the Cobalt Chrome (CoCr) Removable Partial Denture (RPD).

- To investigate the framework hygiene (disclosing), probing depths, and abutment tooth mobility.

- To investigate the professional (operator) based outcomes for the fit, function, occlusion and aesthetics.

- To investigate the patient assessment of the comfort, aesthetics and chewing ability after the polymer Removable Partial Denture (RPD) and Cobalt Chrome (CoCr) Removable Partial Denture (RPD).

- To determine the denture preference of each patient.

3.4. Primary Endpoint

Change in patient Oral Health Related Quality of Life (OHRQoL) after wearing the polymer Removable Partial Denture (RPD) and Cobalt Chrome (CoCr) Removable Partial Denture (RPD).

3.5. Secondary Endpoint

Secondary outcome measures will be included to detect health of the abutment teeth and plaque accumulation, using the whole plaque score and gingival bleeding index of abutment teeth.

- The comparison of the health of the abutment teeth during/following the use of the polymer Removable Partial Denture (RPD) as compared to the Cobalt Chrome (CoCr) Removable Partial Denture (RPD) as assessed by the arch plaque score and gingival bleeding index.
- Operator assessment of the adaptation of the polymer frame, adaption of the tissue base areas and their relationship to the frame adaptation, functional evaluation, aesthetic assessment and oral health assessment of abutment teeth and the periodontium.
- Oral Health parameters associated with the Removable Partial Denture (RPD) abutment teeth (probing depths and mobility) and Removable Partial Denture (RPD) mucosal bearing areas.
- Patient-centered assessment of the comfort, aesthetics and chewing ability before and after construction of the new denture by a 5 point Likert scale.
- Evaluation and photographic documentation of the Polymer Removable Partial Denture (RPD) for cracks, fractures, permanent deformation or other signs of mechanical failure.

4. Investigation Design

4.1. Study Summary

This non-significant risk post-market clinical study utilizes a prospective design to compare patient Oral Health Related Quality of Life (OHRQoL) wearing the arylketone polymer (AKP) Removable Partial Denture (RPD) to their baseline Oral Health Related Quality of Life (OHRQoL) while wearing a Cobalt Chrome (CoCr) Removable Partial Denture (RPD). The study is intended to simulate actual fitting and use to allow the gathering and analysis of data on the comparative oral health related quality of life (OHRQoL) of the arylketone polymer (AKP) and cobalt chrome (CoCr) denture frames.

4.2. Number of Patients and Investigation Sites

A minimum of 40 patients will be enrolled at a maximum of 3 sites in the United States and United Kingdom. It is expected that each site will enroll a minimum of 10 patients.

5. Investigational Device

The Ultaire™ arylketone polymer (AKP) prosthesis are milled from the Dentivera™ Milling Discs using available dental Computer Aided Design / Computer Aided Manufacturing (CAD/CAM) systems. The Dentivera™ Milling Disc is a thermoplastic denture base resin designed for the manufacture of full and partial removable dentures and implant overdentures.

Image 1: Ultaire™ AKP Removable Partial Denture in model

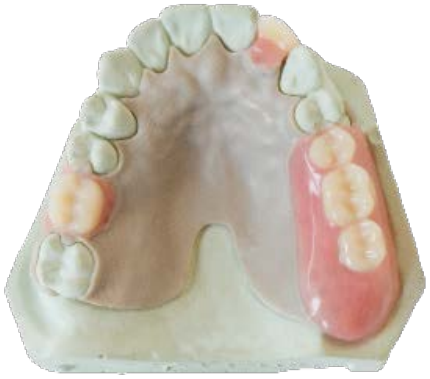
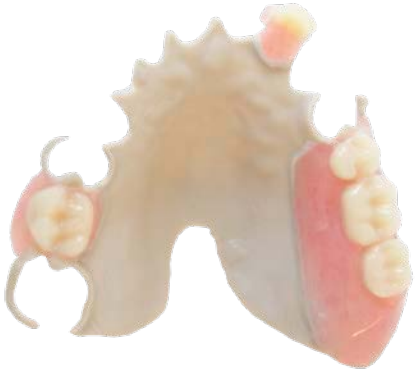


Image 2: Ultaire™ AKP Removable Partial Denture



5.1. Manufacturer Information

The intended use of the arylketone polymer (AKP) denture frames are supported by the device master filing submitted to the FDA in July 2015. Solvay Dental 360™ received FDA clearance for this denture relining, repairing, and rebasing resin as defined under 21 CFR 872.3760, on June 15, 2016.

The Dentivera™ Milling Disc resin testing showed that the material is in accordance with the *ISO 20795-1: Dentistry - Base polymers Part 1: Denture base polymers* standard relating to mechanical properties of denture base materials.

Biocompatibility testing has been completed on the Dentivera™ Milling Disc resin in accordance with ISO 10993-1:2009 (Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process). The following biocompatibility tests were performed: cytotoxicity, sensitisation, irritation, systemic toxicity, subchronic toxicity, implantation, genotoxicity, pyrogenicity, mutagenicity, and physical-chemical testing.

The device milling facility for this clinical trial is ISO 13485 certified, fully audited and qualified by the study Sponsor.

5.2. Packaging and Labelling

All denture frames utilised for this study will be labelled with a unique identifier (reference number). The reference number will be recorded in clinical records (source data) and Electronic Data Capture System (EDC)/Case Report Form (eCRF).

The arylketone polymer (AKP) denture frames will be shipped in commercially available packages. All study products must be kept in a secure place under appropriate storage conditions, away from sunlight, as per the instructions for use.

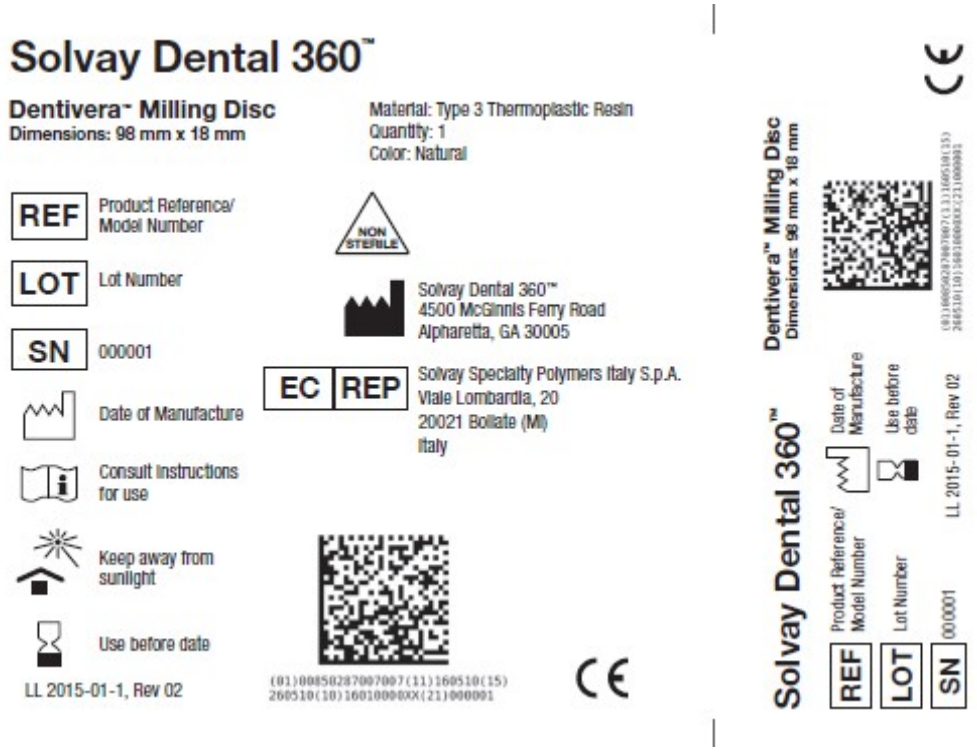


Figure 1: Dentivera Milling Disc Single Pack Shelf Box Label

5.3. Device Accountability

Each denture frame has a unique identifier (reference number) that will be recorded on the study device accountability log. All devices received and shipped must be recorded on this log and kept current in the Electronic Data Capture system (EDC/eCRF) and the Investigator Site File (ISF).

5.4. Device Training/Experience

The fitting and adjustments, completed by the dentist (investigator), of removable partial dentures (RPD) are standard of care.

The design of each arylketone polymer (AKP) denture frame will be agreed jointly by the clinician (the PI or delegated clinician at each site) and the milling facility prior to production. The approval will be recorded by the clinicians' signature on the Case Report Form (eCRF) prior to production.

6. Cohort Study Subject Selection

All subjects who fulfil the inclusion criteria will be invited to participate by signing a study informed consent. Subjects will only be considered enrolled once they sign the study consent form provided.

6.1. Inclusion Criteria

- Adults from age 18 upwards:
- With the absence of 4 or less teeth per saddle, excluding third molars
- Partial denture in one arch only
- With previous denture wearing experience, and Cobalt Chrome (CoCr) Removable Partial Denture (RPD) fitted in the previous 60 months and the patient is currently and routinely wearing the denture
- With a stable oral health in terms of absence of disease activity affecting the periodontium, dental hard tissues (caries), pulp and the structural/aesthetic integrity of restored teeth
- With at least 1 posterior natural tooth occlusal stop (molar or premolar)
- Class I, Class II and Class III (Kennedy's Classification)
- Occlusal spacing (static and dynamic) available around clasp assembly including the occlusal rest

6.2. Exclusion Criteria

- Patients requiring extensive treatment prior to the provision of a removable partial denture (RPD)
- Patients with active primary disease; caries, periodontal disease or symptoms of pulpal or apical pathology to the remaining teeth
- Patients with irreversibly compromised structural/aesthetic integrity of restored teeth that cannot be restored as part of the provision of treatment
- Patients with an opposing Removable Partial Denture (RPD). Removable Partial Denture (RPD) to only be in one arch and must oppose a full denture or a dentate arch which provides a stable occlusal relationship

6.3. Subject Withdrawal and Discontinuation

During the course of the study Subjects will be or may elect to withdraw from further treatment and assessments through any of the following reasons:

- Subject's rescission of consent
- Any unexpected adverse device effect which is, in the opinion of the Principal Investigator, related to the device and will endanger the wellbeing of the subject if treatment is continued
- The development of any undercurrent illness(es), infection or condition(s) that might interfere with the protocol
- Any problem deemed by the Principal Investigator and/or *Solvay Dental 360*™ to be sufficient to cause discontinuation
- Subject Lost to Follow-Up

All subjects who discontinue due to an unexpected adverse device effect, directly related to the study, will be treated until the effect resolves. The Principal Investigator will clearly document the date and reason(s) for subject withdrawal in his/her Case Report Form (eCRF) and the monitor must be notified.

A subject will be classified as lost to follow up only if, he/she has failed to return to the required study visits and his/her dental status remains unknown, despite 3 documented attempts to contact the subject via telephone, fax, email, and/or certified letter.

6.4. Procedures for handling incorrect enrolled subjects

Subjects not meeting the inclusion/exclusion criteria for a study should not be enrolled into the study. If a subject is enrolled who does not meet inclusion/exclusion criteria, a protocol deviation will be completed and this will be noted in the final report.

7. Investigation Procedures

7.1. Screening Evaluations

7.1.1. Informed Consent

After a normal clinical assessment, the Principal Investigator (PI) may approach patients whom he feels may be suitable for entry into this study. The Principal Investigator (PI) should introduce the patient to the study by explaining the Protocol, procedures and objectives to the patient. The Principal Investigator (PI) will then provide an information sheet describing the study, potential discomforts, risks and benefits of participation. The patient will have sufficient time to decide whether they wish to participate in this study.

Any queries that patients may have regarding the study will be addressed appropriately by the Principal Investigator (PI), or another member of the study team at the center. Subjects will be instructed that they are free to obtain further information from the Principal Investigator (PI) at any time, that they are free to withdraw their consent and to discontinue their participation in the study at any time without prejudice.

If the patient is willing to participate in the study, he/she must read, understand and sign the informed consent form. The Principal Investigator (PI) will also sign this at the same occasion. Three copies of the consent form will be made. The original copy of the signed consent form will be kept in the Investigation Site File (ISF). A copy will be kept in the subject's medical notes and a further copy will be provided to the subject.

Written informed consent from the subject must be obtained before any study related procedures are performed.

Prior to evaluation of the study device, the following activities must be recorded as part of the subjects' records:

- Meeting all general inclusion/exclusion criteria
- Signing the Informed Consent Form
- Collecting demographic information

7.1.2. Subject Eligibility

Once written informed consent has been obtained, the Case Report Form (eCRF) will be completed to document adherence to the inclusion and exclusion criteria.

Where a patient fails to fulfil any element of the inclusion and exclusion criteria, this will be documented and the signed consent form and completed inclusion/exclusion criteria retained by the Principal Investigator. The patient will not be advanced any further into this study.

7.1.3. Subject Identification

When a subject is considered eligible for entry into this study, the subject will be allocated the next available investigation number (subject ID number), as assigned within the EDC (Electronic Data Capture) system, in order in which the subjects are entered.

For subjects enrolled, this number will consist of 01 for the first subject, 02 for the second subject and so on. This number will be the unique identifier of the subject and written on each page of the Case Report Forms (CRF) in the EDC system and all other documentation relating to that subject.

Once identified and approached a patient will be asked for consent as per section 7.1.1.

7.2. Pre-Treatment Evaluations

VISIT 1:

- Patient eligibility screening (Registration). Informed consent to be sought.
- Patient Initial exam
- Inter-occlusal space confirmation (static and dynamic) of clearance both for opposing edentulous area and rest area
- Initial impressions of opposing arch (alginate), and treatment arch with and without the existing Removable Partial Denture (RPD) in place
- Initial alginate impressions poured in diestone

Lab Stage1, Post-Clinical Exam:

- Survey & design, confirm contours are adequate for material
- Inter-occlusal space confirmation (static and dynamic) for clearance of both the opposing edentulous area and rest/clasp assembly area
- Custom tray fabrication (2mm spacer thickness) with extensions to adequately capture the edentulous areas

The first visit includes a standard oral examination. During this visit, impressions will be taken of the subject's mouth.

