

# Resorbability of rigid tricalcium phosphate (TCP) in open wedge high tibial osteotomy (OWHTO)

Published: 23-07-2007

Last updated: 08-05-2024

What is the resorbability of rigid 30% macroporosity TCP wedges after OWHTO. Is complete resorption possible?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON30858

### Source

ToetsingOnline

### Brief title

Resorbability of TCP

### Condition

- Joint disorders
- Bone and joint therapeutic procedures

### Synonym

osteoarthritis of the medial compartment of the knee caused by genu vara

### Research involving

Human

### Sponsors and support

**Primary sponsor:** ntoc medische techniek

**Source(s) of monetary or material Support:** ntoc;medische techniek

## Intervention

**Keyword:** Osteo arthritis knee, Osteotomy, Resorbability, Tricalcium phosphate

## Outcome measures

### Primary outcome

The score of resorbability designed by van Hemert\* varying from:

Stage one: Osteopenic bone, clear distinction between TCP and bone.

Stage five: Full reformation: No sign of osteotomy

\*(van Hemert WL, Willems K, Anderson PG, van Heerwaarden RJ, Wymenga AB.

Tricalcium phosphate granules or rigid wedge preforms in open wedge high tibial

osteotomy: a radiological study with a new evaluation system. Knee 2004;

11(6):451-456)

### Secondary outcome

not applicable

## Study description

### Background summary

The open wedge high tibial osteotomy (OWHTO) is a well accepted treatment modality for patients with osteoarthritis of the medial compartment caused by genu varum. Manufactures of tricalcium phosphate (TCP) wedges claim complete resorption and ingrowth after 36 months. A remarkable slow resorbability was observed during two years of follow up, prompting this retrospective study

### Study objective

What is the resorbability of rigid 30% macroporosity TCP wedges after OWHTO.

Is complete resorption possible?

## Study design

Retrospective

Between March 1998 and July 2005 twenty-one surgical procedures in seventeen patients were performed using an OWHTO with insertion of a rigid TCP wedge. In four patients both left and right knees are treated with OWHTO. There are at least six moment of follow up. An AP and a lateral view radiograph are taken to evaluate the resorbability with a scoring system designed by van Hemert\*  
The follow up times that are already done are six weeks, 3 months, 6 months, 12 months, 18 months and one around 2 years. This moments are part of the normal medical treatment. The final moment of follow up, which is the only moment especially for this research differs by patient. Therefore, the length of follow up differs from 2 years to nine years.

\*(van Hemert WL, Willems K, Anderson PG, van Heerwaarden RJ, Wymenga AB. Tricalcium phosphate granules or rigid wedge preforms in open wedge high tibial osteotomy: a radiological study with a new evaluation system. Knee 2004; 11(6):451-456)

## Study burden and risks

The risks are negligible and the burden minimal since the only thing that has to be done is two radiographs.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- The patients underwent the OWHTO surgical procedure as described between March 1998 and July 2005. This are patients wherefrom the attending physician decided that this was the best possibility of treatment
- The patients agree with this research following informed consent

### Exclusion criteria

- Lost of follow up for any reason
- Conversion to total knee artroplasty

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated):	14-05-2007
Enrollment:	17
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL16596.029.07