

# Morse taper connection implants placed in grafted sinuses

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<b>Registration date</b> 21/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/08/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## 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  
francescomangano1@mclink.net

## 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**  
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)**

**Study design**

Retrospective observational clinical study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**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**

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 measure**

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

**Secondary outcome measures**

Biologic and prosthetic complications affecting the fixed implant-supported restorations are measured clinically during the ten year follow up

**Overall study start date**

03/10/2013

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

65

**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**

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via Cavour 10, 45100 Rovigo

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## **Sponsor information**

**Organisation**

Dental Surgery Mangano (Studio Odontoiatrico Mangano)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

www.drmangano.com

**ROR**

https://ror.org/00828d816

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Dental Surgery Mangano (Studio Odontoiatrico Mangano)

## Results and Publications

**Publication and dissemination plan**

This retrospective study has been submitted for publication.

**Intention to publish date**

30/08/2017

**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?
<a href="#">Results article</a>	results	01/01/2017		Yes	No