7.3. Treatment Evaluations

VISIT 2: Patient Identification number assigned.

Dentist and/or dental technician performs / records the following:

- Plaque scores
- An individual custom impression tray will be constructed by the clinician for each patient (to design of the Principal Investigator at each research site)
- Polyvinylsiloxane impressions will be completed
- Polyvinylsiloxane (PVS) impression poured in Diestone
- Framework hygiene disclose (of original appliance (Photograph)
- Bleeding on Probing (BOP) of abutment and adjacent teeth (limited perio exam; 6 point assessment)
- Pocket depths
- Mobility of the abutment teeth
- Health of Mucosal Bearing area
- Classification of occlusion: static and function
- Aesthetics (operator assessed)
- Photographs with and without appliance frontal, RL lateral & occlusal

Patient assessments:

- Assessment of satisfaction of current Removable Partial Denture (RPD) prostheses including: aesthetics, function, speech, eating, general comfort and complaints
    - clinician to confirm assessment
- Oral Health Impact Profile (OHIP) questionnaire completion

LAB Stage 2:

- Design on initial alginate cast (working cast not to be modified): teleconference confirmation / discussion between milling center, Dental technician, treating Dentist and Sponsor representative. To include clasp assembly design, location, bulk, undercuts, as well as major connector and other Removable Partial Denture (RPD) aspects
    - If consensus is not reached, treating Dentist will make final determination.
- Transfer of cast to milling center
- Milling Center scan
- Mill RPD
- Add occlusal wax rim on the Removable Partial Denture (RPD) frame edentulous area to accurately demonstrate tooth position and allow occlusal registration. Wax must be out of occlusion by 2mm space
- Verification of framework returned to treating Dentist

At the patients second visit a working impression will be constructed using the custom impression tray and an elastomeric impression material (polyvinyl siloxane or polyether).

VISIT 3

Dentist and/or dental technician performs / records the following:

- Tooth shade and mould selection
- Photographic verification of Removable Partial Denture (RPD) polymer frame fit: frontal, RL lateral, & occlusal
    - Only minimal adjustments permitted. If adjusted - record via photograph after adjustment
- Assess framework only on cast and in mouth for adaption and adequacy. Confirmation of occlusion with the polymer frame in place
- Confirm wax rim clinically including confirmation that there is 2mm of occlusion before proceeding with occlusal registration
- Jaw registration utilizing Polyvinylsiloxane (PVS) registration material. Confirmation by clinician that there is no occlusal contact or deformation of the polymer frame during this procedure
- Balance occlusion to be established if opposing a denture
- Ensure occlusal consistent with presenting condition and shape

LAB Stage 3:

- Articulate the casts on an articulator as indicated by the clinical center.
- Lab completes tooth set up in ideal occlusion, ensuring occlusion is consistent with the patient's presenting condition and CoCr RPD. Balanced occlusion to be established if opposing denture
- Photographs on cast

VISIT 4

- Patient wax tooth set-up and frame try-in
    - Clinician Assessment: evaluate occlusion, aesthetics, adaptation

LAB Stage 4

- Dental technical processes to finish

VISIT 5

Dentist performs and records the following:

- Assess fit
- Health of Mucosal Bearing area
- Mobility of the abutment teeth
- Classification of occlusal: static and function
- Aesthetics (operator assessed)
- Photograph of prosthesis in situ, ensuring fit of appliance
- Photographs with and without appliance frontal, RL lateral & occlusal
- Dentist delivers the Polymer Removable Partial Denture (RPD)

Patient assesses their current Cobalt Chrome dentures for the following, via the 5 point Likert scale:

- Comfort
- Aesthetics
- Chewing ability

The patient's original CoCr RPD will be taken and securely stored at the dentist's office for the 8 week test period. It may be tried in at the 1 week, 4 week and 8 week recall appointments to ensure they are still fitting and to assess any changes in tooth position and adaptation.

