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Morse taper connection implants placed in grafted sinuses

Submission date	Recruitment status	[_] Prospectively registered
19/06/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/06/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/08/2017	Oral Health	

Plain English summary of protocol

Background and study aims
Dental implants are used to support false teeth. This is done to replace a root of a tooth by using a screw that connects the tooth into the jawbone. Dental implants can usually last a long time, however depending on the technique that the dentist uses could impact how long they can survive. Dental implants with a locking connection (such as Morse taper connection implants) can be placed in the mouth using two different grafting techniques. The aim of this study is to investigate the long-term survival and complication rates of dental implants placed using the Morse taper connection technique, in order to evaluate the predictability of this treatment procedure.

Who can participate?
Patients who underwent tooth implants from January 2003 to August 2006

What does the study involve?
Participants who underwent dental implants have their medical records reviewed in order to see what the ten year survival and complications rates are. Researchers gather data the implant survival, functioning, complications, infections and other clinically important events over ten years in order to evaluate the predictability of the treatment.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating

Where is the study run from?
1. Dental Surgery Mangano (Studio Odontoiatrico Mangano)
2. Dental Surgery Frezzato (Studio Dentistico Frezzato)

When is the study starting and how long is it expected to run for?
October 2013 to May 2017

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

Who is the main contact?
Dr Francesco Mangano
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
0001

Study information

Scientific Title
Morse Taper Connection Implants placed in Grafted Sinuses of 65 patients: a retrospective clinical study with 10 years of follow-up

Acronym
MTCIsGS

Study objectives
The aim of this study is to investigate the 10-year survival and complication rates of Morse taper connection implants (MTCIs) placed in grafted sinuses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital of Varese (Comitato Etico Ospedale di Circolo e Fondazione Macchi), 03/10/2013, ref: 826

Study design
Retrospective observational clinical study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
This is a retrospective chart review study. The focus of the data collected is about the ten year implant survival and complication rates of a particular implant-abutment connection, the Morse taper.

These records included all information about each enrolled patient (patient-related information: systemic health, age at surgery, gender, smoking habit, oral hygiene), each implant-supported restoration placed (implant-related information: position – premolar or molar – length and diameter; restoration-related information: type of prosthesis – SC or FPD - date of deliveries). The customized records included all information about any implant failure and/or biological /prosthetic complication occurred during the 10-year follow-up.

The data collected from the medical record includes clinical functioning (implant survival and implant-supported restorations) and biologic and prosthetic complications.

Implants were classified as “surviving” when still clinically in function at the final 10-year follow-up. Conversely, all implants that were lost and/or had to be removed (for implant mobility due to absence and/or loss of osseointegration in absence of infection, for recurrent/persistent peri-implantitis and for implant body fracture) during the entire period of the study, were considered as “failed”. Implant-supported restorations were classified as “surviving” when still clinically in function at the final 10-year follow-up. Conversely, all implant-supported restorations that had to be removed (for implant failure) during the entire period of the study, were considered as “failed”.

Among the biologic complications, loss of the graft, sinus infection, peri-implant mucositis and peri-implantitis were considered. Among the prosthetic complications, all mechanical complications (i.e., complications affecting the pre-fabricated implant components at the implant-abutment interface such as abutment loosening and abutment fracture) and all technical complications (i.e., complications affecting the superstructures made by the dental technician, such as loss of retention, ceramic chipping/fracture, fracture of the metallic framework of restoration) were considered.

Intervention Type
Other

Primary outcome(s)
The 10-year implant survival (still clinically functioning) are measured clinically at the 10-year follow-up

Key secondary outcome(s))
Biologic and prosthetic complications affecting the fixed implant-supported restorations are measured clinically during the ten year follow up

Completion date
30/05/2017

Eligibility

Key inclusion criteria
1. Patients that been treated with maxillary sinus augmentation (with the lateral window or the transalveolar osteotomy technique)
2. Restored with fixed prosthetic restorations (SCs and FPDs) supported by MTCIs
3. Received treatment in the period from January 2003 to August 2006 in two private dental clinics (located in Gravedona, Como, Italy; and in Padua, Italy, respectively)
4. Aged 18 and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Systemic diseases or ongoing treatments/conditions that may contra-indicate intervention (uncontrolled diabetes, immunocompromised states, chemo/radiotherapy of the head/neck region, treatment with amino-bisphosphonates, psychiatric disorders and abuse of drugs /alcohol)
2. Oral diseases (non-treated periodontal disease, active/ chronic/ persistent sinus infections)

Date of first enrolment
01/01/2015

Date of final enrolment
30/08/2016

Locations

Countries of recruitment
Italy

Study participating centre

Studio Odontoiatrico Mangano
Studio Odontoiatrico Mangano
Piazza Trento 4, 22015 Gravedona (Como)
Gravedona (Como)
Italy
22015

Study participating centre
Studio Dentistico Frezzato
Studio Dentistico Frezzato
via Cavour 10, 45100 Rovigo
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45100

Sponsor information

Organisation
Dental Surgery Mangano (Studio Odontoiatrico Mangano)

ROR
https://ror.org/00828d816

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dental Surgery Mangano (Studio Odontoiatrico Mangano)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Principal Investigator Francesco Mangano at francescomangano1@mclink.net

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017		Yes	No