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Digital versus analog procedures for the prosthetic restoration of single implants

Submission date	Recruitment status	[_] Prospectively registered
25/04/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/05/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2018	Oral Health	

Plain English summary of protocol

Background and study aims
The replacement of the single missing or failing tooth with a dental implant (i.e. a titanium fixture inserted in the bone) is a frequent procedure with a high rate of success. Until now, implant-supported prosthetic restorations have been made with analog (conventional) techniques, but in the last few years the digital revolution has been changing the world of dentistry, and implant-supported crowns can be made using digital technology. Although digital techniques are rapidly spreading in dentistry, there are very few studies that compare the procedures and the results obtained in the replacement of single teeth with digital vs analog (conventional) procedures. The aim of this study is compare the success and complications encountered with digital and analog procedures for the prosthetic restoration of single-tooth implants.

Who can participate?
Patients who have undergone surgical treatment with the insertion of a single Morse taper connection implant in the posterior areas (premolars and molars) of both jaws

What does the study involve?
Participants are randomly allocated to receive an implant-supported crown made with either analog (conventional) or digital technologies. All patients are followed for 1 year after the delivery of the final crown to measure implant-crown success, complications, marginal bone loss around the implant, patient satisfaction, and the time and cost of the treatment.

What are the possible benefits and risks of participating?
The possible benefits of the use of digital techniques for making implant crowns are less patient discomfort, and more time-efficient and less expensive treatment.

Where is the study run from?
Studio Odontoiatrico Mangano (Italy)

When is the study starting and how long is it expected to run for?
September 2014 to September 2017

Who is funding the study?
Studio Odontoiatrico Mangano (Italy)

Who is the main contact?
Dr Francesco Mangano

Contact information

Type(s)
Scientific

Contact name
Dr Francesco Mangano

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0001

Study information

Scientific Title
Digital versus analog procedures for the prosthetic restoration of single implants: a randomized controlled trial with 1 year of follow-up

Acronym
DAPRSI

Study objectives
The study aimed to evaluate if a different exists in the the success and complications encountered in the prosthetic restoration of single-tooth Morse taper connection implants with digital and analog procedures, comparing the two methods; moreover, the study aimed to analyze and compare the patients' preference, the treatment times, and the costs, relative to the two different methodologies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Varese - Insubria, 09/10/2013, ref: 826-0034086

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Implant dentistry

Interventions
Over a two-year period (2014-2016), all patients who had received a single Morse taper connection implant in posterior areas of their jaws were randomly assigned either to receive a monolithic zirconia crown fabricated with digital workflow (test group), or a metal-ceramic crown fabricated with analog workflow (control group). All patients were followed for 1 year after the delivery of the final crown. The primary outcomes were implant-crown success, complications, peri-implant marginal bone loss (PIMBL); the secondary outcomes were patient satisfaction, and time and cost of the treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Implant-crown success. An implant-supported restoration was defined as clinically successful if it was still functioning at the end of the study without any complication, either biological or prosthetic, at the last control appointment, 1 year after delivery. On the other hand, if only a single complication involving the implant-supported restoration occurred, the crown was included in the group of failures
2. The biologic and prosthetic complications encountered during the 1-year observation period
3. Peri-implant marginal bone loss, a radiographic measure of peri-implant bone stability, measured on intraoral radiographs comparing the peri-implant bone peaks (mesial and distal) at the time of implant placement (T1) and 1 year after delivery of the definitive crown (T2)

Secondary outcome measures
1. The degree of satisfaction and the perception of the quality of the treatment received by patients with digital and with analog procedures were investigated by means of a visual

analogue score (VAS) questionnaire, based on 10 specific questions, 1 year after delivery of the definitive crown. For each of the selected questions, patients were asked to assign a score of 0 - 10 - 20 - 30 - 40 - 50 - 60 - 70 - 80 - 90 - 100, based on their satisfaction with the treatment received (0 = absolutely dissatisfied with the treatment; 10-20-30-40 = strongly dissatisfied with the treatment; 50 = insufficiently satisfied with the treatment; 60 = sufficiently satisfied with the treatment; 70-80-90 = very satisfied with the treatment; and 100 = fully satisfied with the treatment).
2. The overall treatment time and the active working time (i.e., the effective working time, excluding machine time) required for the prosthetic restoration of 1 single implant with both treatments (digital vs analog procedure)
3. The cost of both procedures (digital vs analog procedure) for the dentist, including all the expenses related to the purchase of materials and the services of the dental laboratory, examined at the end of treatment

Overall study start date
01/09/2014

Completion date
30/09/2017

Eligibility

Key inclusion criteria
Only patients who had undergone surgical treatment with the insertion of a single Morse taper connection implant in the posterior areas (premolars and molars) of both jaws, in the period between September 2014 and September 2016, in a single dental center, were considered for enrollment in the present randomized controlled trial. A further inclusion criterion was the diameter and height of the implant received: the patients had to be installed with a fixture of a minimum diameter of 4.1 mm and a height of at least 8 mm. In order to be enrolled in the study, patients had to have dentition in the opposite jaw and therefore occlusal contacts. Finally, to be enrolled, patients had to read and sign a document of adhesion to the present study, on the nature (and possible therapeutic alternatives) of which they were informed in detail; by signing this document, they committed themselves to come to the dental clinic for the required follow-up appointments.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50 (25 patients per group)

Key exclusion criteria
All patients who received a single implant with a diameter of less than 4.1 mm and a height of less than 8 mm were automatically excluded from this study, as were all patients who had

undergone pre-implant regenerative bone therapies or who had been treated with guided bone regeneration and membranes for the presence of peri-implant defects. Additional exclusion criteria included systemic diseases such as uncompensated diabetes, immunocompromised states, head and neck tumors, and osteoporosis treated with amino-bisphosphonates (administered orally and / or parenterally). Active periodontal infections and oral mucosa pathologies also represented exclusion criteria for enrollment in the present study.

Date of first enrolment
01/09/2014

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Italy

Study participating centre
Studio Odontoiatrico Mangano
Piazza Trento 4
Gravedona (Como)
Italy
22015

Sponsor information

Organisation
Studio Odontoiatrico Mangano

Sponsor details
Piazza Trento 4
Gravedona ed Uniti
Italy
22015

Sponsor type
Hospital/treatment centre

Website
www.drmangano.com

ROR
https://ror.org/00828d816

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Studio Odontoiatrico Mangano

Results and Publications

Publication and dissemination plan
Additional documents will be available upon reasonable request from Dr Francesco Mangano. The trialists are willing to publish their 1-year follow-up results within the next 6 months.

Intention to publish date
26/10/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Francesco Mangano.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/07/2018		Yes	No