VISIT 6: Recall 1 week

- Patient assessment of satisfaction of polymer appliance aesthetics, function, speech, eating, general comfort and complaint wearer – self reported and clinician confirmation

Dentist performs and records the following:

- Health of Mucosal Bearing area
- Abutment tooth mobility
- Classification of occlusal: static and function
- Aesthetics (operator assessed)
- Photographs with and without appliance frontal, RL lateral & occlusal
- Evaluation and photographic documentation of the Polymer Removable Partial Denture (RPD) for cracks, fractures, permanent deformation or other signs of mechanical failure
- Try-in of original CoCr RPD to assess fit and any changes in tooth position and adaptation

VISIT 7: Recall 4 week

- Patient assessment of satisfaction of polymer appliance aesthetics, function, speech, eating, general comfort and complaint wearer – self reported and clinician confirmation

Dentist performs and records the following:

- Health of Mucosal Bearing area
- Abutment tooth mobility
- Classification of occlusal: static and function
- Aesthetics (operator assessed)
- Photographs with and without appliance frontal, RL lateral & occlusal
- Evaluation and photographic documentation of the Polymer Removable Partial Denture (RPD) for cracks, fractures, permanent deformation or other signs of mechanical failure
- Try-in of original CoCr RPD to assess fit and any changes in tooth position and adaptation

VISIT 8: Recall 8 week

Patient assesses the polymer denture for the following, via the 5 point Likert scale:

- Comfort
- Aesthetics
- Chewing ability
- Oral Health Impact Profile (OHIP) questionnaire completion

Dentist performs and records the following:

- Plaque scores
- Framework hygiene disclose
- Bleeding on Probing (BOP)
- Pocket depths
- Abutment tooth mobility
- Health of Mucosal Bearing area
- Classification of occlusal: static and function
- Aesthetics (operator assessed)
- Evaluation and photographic documentation of the Polymer Removable Partial Denture (RPD) for cracks, fractures, permanent deformation or other signs of mechanical failure
- Photographs with and w/o appliance frontal, RL lateral, occlusal
- Try-in of original CoCr RPD to assess fit and any changes in tooth position and adaptation
- Patient's original CoCr RPD is returned to the patient

8. Adverse Events and Device Observations

8.1. Adverse Event (AE)

An adverse event (AE) is defined according to the European Standard EN ISO 14155: as 'any untoward medical occurrence in a subject. An adverse event related to a device is defined as an 'adverse device effect' (ADE) and is defined as 'any untoward and unintended response to an investigational medical device'.

An adverse event or an adverse device effect may be mild, moderate or severe and are usually unexpected.

A device deficiency is defined as the inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance, which may include device malfunctions, user errors and inadequate labelling.

All adverse events, adverse device effects and or device deficiencies either observed by the Principal Investigator or reported by the subject, must be reported to the Sponsor within 24 hours.

To report an adverse event or adverse device effect or device deficiency, the Principal Investigator will complete an adverse event report form or relevant form located in the Case Report Form. The report will include the following information: device name, model number, lot/serial number, manufacturers date, expiry date, nature of event, severity, date of onset, duration, course and history of the adverse event/adverse device effect and causality. The subject will be questioned about any adverse event(s) and adverse device effect(s) at each visit.

8.1.1. Expected adverse events are as follows

There are no expected Adverse Events for this study.

8.2. Reporting of Serious Adverse Events (SAE)/Serous Adverse Device Effects (SADE), Unanticipated Adverse Device Defects (UADE) and Device Deficiencies

A serious adverse event is defined an adverse event that:

- led to death
- led to a serious deterioration in the health of the subject that either resulted in: a life-threatening illness or injury, or a permanent impairment of a body structure or a body function, or in-patient hospitalization or prolongation of existing hospitalization, or in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- led to foetal distress, foetal death or a congenital abnormality or birth defect

Hospitalization is defined as greater than 24 hours in hospital.

A serious adverse device effect is defined as an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune.

An unanticipated serious adverse device effect (USADE) is defined as a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

All serious adverse events, serious adverse device effects and/or device deficiencies that may have led to a USADE must be reported to the Sponsor or Sponsor Representative by telephone within 24 hours of the Principal Investigator becoming aware of it.

The Sponsor Representative can be contacted at the following numbers:

Contact Name: Anna Bader

Telephone Number: 612-237-6465

Email: abader@namsa.com

The Principal Investigator should institute appropriate therapeutic and follow-up measures in accordance with good medical practice but should notify the monitor of such actions and record them in the subject's electronic Case Report Form. Each telephone reported reaction must be reported in writing to *Solvay Dental 360™* within 2 working days of the event.

It is also the responsibility of the Principal Investigator to inform the representative of the Institutional Review Board (IRB) in a timely manner.

8.3. Follow-up of Unresolved Events

All serious adverse events, serious adverse device effects and/or unexpected adverse device effects will be followed until they are resolved or for 30 days after the subject's participation in the study ends.

8.3.1. Anticipated clinical benefits

The public will benefit from the study results which will help to refine the use of arylketone polymer (AKP) removable partial dentures (RPDs). This will help aid clinicians in the selection of materials to optimize their clinical outcomes of treatment.

8.3.2. Risks associated with participation in the study

Tooth movement may occur from the 1 week to 8 week recall visit that may result in the patient's original CoCr RPD not fitting as it used to. If this occurs a new metal RPD may have to be fabricated for the patient after the study has been completed.

There are no additional risks to the patient for participating in the study which he/she would not otherwise encounter with standard removable partial denture (RPD) assessments and fitting

9. Data Collection

9.1. Retention of documentation

The Principal Investigator (PI) will retain all copies of the records relating to the study for a minimum period of 5 years from the completion or discontinuation of the study. In all cases, the Principal Investigator (PI) must contact the Study Sponsor prior to disposing of any records related to the study. Included in records to be maintained are signed Protocol, copies of the Case Report Forms, signed consent forms, IRB approval letters, correspondence concerning the clinical study and any other documents to identify the subjects.

In addition, if the Principal Investigator (PI) moves/retires, etc., they should provide Solvay Dental 360™ with the name and address of the person who will look after and be responsible for the study related records.

9.2. Site Qualification / Selection

Principal Investigator's (PI) and investigation sites will be selected by the Sponsor or Sponsor's representative through the Principal Investigator and site qualification process. All selected Investigators will be responsible for complying with all study-related and regulatory requirements and will be ultimately responsible for overseeing the conduct of the study at their respective investigation sites, per the Investigation Agreement.

Selected Principal Investigators (PIs) will have the required training and expertise to conduct the study. The investigation sites where assessments are to be performed must have the adequate volume of the target subject population, experienced staff, as well as the appropriate facilities and equipment to meet the requirements of the study protocol and the expected enrollment time frames.

All Principal Investigators (PIs) and research staff must be willing to undergo all study related training and participate and assist with monitoring initiated by the Sponsor or Sponsor's representative.

10. Termination of the Study

10.1. Subject Withdrawals and Discontinuation

During the course of this study, subjects will be or may elect to withdraw from further treatment through any of the following reasons:

- Subject's rescission of consent.
- Any unexpected adverse device effect which is, in the opinion of the Principal Investigator, related to the device and will endanger the well-being of the subject if the treatment is continued.
- The development of any undercurrent illness(es), infection or condition(s) that might interfere with the Protocol.
- Any problem deemed by the Principal Investigator (PI) and/or Solvay Dental 360™ to be sufficient to cause discontinuation.

All subjects discontinued from the study due to an unexpected adverse device effect, directly related to the study, will be treated until the effect resolves. The Principal Investigator (PI) will clearly document the date and reason(s) for subject withdrawal in his/her Case Report Form and the monitor must be notified.

Subjects who are withdrawn will not be replaced if they have received the investigational device. If possible, any procedures or assessments planned for the subject on withdrawal from the study should be performed when intention to withdraw the subject is announced.

Subjects who are withdrawn prior to receiving investigation device will be replaced.

10.2. Early Termination of the Clinical Investigation

Both the Sponsor and the Principal investigator (PI) reserve the right to terminate the clinical investigation at any time. Should this be necessary, the procedures will be arranged on an individual basis after review and consultation by both parties. In terminating the clinical investigation Solvay Dental 360™ and the Principal investigator (PI) will assure that adequate consideration is given to the protection of the subject's interests.

11. Data Management

Electronic case report forms (eCRF) via a web-based Electronic Data Capture (EDC) system will be utilised for the study. The eCRF will be completed for each included patient. The completed eCRFs will not be made available in any form to third parties without written permission from Data Management. The data will be reviewed by Data Management, monitor or designee and queries will be issued. The study site personnel are required to resolve any such queries. At the end of the study, Data Management will perform final validation checks, including central consistency checks, after which Clean File will be declared and the database locked.

12. Statistics

This section provides a summary of the planned statistical analyses.

12.1. Description of Statistical Methods

12.1.1. General Statistical Considerations

The primary endpoint will be the difference in the overall score from the Oral Health Impact Profile (OHIP-14) questionnaire between baseline (assessing the metal RPD) and follow-up (assessing the polymer RPD). This overall score for each frame is calculated by a summation of the score from each of the 14 questions; each having the following scoring:

Response	Score
Never	0 Points
Hardly Ever	1 Point
Occasionally	2 Points
Fairly Often	3 Points
Very Often	4 Points

Thus the range of possible scores for the overall score is 0 to 56.

The overall score from the questionnaire provided at baseline to assess the cobalt chrome frame will be subtracted from the overall score obtained at 8 weeks follow-up when assessing the polymer frame. This difference that is calculated, along with other continuous variables will be summarized using the mean, median, standard deviation, and inter-quartile range. A one-sample t-test will be used to test the difference in the overall scores against a performance goal.

