

Plan Overview

A Data Management Plan created using DMPTool

Title: Study and analysis of the behavior of hydrogel based on chitosan and xanthan: alternative treatments for peri-implantitis in different applications

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Project abstract:

The rehabilitation success of osseointegrated implants is already established, however, bacterial contamination can occur during the surgical procedure and, in patients who already have a prosthesis, if there is no periodicity of plaque control, inflammation in the adjacent tissues can lead to severe conditions of peri-implantitis. The present in vitro study (phases 1 and 2) aims to develop forms of hydrogel based on chitosan and xanthan and to evaluate their antimicrobial behavior and possible mechanical interference at the implant/abutment interface. In phase 1 the specimens will be developed in 4 different ways: (AR) Chitosan and xanthan hydrogel (washer format); (ARP) Chitosan and xanthan hydrogel + polycaprolactone (PCL) nanofibers (washer format); (FLU) Chitosan and xanthan hydrogel (fluid gel); (FLUP) Chitosan and xanthan hydrogel + PCL nanofibers (fluid gel) and morphological analysis in Scanning Electron Microscopy (SEM) and swelling analysis will occur. In phase 2, the antimicrobial activities will be evaluated by means of tests of Minimum Inhibitory Concentration (MIC), Minimum Bactericidal Concentration (CBM) and from the bacterial infiltrate at the implant/abutment interface, 40 implant sets will be

used where and HE abutment divided into 4 groups (n = 10) according to the treatment: (AR) chitosan and xanthan hydrogel; (ARP) chitosan and xanthan hydrogel + PCL nanofibers; (CN) negative control (without treatment); (CP) positive control (2% chlorhexidine digluconate solution). The sets will be covered by the reverse bacterial infiltration technique, where a suspension of standardized microorganisms will be inoculated inside the implants, and then the respective pillars (TiBase®, Connection Prosthesis Systems) will be installed with a torque of 30N according to the manufacturer. The sets tested for immediate external contamination, by turbidity of the culture medium. After incubation in aerobiosis at 37oC, for 120 hours the pillars will be unscrewed and the internal content of the implants collected with the aid of a sterile paper cone and sown in agar to determine the number of viable cells. The data will be provided statistically and the group with the best results will be applied in phase 3 of the in vivo study, to determine application protocols.

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Study and analysis of the behavior of hydrogel based on chitosan and xanthan: alternative treatments for peri-implantitis in different applications

Data Collection

What data will you collect or create?

The data will be collected and created through in vitro laboratory analysis. The analyses quantitative data will produce numerical data that will be arranged in electronic spreadsheets and qualitative analyzes will produce textual and image data. The volume of data will occupy a maximum of 15 GB.

How will the data be collected or created?

We will collect the data starting from an analysis of responses of experiments, through images, measurements and counts by a member of the research group responsible for this, previously calibrated. The collection and documentation of the data will be described initially in a laboratory notebook another member will review that to so be transferred to the electronic medium. All generated content will be described according to scientific standards for publication and will be organized and identified appropriately for future consultation.

Documentation and Metadata

What documentation and metadata will accompany the data?

All data must have detailed textual reports about their capture, about the experimental conditions, method and technique used, and the identification of the researcher who performed the analyzes and data. All files and folders have defined nomenclature defined for all members of the research group and a file named “readme” will be part of the set documentation containing a detailed description of each item to guide future consultations

Ethics and Legal Compliance

How will you manage any ethical issues?

All stages of the research will follow ethical protocols in accordance with existing regulations.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

We will deal copyright and intellectual property issues with with the members of the research group

for this project, and the Unesp Innovation Agency will guide any bureaucratic and legal issues if necessary.

Storage and Backup

How will the data be stored and backed up during the research?

The data will be stored with institutional access from Unesp in the cloud (Google Drive and / or institutional repository), so that everyone involved has shared access. On these platforms there is sufficient capacity for all data and backups are already preconfigured as a security measure.

How will you manage access and security?

All researchers involved will access the files as readers, but only the responsible researcher and coordinator will edit them.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Research data that may contribute to future projects and / or scientific publications.

What is the long-term preservation plan for the dataset?

We will store the data in the cloud (Google Drive and / or institutional repository) for 10 years.

Data Sharing

How will you share the data?

The data will be partially and / or fully disclosed in congresses and scientific events. With the last results analyzed, preparation and submission for publication in periodicals in the area will also be done. In addition, all data stored in the repository will have free access to the public and can be cited by third parties.

Are any restrictions on data sharing required?

If the research project has a potential patent application, we will restrict public sharing until

completion of the patent process.

Responsibilities and Resources

Who will be responsible for data management?

All integrating parties will have specific functions and will be responsible for capturing and organizing the data, however only the coordinator and responsible researcher will edit the files containing the last information.

What resources will you require to deliver your plan?

It will be necessary to spend an initial time with the calibration of the researchers who will carry out the data collections, and technical support from the Information Technology and Library teams for any doubts regarding the handling on the online storage platforms.
