OTN Implants BADAL X®

OT World presentation
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SAFETY AND EFFECTIVENESS OF A NEW BONE ANCHORING DEVICE FOR ARTIFICIAL LIMBS (BADAL X)

A PROSPECTIVE TWO-YEARS-FOLLOW-UP IN 90 LOWER LIMB AMPUTEES

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Conflict of interest: Prof. Dr Hendrik van de Meent MD PhD

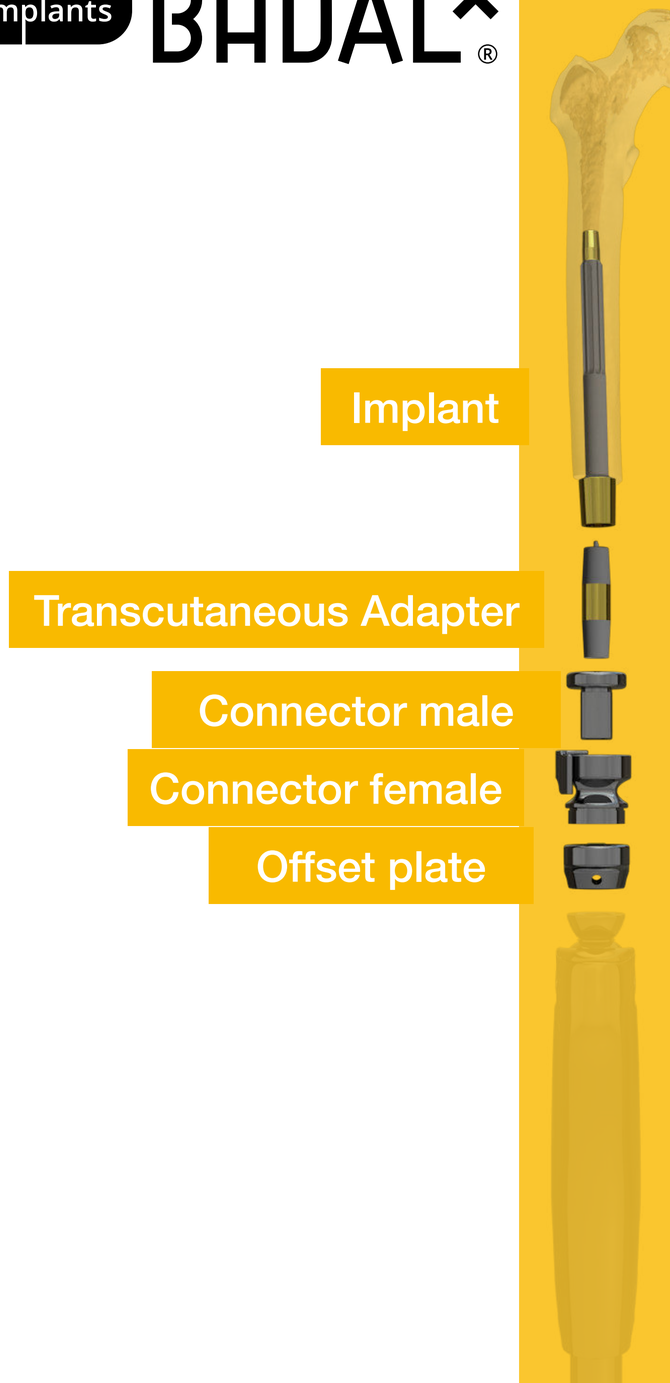
Rehabilitation physician, Radboud University Medical Center, Nijmegen, Netherlands

Visiting professor rehabilitation Medicine University Piemonte Orientale, Novara Italy

Is CEO of medical device company OTN Implants BV Netherlands

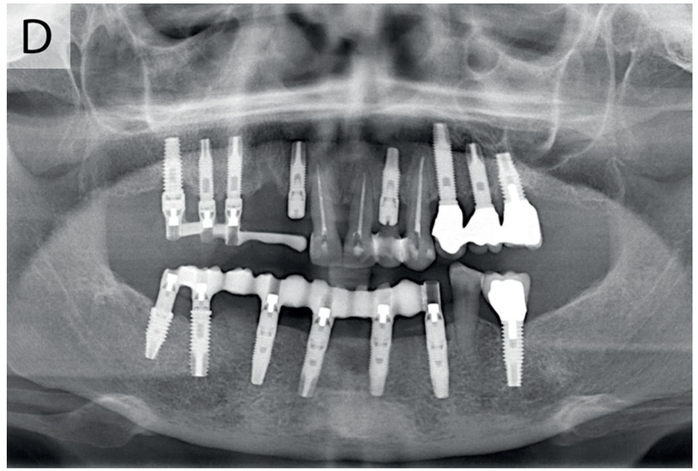
Background

- BADAL-X is a modular press-fit **B**one **A**nchoring **D**evice for **A**rtificial **L**imbs



Background

- BADAL-X is a modular press-fit **B**one **A**nchoring **D**evice for **A**rtificial **L**imbs
- **Bone anchored dental implants and hearing devices are widely accepted**



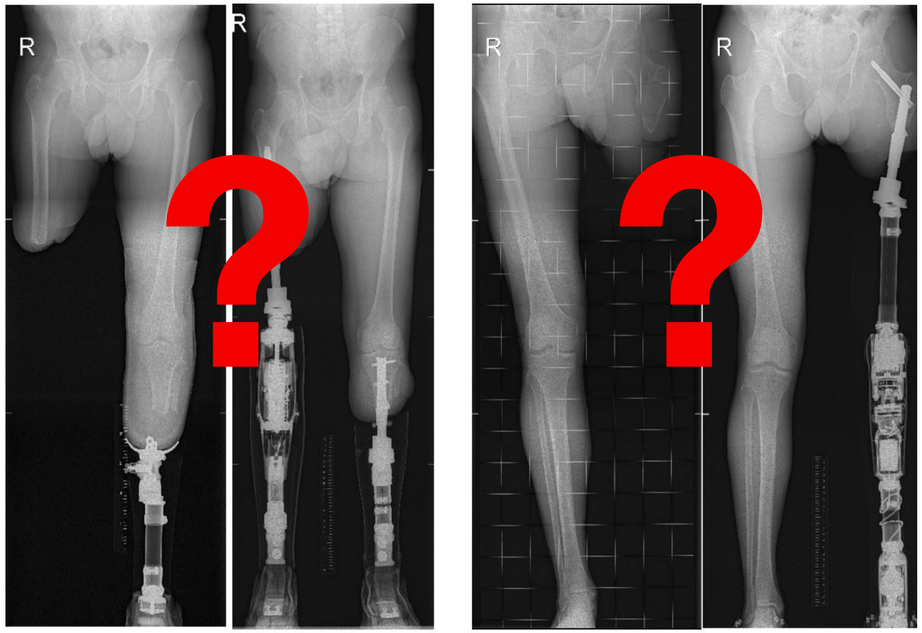
The small titanium implant

The abutment without sound processor

The sound processor on the abutment

Background

- BADAL-X is a modular press-fit **B**one **A**nchoring **D**evice for **A**rtificial **L**imbs
- Bone anchored dental implants are widely accepted
- **Reluctancy rules to use femur/tibia implants for attachment of artificial limbs.**