Change from baseline will be calculated by subtracting the overall score of the cobalt chrome frame from the overall score of the polymer frame. The mean change will be used to assess the hypothesis. A one sample t-test against a performance goal will be conducted with the following hypothesis:

$H0: OS_{diff} > \Delta$

$Ha: OS_{diff} \leq \Delta;$

Where OS_{diff} is the overall score for the cobalt chrome frame subtracted from the overall score for the polymer frame, and Δ is the performance goal. The performance goal is 1.5.

12.1.2. Study Cohorts for Analyses

Because this is a prospective observational study, all subjects with available questionnaire data at both baseline and follow-up will be included in the study cohort for analysis.

12.1.3. Primary Outcome

The primary endpoint will be the difference in the overall score from the Oral Health related Quality of Life questionnaire between baseline and follow-up. This score is calculated by a summation of the score from each question; each having the following scoring:

Response	Score
Never	0 Points
Hardly Ever	1 Point
Occasionally	2 Points
Fairly Often	3 Points
Very Often	4 Points

A non-inferiority test will be conducted with the following hypothesis:

H0: $OS_{diff} > \Delta$
Ha: $OS_{diff} \leq \Delta$;

Where OS_{diff} is the overall score for the cobalt chrome frame subtracted from the overall score for the polymer frame, and Δ is the performance goal. The performance goal is 1.5.

12.1.4. Secondary Outcomes

Plaque score and gingival bleeding index are considered secondary endpoints and will be summarised at both baseline and follow-up. In addition, framework hygiene (disclosing), BOP, probing depths, abutment teeth mobility and health of the RPD mucosal bearing areas, as well as professional (operator) based outcomes of the function, occlusion and aesthetics are important outcomes. Additionally, the denture preference will be summarised and considered a secondary endpoint for the study as well.

12.1.5. Poolability Analyses

Poolability analyses will be performed on the primary endpoint to assess whether results are poolable across the participating centers.

A linear regression model with change in the summary score of the Oral Health related Quality of Life Questionnaire as the dependent variable will be reported using a categorical variable for site. If there is evidence that the data is not poolable across centers, examination of the data will be performed to determine the underlying cause(s).

12.1.6. Missing Data

It is anticipated that missing data will be very minimal. Every effort will be made to collect complete data from all patients. In the event of missing data, the extent and types of missing data will be assessed and reported.

12.2. Sample Size Determination

In a previous study (S. Shaghaghian, 2014), the average overall score on the OHIP questionnaire for subjects wearing a cobalt chrome denture was 13.8 (standard deviation = 10.1). Based on the anticipated improved performance of the polymer frame, 36 subjects with an alpha level of 0.05 provides approximately 80% power to detect a difference of -3 (standard deviation = 11) between the 2 overall scores with a non-inferiority margin of 1.5. The total number of subjects enrolled will be 40, given the anticipated attrition rate of 10%.

12.3. Additional Analyses

Additional study analyses are possible and may be performed.

13. Reports and Publications

13.1. Interim Report

An interim report will not be issued during the conduct of this study

13.2. Final Report

The final report will be compiled by Solvay Dental 360™ or Sponsor Representative and reviewed, approved and signed off by the Principal Investigator. The Principal Investigator shall submit a final report to the IRB as per local policy and procedures.

13.3. Publications

Details of publications will be addressed in each Clinical Investigation Agreement.

14. Ethical Considerations

14.1. Institutional Review Board Approval

Prior to the initiation of this study, the Principal Investigator must submit the Protocol, patient information sheet, patient consent form and any other documents as may be required to the appropriate IRB for review and approval. The Principal Investigator, and any other member of the investigative team, if a member of the IRB, must not participate in the decision-making. A signed and dated letter granting approval must be provided to Solvay Dental 360™ prior to the initiation of the study. A list of the members of the IRB reviewing this Protocol will be requested.

14.2. Informed Consent and Patient Information

The Principal Investigator must explain to each patient the nature of the study, including any risks and benefits, its purpose and procedures, and expected duration of involvement in the study. Each patient must be informed that participation in the study is voluntary and non-participation will not affect his/her right to the most appropriate treatment or affect the doctor/clinician-patient

relationship. Patients have full rights to withdraw from the study at any time, irrespective of their initial consent.

Each subject must also give their permission for representatives of the Sponsor, auditor and regulatory authorities to review their hospital records for the purposes of source data verification.

The principal investigator(s) at each center will ensure that the subject is given full and adequate oral and written information about the nature, purpose, possible risk and benefit of the study. Informed consent process will be conducted in accordance with Code of Federal Regulations Title 21. Subjects must also be notified that they are free to discontinue from the study at any time. The subject should be given the opportunity to ask questions and allowed time to consider the information provided.
The subject's signed and dated informed consent must be obtained before conducting any procedure specifically for the study. The principal investigator(s) must store the original, signed Informed Consent Form in the subject's medical record. A copy of the signed Informed Consent Form must be given to the subject.

14.3. Subject Confidentiality

Subject Confidentiality will be maintained throughout the study, in a way that ensures the information can always be tracked back to the source data. For this purpose a unique identification code (ID number and patient name code) will be used that allows identification of all data reported for each patient. Subject anonymity will be guaranteed and all documentation relating to a subject will be kept in a secure location.

14.4. Declaration of Helsinki

This study will be conducted in accordance with the relevant articles of the Declaration of Helsinki as adopted by the 18th World Medical Assembly in 1964 and as revised in Tokyo (1975), Venice (1983), Hong Kong (1989), South Africa (1996) and Edinburgh (2000) Washington (2002), Tokyo (2004) and Seoul (2008).

14.5. Insurance

All research subjects enrolled in this study are covered by general liability insurance.

15. Regulatory Requirements

This is a post-marketing surveillance study with a FDA clearance and CE marked device approved for this indication, hence, this study does not require submission to the Regulatory Authority.

16. Good Clinical Practice Compliance

This study will be conducted in accordance with the principles of the European Standard EN ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice.

16.1. Study Personnel and Responsibilities

Before a subject's enrollment in the study and any study-related procedures are undertaken the following should be fulfilled:

- Signed Clinical Study Protocol and other agreements
- Approval of the study, investigator and Informed Consent by the IRB
- Collection of study required documents
- Formal written approval by NAMSA

16.2. Monitoring

Before first subject is recruited into the study, a representative from the Sponsor or Sponsor's representative will visit the clinical study site to:

- Determine the adequacy of the facilities
- Discuss with the investigator(s) (and other personnel involved with the study) their responsibilities with regard to protocol adherence, and the responsibilities of the Sponsor or Sponsor's designee.

  The monitor (Sponsor or designee) will be responsible for securing the compliance of the Principal Investigators to the signed agreement, the study Protocol and all applicable national regulations, guidelines and standards in the country where the study is being conducted.

During the study, the monitor will have regular contact with the study site, including regular monitoring visits to:

- Provide information and support to the investigator(s)
- Confirm that facilities remain acceptable
- Confirm the study team is adhering to the protocol and that data are being accurately recorded in the eCRFs
- Perform source data verification (a comparison of the data in the eCRFs with the subject's medical records at the hospital or practice, and other records relevant to the study). This will require direct access to all original records for each subject (e.g., clinic charts)

The Principal Investigator will allow the study monitor to inspect all electronic Case Report Forms and the subject's clinic records and/or original hospital medical records at these visits. These visits are for the purpose of verifying adherence to the Protocol and the completeness and accuracy of the data being entered on the electronic Case Report Forms.

The planned extent of study monitoring and source data verification (SDV) is detailed in the monitoring plan.

A Principal Investigator found not be in compliance will receive telephone and/or written notification of the deficiency, which will include a request that deviation be corrected immediately.

16.3. Auditing

During the running of the study, Solvay Dental 360™ may appoint Quality Assurance (QA) personnel to provide audit of the administration and conduct of the study, both at the investigation site and at Solvay Dental 360™.

The relevant Regulatory Authority also has the right to conduct an audit of the study, that the study was, in fact, performed at stated investigation sites and that the data reported to the authority in support of a marketing application accurately reflects the data in the records of the Principal Investigator. The authority also inspects such studies to verify that the studies were conducted in accordance with Government regulations relating to the IRB and informed consent. It is the joint responsibility of the Sponsor and the Principal Investigator to ensure that the study has been conducted in line with all government regulations.

In the event that the regulatory authority desires to inspect this study, the Principal Investigator will permit authorized inspectors to inspect all facilities and records relating to the study and aid the Inspector to perform the audit in a timely fashion.

16.4. Modifications to protocol

Except in emergency situations, prior approval by the Sponsor is required for changes in or deviations from this Protocol. This provision does not apply to those changes made to reduce discomfort or overt risks to the subject. In the event of an emergency situation, the Principal Investigator must institute any and all medical procedures he/she deems to be medically sound. All such events and procedures must be documented in the subjects electronic Case Report Form and reported to the sponsor or designee within 3 days.

16.5. Procedure for reporting any protocol deviations

The investigator should avoid deviating from the protocol. All deviations related to the study inclusion or exclusion criteria, conduct of the investigation, patient management, or patient assessment are to be documented on the eCRF provided for that purpose. Notification to the IRB should be documented and maintained in the clinical investigator file (as required).

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