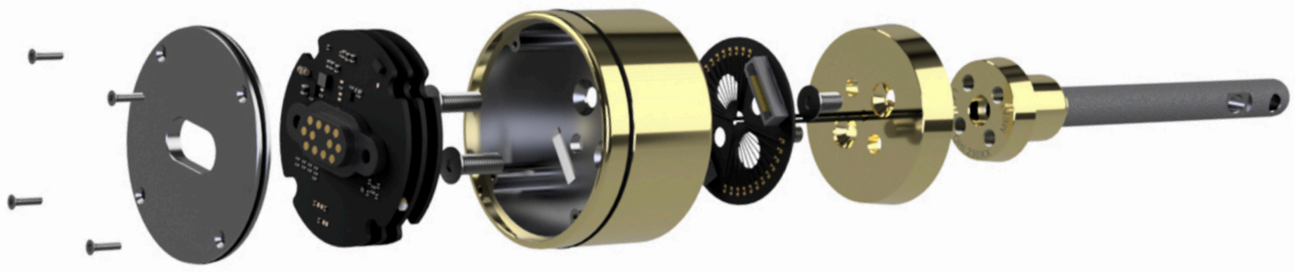
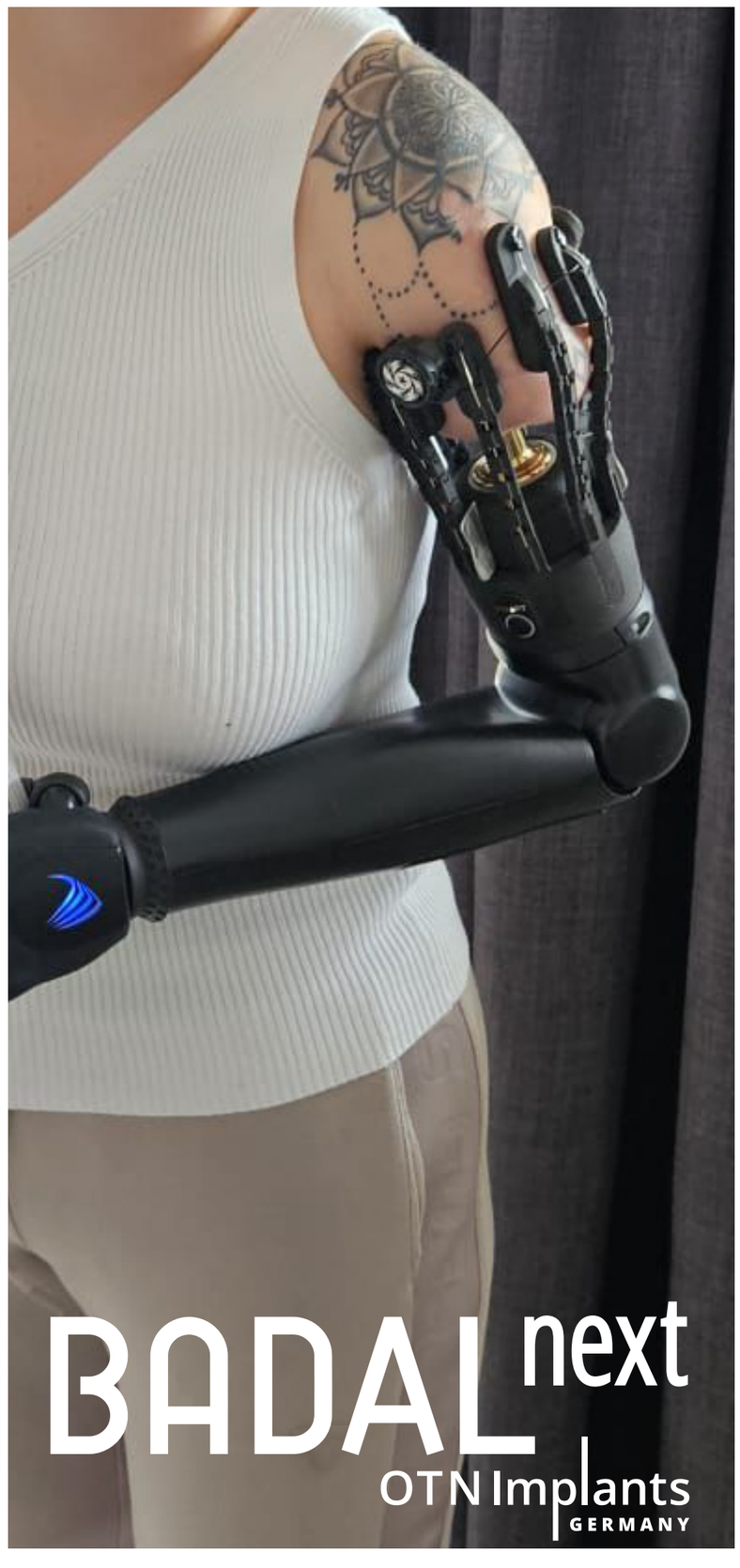
Safety and effectiveness of bone anchoring prostheses for trans-humeral amputees; a pilot study





