

# Efficacy and safety aspects of biodegradable fixation systems: a randomised clinical trial

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/05/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Efficacy and safety aspects of biodegradable fixation systems: a randomised clinical trial

## **Acronym**

FixITT

## **Study objectives**

The performance of the Inion biodegradable osteofixation system is inferior compared to a titanium system regarding the treatment of zygoma, Le Fort I fractures, Le Fort I osteotomies, mandibula fractures and Bi-lateral Sagittal Split Osteotomies (BSSO) of the maxillofacial skeleton by healthy patients with regard to bone healing, stability and complications like, infections, plate dehiscence, hypersensitivity and palpability.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Medisch Ethische Toetsingscommissie Universitair Medisch Centrum Groningen, 01/05/2006, ref: 2006/035

## **Study design**

Randomised controlled parallel-group double-blinded multicentre trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Maxillofacial trauma and orthognathic anomalies in the maxillofacial skeleton

## **Interventions**

Fixing bone segments in the maxillofacial skeleton with titanium or biodegradable fixation devices.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Bone healing is the primary outcome measure. The definition of bone healing is: healing of the bone segments after eight weeks without clinical and radiological signs of disturbed bone healing.

Bone healing related complications are not allowed during this period.

## **Key secondary outcome(s)**

1. Inflammatory reaction present (redness, swelling, sensitivity, warmth, function impairment, fistula or pus drainage), assessment visual and manually
2. Seriousness inflammatory reaction (mild, serious), assessment visual and manually
3. Palpability, assessment manually
4. Dehiscence, assessment visual
5. Occlusion, assessment visual
6. Bone formation (screw holes, fracture crevice)

7. Pain, evaluated by a Visual Analogue Scale (VAS)
8. Cold/warm sensitivity
9. Mandibular function, evaluated by a Mandibular Function Impairment Questionnaire (MFIQ)
10. Direct costs within the health care
11. Direct costs outside the health care
12. Indirect costs outside the health care
13. Antibiotic use
14. Analgesic use
15. Re-operation required
16. Reasons re-operations (plate/screw exposition, plat/screw fracture, loosening of plates and screws, inadequate bone healing, inadequate reduction, infection or other reasons)

**Completion date**

01/10/2008

## **Eligibility**

**Key inclusion criteria**

1. Patients scheduled for a solitair Le Fort I fractures, and/or
2. Patients scheduled for a solitair of multiple mandibula fracture(s), and/or
3. Patients scheduled for a solitair zygoma fracture, and/or
4. Patients scheduled for a Le Fort I osteotomy, and/or
5. Patients scheduled for a BSSO
6. Patients who signed the informed consent form

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

1. Severe chronically ill patients (i.e.. diabetes mellitus)
2. Patients by whom compromised bone healing has been established (i.e. osteoporosis)
3. Patients who are submerged through an infection
4. Patients who are pregnant
5. Patients who could not participate in a long follow-up (reasons)
6. Patients who already have received maxillary surgery in the past (i.e., schisis)
7. Patients who are diagnosed with a psychiatric disorder (diagnosed by a psychiatrist)
8. Patients who will not agree with a random assignment to one of the treatment groups or one of the methods of treatment used in the study
9. Patients younger than 18 years regarding patients treated for fractures and patients younger than 14 regarding patients treated for osteotomies

**Date of first enrolment**

01/10/2006

**Date of final enrolment**

01/10/2008

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**University Medical Center Groningen (UMCG)**

Groningen

Netherlands

9700 RB

## Sponsor information

**Organisation**

University Medical Center Groningen (UMCG) (The Netherlands)

**ROR**

<https://ror.org/03cv38k47>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Stryker Nederland (The Netherlands)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2012		Yes	No
<a href="#">Results article</a>	results	01/12/2013		Yes	No
<a href="#">Results article</a>	results	20/07/2015		Yes	No
<a href="#">Results article</a>	results	11/05/2017		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes