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A prospective, randomized trial to compare correction of ridge contour deficiency (shrinking of the gum and bone) using OSSIX® Volumax or Fibro-Gide.

Submission date
11/10/2022

Registration date
18/10/2022

Last Edited
13/10/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
OSSIX Volumax is already approved for sale product that is used in various dental procedures together with bone fillers. The purpose of the study is to see OSSIX Volumax safety and performance also in a thickening of the jaw treatment without other bone fillers.
The study aims to compare a treatment of jaw thickness improvement with OSSIX® Volumax compared to FibroGide®

Who can participate?
Adults over the age of 18 years that need to have a dental implant and have a narrow jaw

What does the study involve?
The study involves a standard dental implantation operation. The study starts with a dental operation and a patient will be followed up with standard tests and scans for 1 year.

What are the possible benefits and risks of participating?
A benefit for a patient is to have a thicker jaw which will assist better esthetic and functional results of dental treatment.
A risk in this case is similar to every standard dental procedure which includes pain, minor swelling.

Where is the study run from?
Bologna University (Italy)

When is the study starting and how long is it expected to run for?
September 2021 to March 2025

Who is funding the study?
Datum Dental Ltd (Israel)

Who is the main contact?
Prof. Pietro Felice, pietro.felice@unibo.it

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Eudamed CIV-22-04-039446

Study information

Scientific Title
A prospective, randomized controlled trial to evaluate correction of ridge contour deficiency using OSSIX® Volumax vs Fibro-Gide.

Acronym
volumax SA

Study objectives
The treatment of tissue augmentation with OSSIX® Volumax is non-inferior to the treatment with FibroGide as will be evaluated after 12 months from the treatment day.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/02/2022, Bologna Ethics Committee (Comitato Etico di Area Vasta Emilia Centro della Regione Emilia-Romagna, presso IRCCS Azienda Ospedaliero – Universitaria di Bologna, Policlinico S.Orsola-Malpighi, Via Albertoni, 15 – 40138 BOLOGNA, Italy; no telephone number provided; comet.speri@ausl.bologna.it), ref: 32-2022-DISP-AUSLBO

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental ridge contour deficiency

Interventions
OSSIX® Volumax is a biodegradable and biocompatible collagen scaffold designed to support the formation of new alveolar bone and new attachment apparatus in teeth when the technique of Guided bone/tissue regeneration is utilized.

Fibro-Gide® is one of the available collagen scaffolds/matrices specifically designed for soft-tissue regeneration.

Subjects will be randomized into one of the treatment arms:
Study arm 1: OSSIX Volumax
Study arm 2: Fibro-Gide

Treatment indication: patients who need 1-3 dental implant with soft tissue deficiency.
The study device (or the control device) will be placed together with implant placements and healing abutments placement

Total duration of the study is 13 months. This including the screening period, the surgery of implantation, and the follow up visits.

The randomization will be done through the EDC system.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
OSSIX® Volumax

Primary outcome(s)
Measuring the width of the ridge by intra oral scanner at 6 and 12 months

Key secondary outcome(s))

1. Volumetric changes of the augmented site calculated by intraoral scan impression (mm^3) at 6 and 12 months
2. Soft tissue healing measured by clinical evaluation at the surgery site at 6 and 12 months:
2.1. Keratinized tissue width on the buccal side of the two neighboring teeth; measured from a fixed referenced point to the mucogingival line (mm)
2.2. Wound closure (according to the wound healing index) at all time points.
2.3. Membrane/scaffold exposure, color, redness, and swelling, inflammation
2.4. Bleeding on probing (BOP)
2.5. Periodontal probing depth (PPD)
2.6. Clinical attachment level (CAL)
2.7. Recession depth (RD)

Exploratory:
1. Evaluation of OSSIX® Volumax clinical bone formation parameters from CBCT superposition:
1.1. Radiographic bone changes (horizontal and vertical) change in mm at 12 months
1.2. Implant stability (ISQ) and survival at 12 months
2. Esthetic outcome determined by a masked and calibrated examiner evaluated the results with predefined questionnaire at 12 months
3. Patient subjective oral health impact profile will be assessed with the OHIP-14 questionnaire at 2 weeks
4. Documentation of the related adverse events at all visits

Safety:
1. The safety will be assessed by evaluation of the number and severity of documented adverse events such as wound closure complications) and concomitant medications that will be recorded at all visits during the entire study period.

Completion date

01/03/2025

Eligibility

Key inclusion criteria

1. Males and females ≥18 years
2. General good health (ASA 1 and ASA 2)
3. Presence of a tissue contour deficiency leading to an unesthetic implant rehabilitation, not associated with bone dehiscence and/or fenestration defects.
4. Patients require 1-3 implants placed between two periodontally stable natural teeth.
5. Good oral hygiene (full mouth plaque index <25%)
6. Adequate control of inflammation (full mouth bleeding on probing <25%)
7. Patients that are willing to sign an informed consent and participate in the clinical study
8. Patient that are able to understand and to comply with the study related procedures such as exercising good oral hygiene and attending all follow-up examinations

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Implant sites with associated alveolar bone dehiscence and/or fenestration defects that necessitate bone grafting in combination with correction of ridge contour deficiency.
2. General contraindications for dental and/or surgical treatments
3. Inflammatory and autoimmune disease of the oral cavity
4. Allergy to collagen
5. Uncontrolled diabetes (A1C > 6.5 %)
6. Disease of oral mucosa
7. Disease affecting connective tissue metabolism (e.g. collagenases)
8. Uncontrolled Periodontal disease
9. History of myeloma, respiratory tract cancer, breast cancer, prostate cancer, or kidney cancer requiring chemotherapy or radiotherapy.
10. Concurrent or previous radiotherapy of head area
11. Concurrent or previous immunosuppressant, bisphosphonate, or high-dose corticosteroid therapy
12. Heavy Smokers (over 10 cigarettes a day)
13. Pregnant or lactating women.
14. Women of childbearing age, who are not using a highly effective method of birth control
15. Participation in another investigational device, drug, or biologics study within the last 24 weeks prior to the study start.

Date of first enrolment
07/11/2022

Date of final enrolment
01/11/2023

Locations

Countries of recruitment
Italy

Study participating centre
Università di Bologna
Via San Vitale 59
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Sponsor information

Organisation
Datum Dental

Funder(s)

Funder type
Industry

Funder Name
Datum Dental Ltd

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication, Data sharing statement to be made available at a later date