Background

UE Socket fixation is often unstable un uncomfortable Prosthetic rejection:

- Rate: 24-77% (Review Piscitelli et al, Riv Psichiatr 2021)
- Amputation level: proximal > distal (Biddiss and Chau, Prosthet Orthot Int 2007)
- Sex: F > M; Body perception is crucial prosthesis acceptance (Review Piscitelli et al, Riv Psichiatr 2021)

Objective

- Investigate short term (1 yr), pre-post surgery safety and effectiveness in a pilot study
- Experimental device: BADAL next humerus implant (OTN Implants Germany GmbH)
- Safety: Implant survival and adverse events
- Effectiveness: Prosthetic use (hrs) and ADL activities performed with prosthesis 33 ADL PWP questionnaire

Exclusion criteria

- Inflammatory or septic, acute or chronic, local or systemic processes
- Bone metabolism disorders /post-radiation therapy
- Actual use of immunosuppressive drugs or chemotherapy
- Patients unclear pain syndrome/ medical conditions
- Skeletal immaturity

Inclusion criteria

- Trans-humeral amputation
- Insufficient functional effect of conventional socket attached prostheses

Methods

- 4 traumatic TH amputees, 1 AOFE Clinics Arnhem NL, 3 UMR Rostock BRD
- 2M/ 2F
- Age: 29, 50, 69, 30
- Pre-surgical prosthetic use 0 hrs/week

On stage surgery

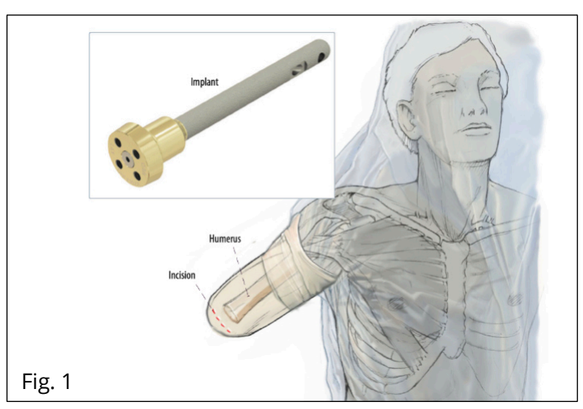


Fig. 1

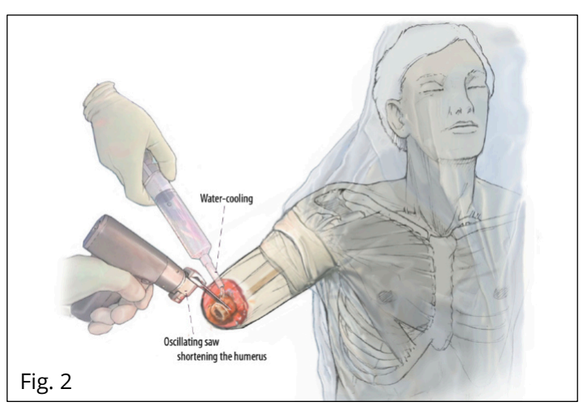


Fig. 2

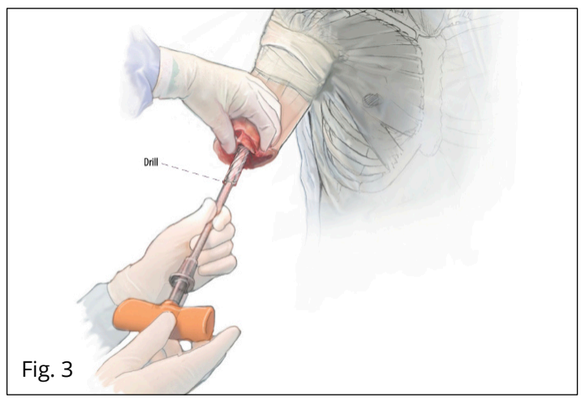


Fig. 3

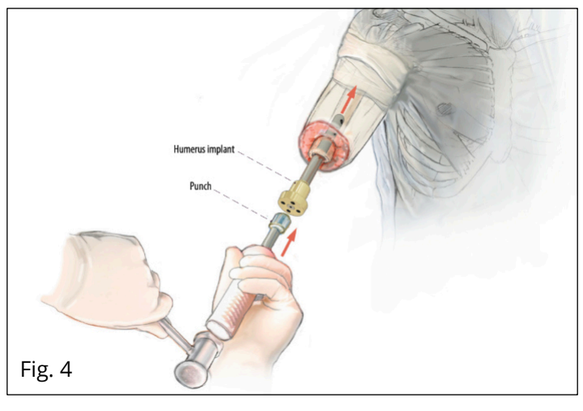


Fig. 4

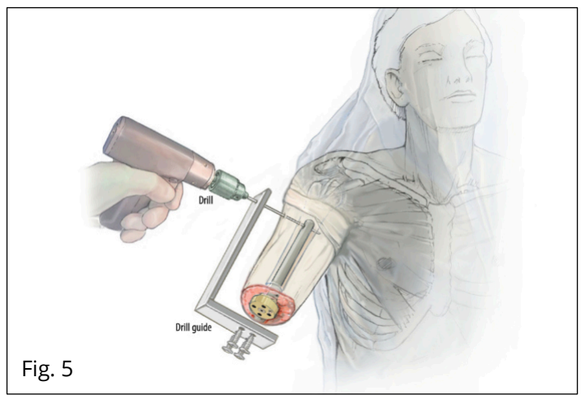


Fig. 5

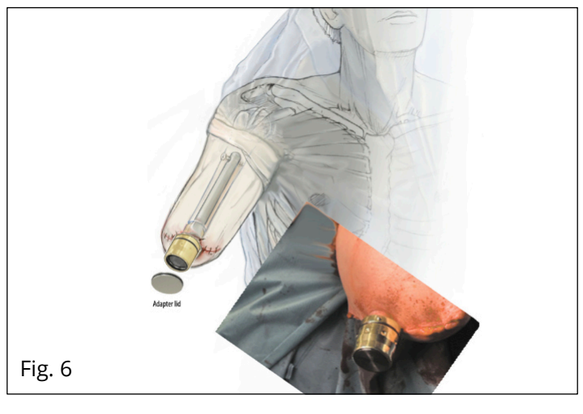


Fig. 6

Results

patient	1	2	3	4
Age	29	50	69	30
Sex	M	M	F	F
FU (M)	25	21	13	13
Implants survival	Y	Y	Y	Y
Adverse events	Shoulder pain during loading phase			Shoulder pain during loading phase
Prosthetic use pre (hrs/d)	0	0	0	0
Prosthetic use 1 yr post (hrs/d)	14	8		12
Prosthetic rejection	N	N		N
33 ADL PWP pre	0	0	0	0
33 ADL PWP 1 yr post	5	6		6

Discussion

- First pilot study with new bone anchoring device for trans-humeral amputees
- Safety: 1 yr implant survival 100%, no serious adverse events
- Effectiveness: Increase in prosthetic use, no rejection, functional improvement with 33ADL PWP

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