Background

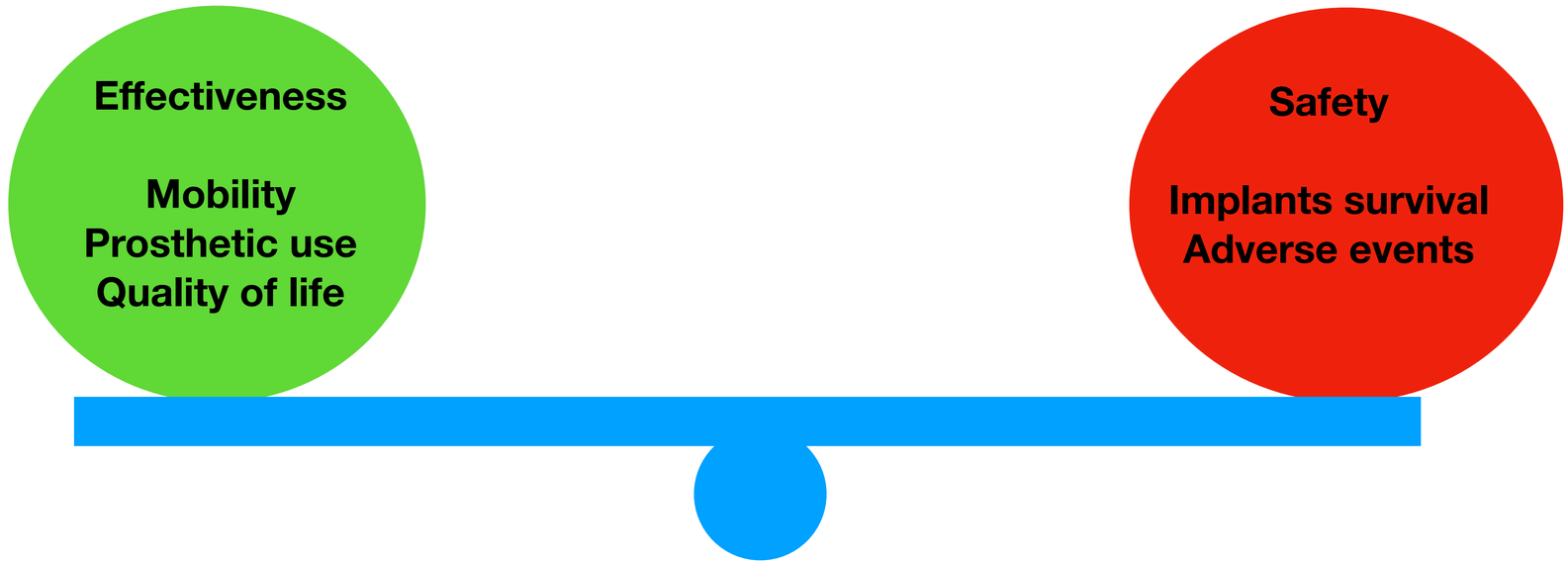
- BADAL-X is a modular press-fit **B**one **A**nchoring **D**evice for **A**rtificial **L**imbs
- Bone anchored dental implants are widely accepted
- Reluctancy rules to use femur/tibia implants for attachment of artificial limbs.
- **Prospective safety and effectiveness data are important.**
- **Previously we published the one year follow-up data of this cohort.[1]**

Reference

1. Atallah R, Van de Meent H, Verhamme L, Frölke JP, Leijendekkers RA. PLoS One. 2020 Mar 9;15(3).

Aim

To describe safety and effectiveness of Bone Anchoring Device for subjects with above and below knee amputation



Methods

All consecutive individuals treated between March 2015 and June 2018 at Radboudumc Nijmegen, NL

Safety measures: Counting adverse events retrospectively from the medical records.

- Infectious adverse events: OI Grading system 1-4
- Other events

Effectiveness measures: (QTFA: Questionnaire of persons with trans-femoral amputation)

- Prosthetic Use Score: Hours/week converted to range 0-100
- Global Score: Prosthesis related quality of life converted to range 0-100

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Inclusion criteria

Lower limb amputees with difficulties with the socket attached prosthesis

Exclusion Criteria:

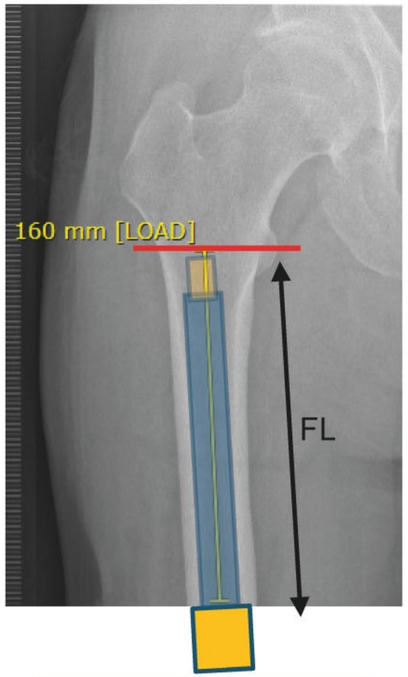
Atypical bone anatomy (eg deformity, dysplasia) or nearby hip-, knee joint dysfunction
Radiation therapy at target limb or chemotherapy within past 18 months
Peripheral vascular disease with local critical ischemia (TcPO2<40mmHg)
Diabetic mellitus with polyneuropathy
Local skin infection or systemic inflammatory disease
Immunocompromised or immunosuppressive drug use
Cardiorespiratory conditions that limit current and future potential for walking
Cognitive impairment with problems to adhere to medical instructions
Somatically unexplained pain or physical condition(s)

Results

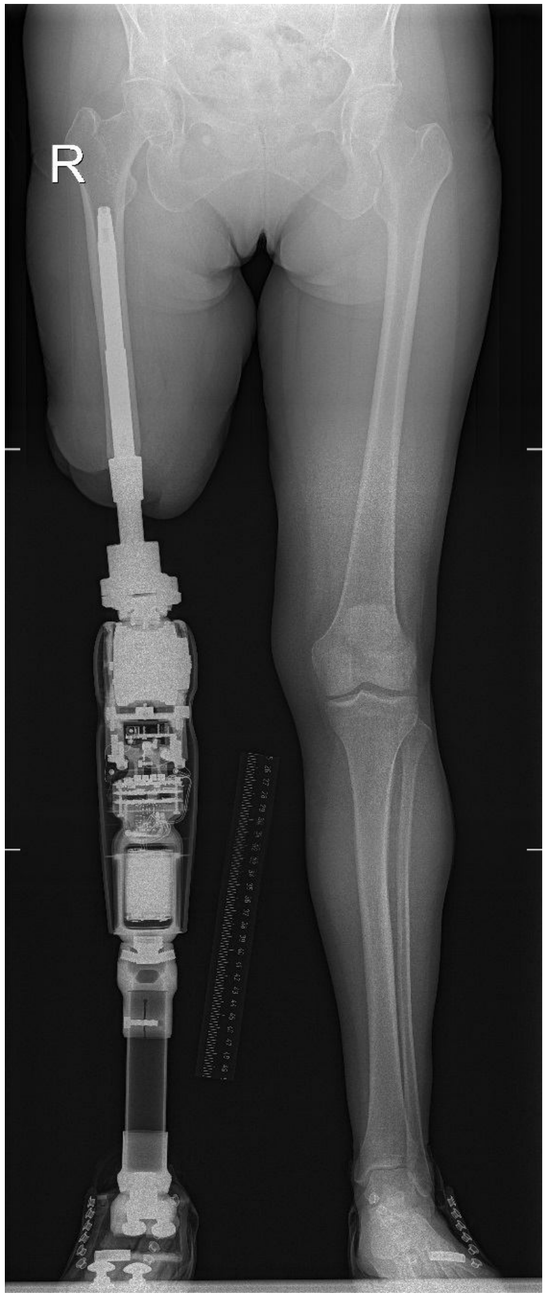
Ninety amputees (mean 54±14 yrs, 26 females), 3 bilaterals: 93 BADAL X systems

Safety data 90 subjects
Effectiveness data 83 subjects.

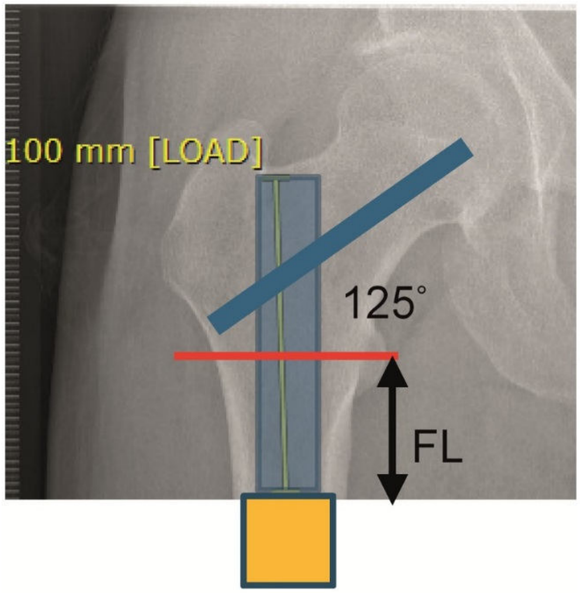
BADAL X Standard TFA Implant (OFI-C) n=55



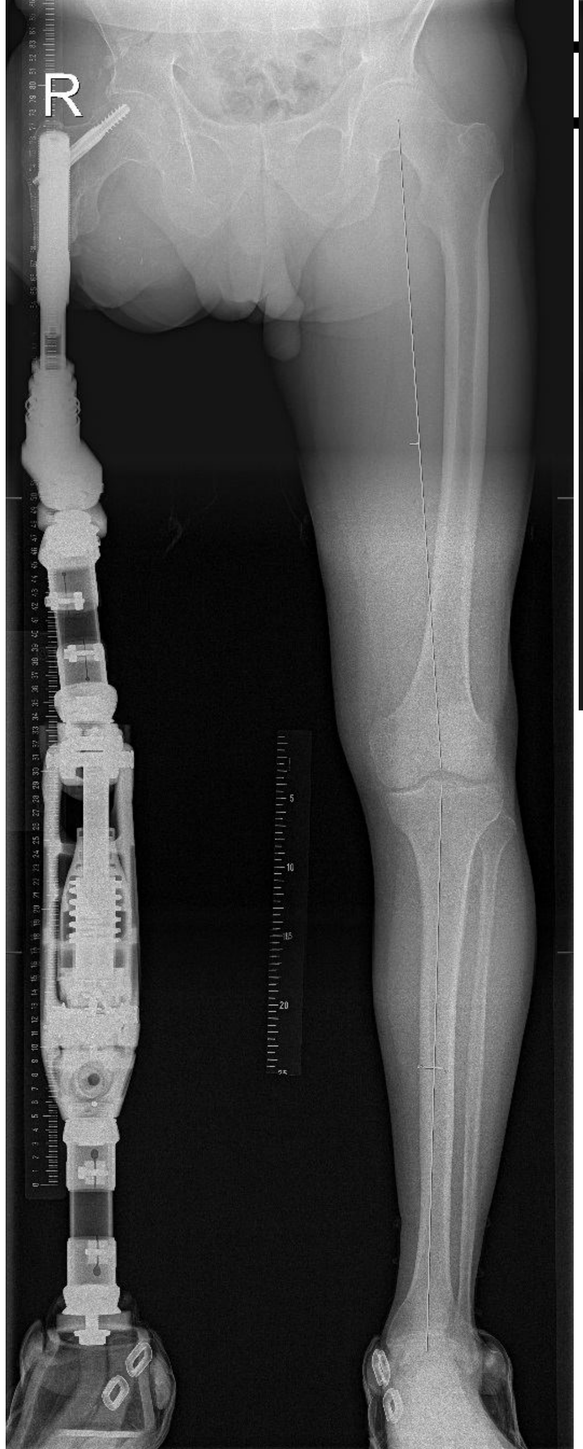
OFI-C (Curved)
if
FL= >160 mm

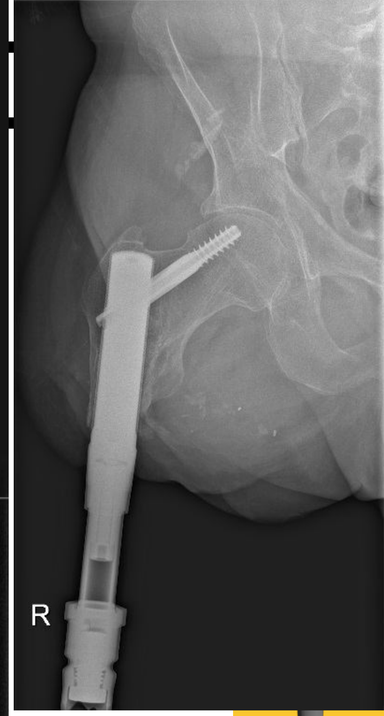


BADAL X Short TFA Implant (OFI-Y) n=16

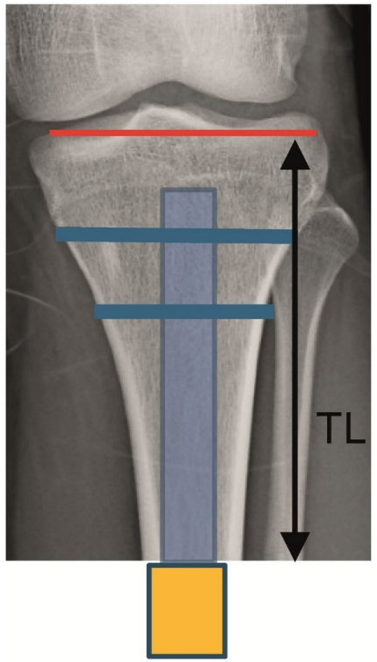


OFI-Y (gamma)
if
FL= 40-160 mm

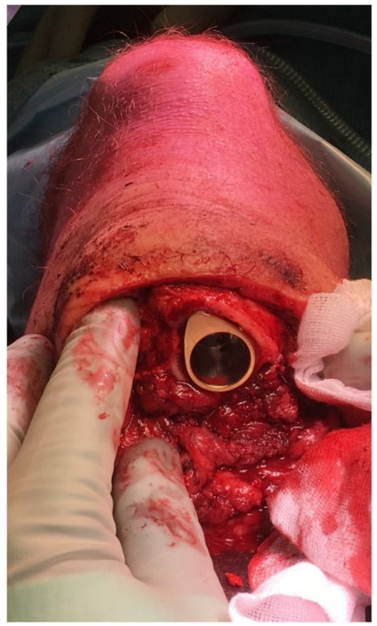




BADAL X TT Implant (OTI) n=22



OTI
If
TL= >60 mm



Results: Safety

Measure	Events First year	Events Second year
Grade 1: Soft tissue normal CRP	11	3
Grade 2: Soft tissue high CRP	10	2
Grade 3: Osteitis		1
Grade 4: Septic implant loosening	1	

Other adverse events:

- Stoma/myogenic pain (n=20)
- Nerve/phantom limb pain (n=12)
- Hip-joint pain (n=3)
- Proximal femur fracture (n=2)
- Abutment breakages (n=4).

Results: Effectiveness

Measure	Baseline Mean (SD), median (range)	2 yrs FU Mean (SD), median (range)	Significance level (p)	% increase
Prosthetic use score (hrs/week)	52±39, 52(7-90)	85±25, 100 (90-100)	<0.05	63%
Global score (QoL)	40±19, 42(25-50)	66±20, 75 (50-75)	<0.05	65%

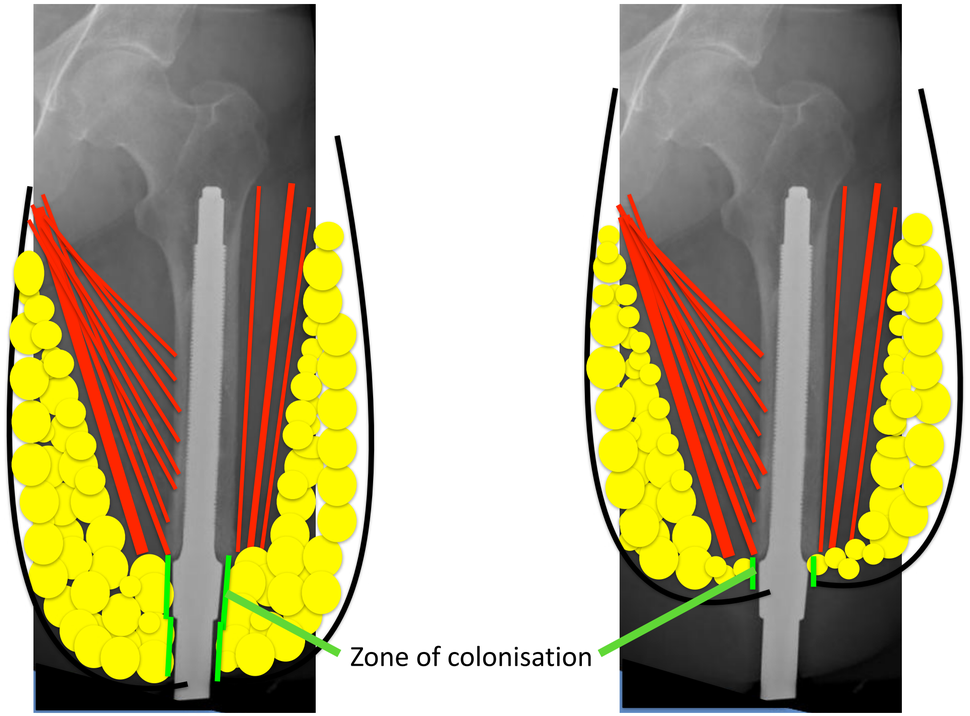
Discussion/conclusion

- Sharp decrease of stoma issues: 21-> 6
- Excellent implant survival: 99%
- Enormous improvement in prosthetic use and prosthesis related quality of life

Discussion: Preventive measures

Brush the stoma pocket twice a day !!!

Discussion: Preventive measures



Deep stoma

Shallow stoma

Make the stoma pocket shallow !!!

Discussion: Preventive measures

Stop smoking !!!

Discussion: Preventive measures

Loose weight !!!

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OTN Implants: Halle 5, Stand D34