COMUNICAÇÃO TÉCNICA

Nº 179296

Failure analysis of a fractures orthopedic implant

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Palestra apresentado no INTERNATIONAL CONFERENCE ON ENGINEERING FAILURE ANALYSIS, ICEFA, 10., 2024, Athens, Greece. ***Lecture..*** *15 slides.*

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Failure analysis of a fractured orthopedic implant

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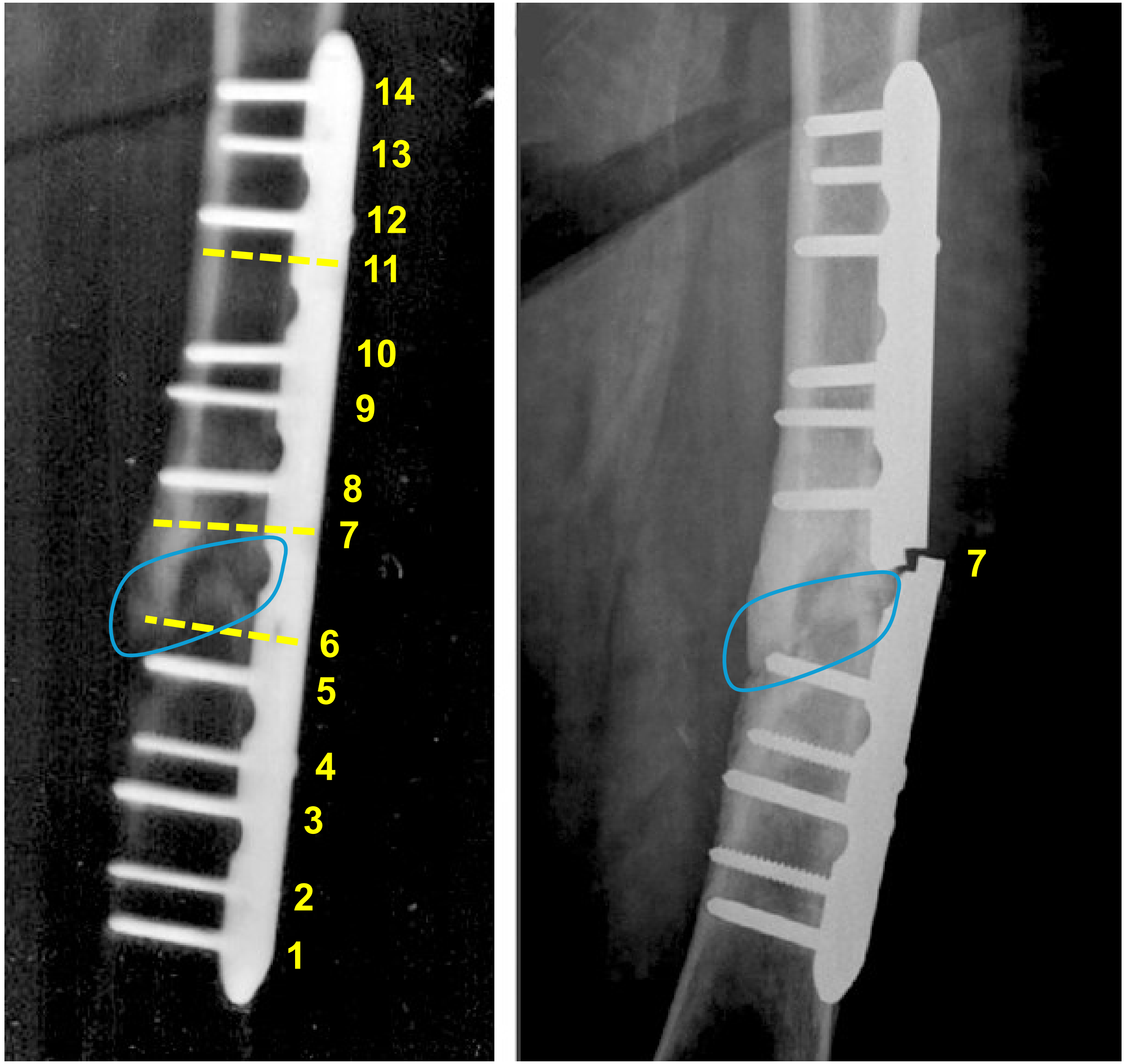
July 10th, 2024

Tenth International Conference on Engineering Failure Analysis – ICEFA X

Failure case

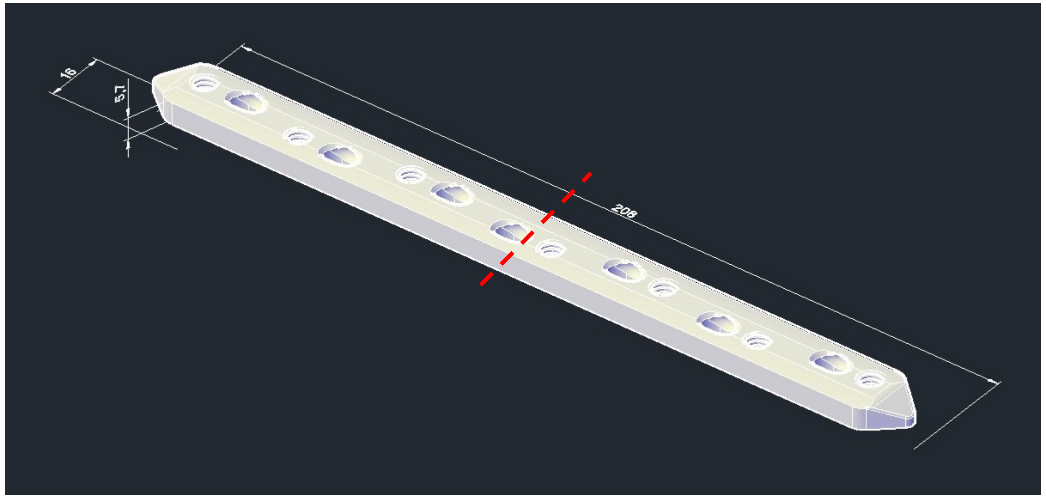
- Stainless steel bone plate + screws - internal fixation device
- 84-year-old, 60 kg, female patient
- Not the first implant to fail

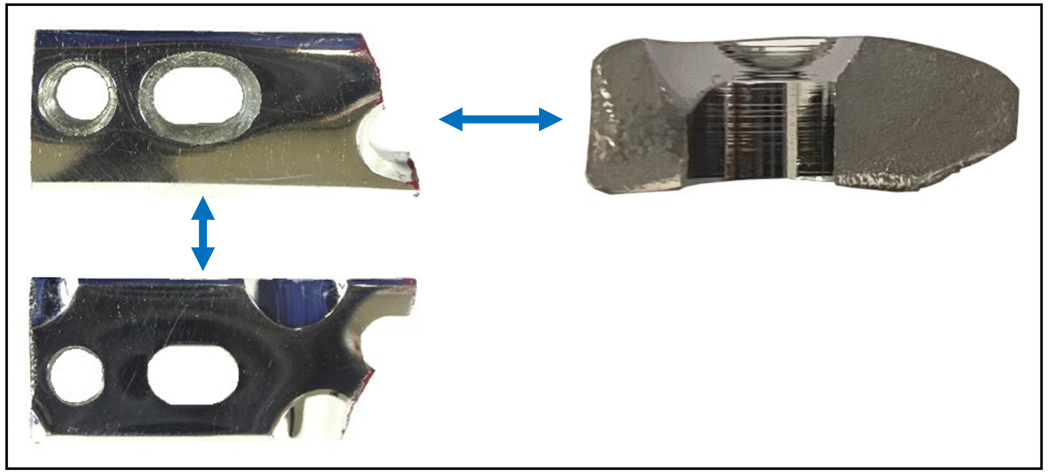


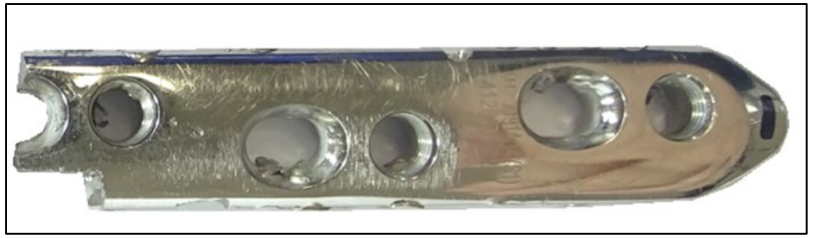
Patient’s left femur. Implant fracture 6 months after surgery.

Failure case

- Stainless steel bone plate - internal fixation device
- 84-year-old, 60 kg, female patient
- Not the first implant to fail
- Only a few parts available for this study. No screws.







Results

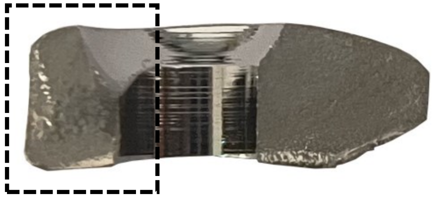
Chemical composition
Microstructure

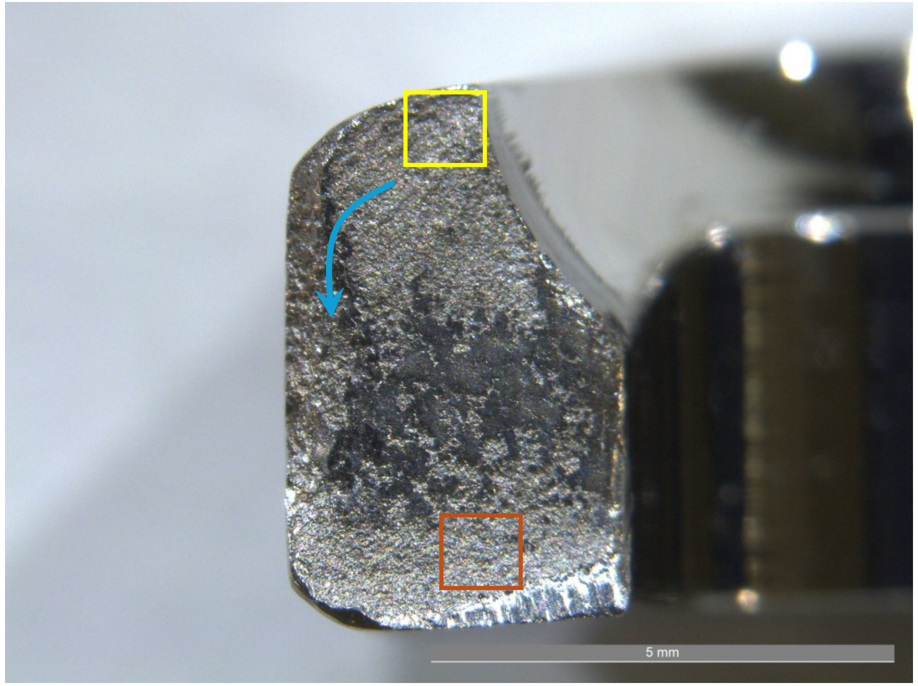
} In accordance with ISO 5832-1 requeriments (similar to AISI 316L)

Hardness: (305 ± 10) HV1

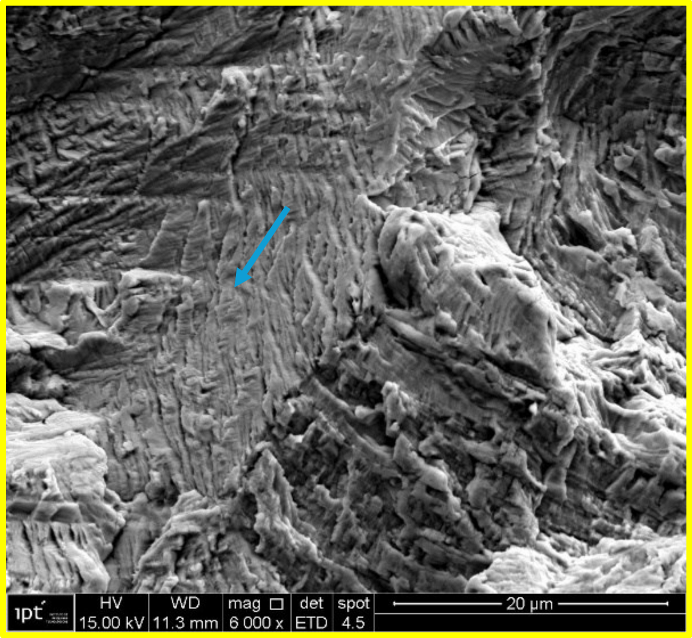
Element	Failed implant (wt%)	ISO 5832-1 requirements (wt%)
C	0.021 ± 0.002	≤ 0.030
Si	0.335 ± 0.153	≤ 1.0
Mn	1.637 ± 0.061	≤ 2.0
P	0.0082 ± 0.0003	≤ 0.025
S	0.0011 ± 0.0002	≤ 0.010
N	0.062 ± 0.002	≤ 0.10
Cr	18.2 ± 0.8	17.0 – 19.0
Mo	2.71 ± 0.11	2.25 – 3.00
Ni	14.8 ± 0.7	13.0 – 15.0
Cu	0.072 ± 0.004	≤ 0.50
X = 3.3%Mo + %Cr	27.14	≥ 26

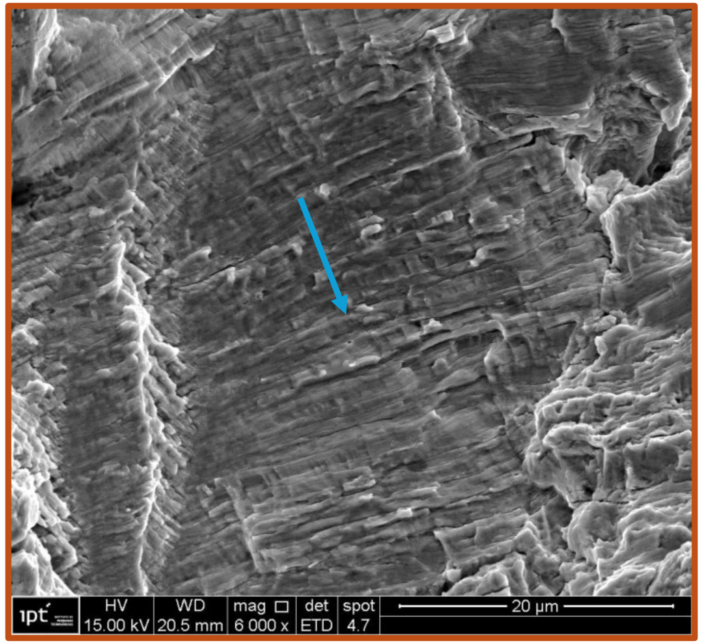
Results



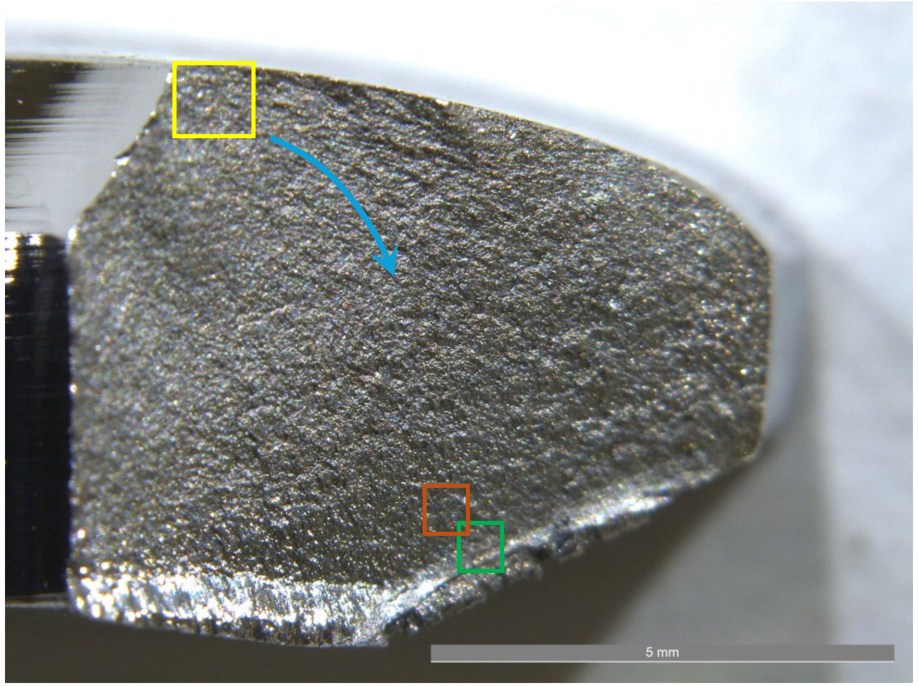


Fatigue crack propagation towards the bottom of the plate (next to the bone)

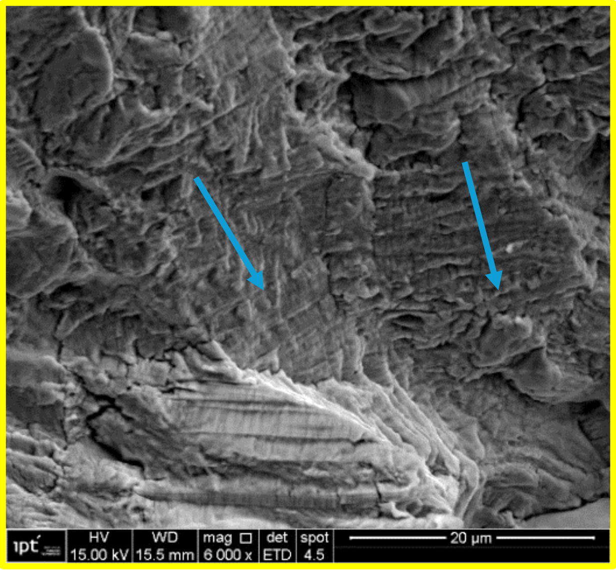


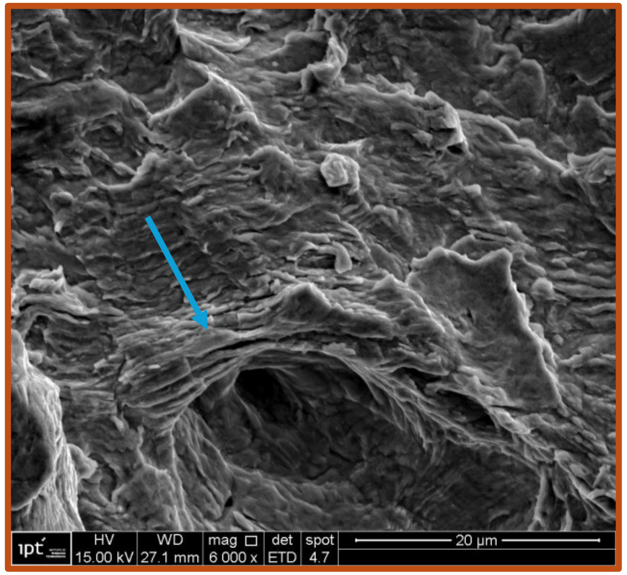


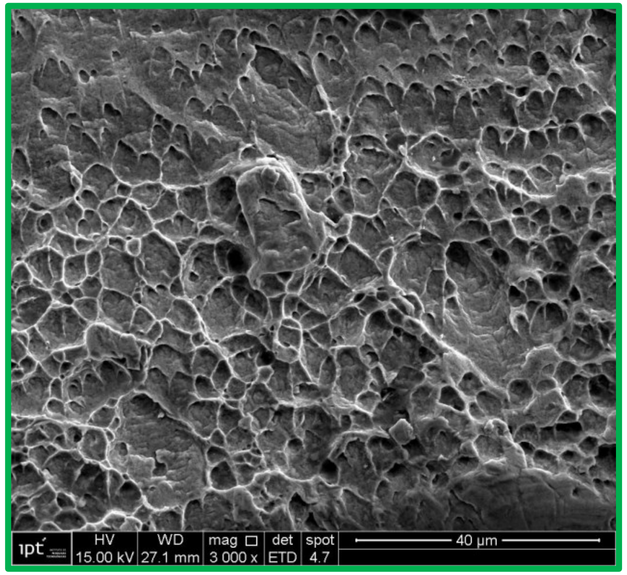
Results



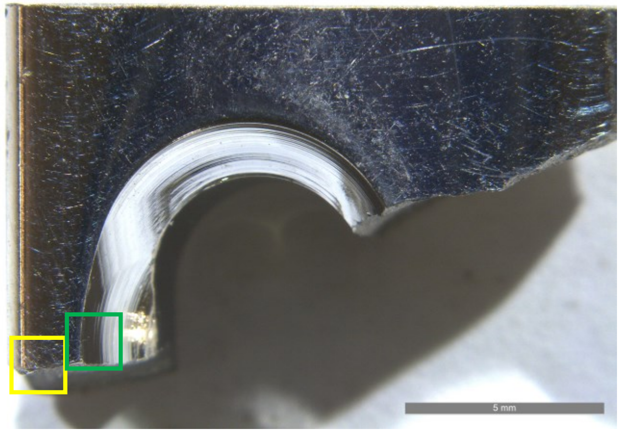
Most of the fracture surface corresponds to stable crack propagation

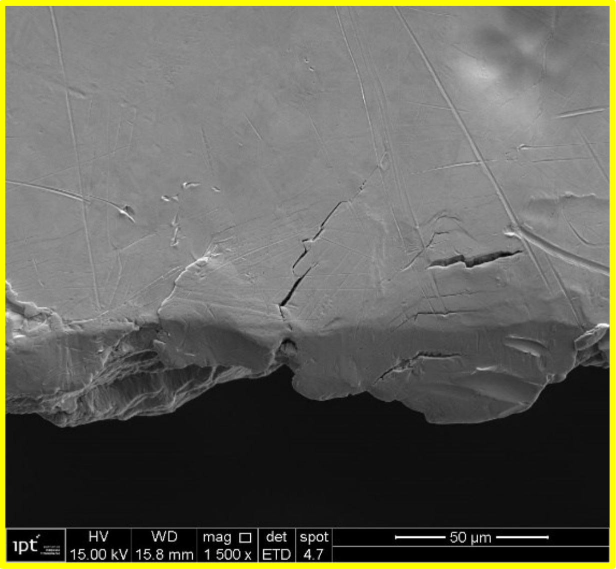


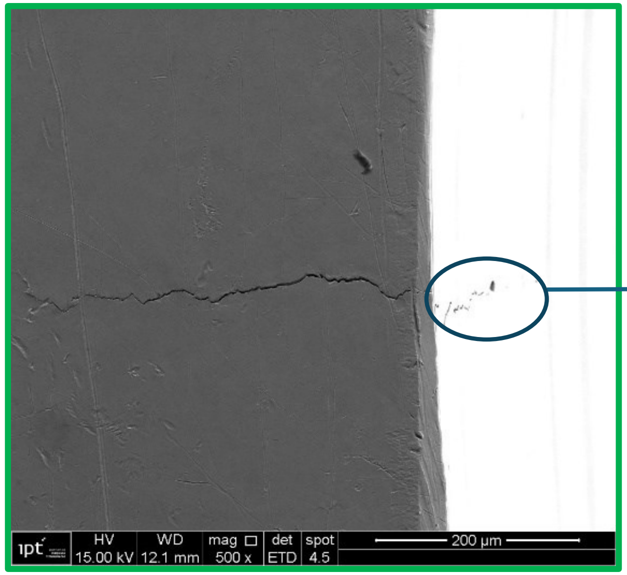


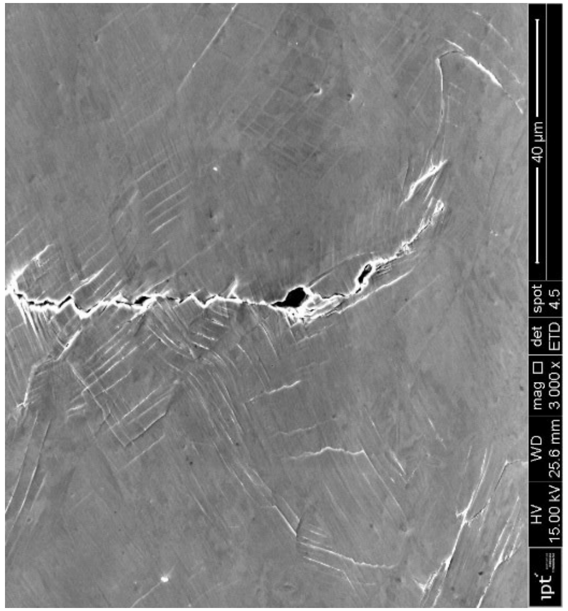


Results



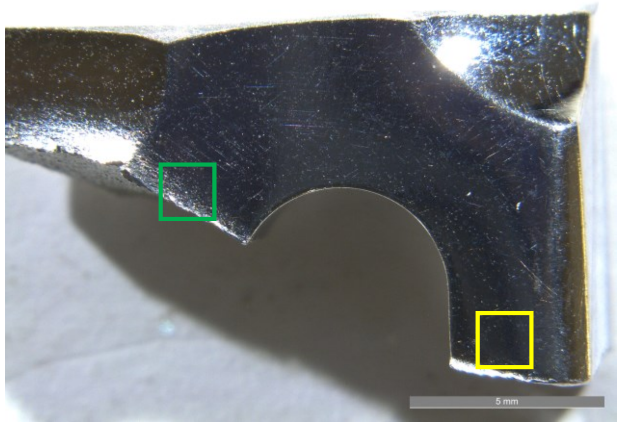


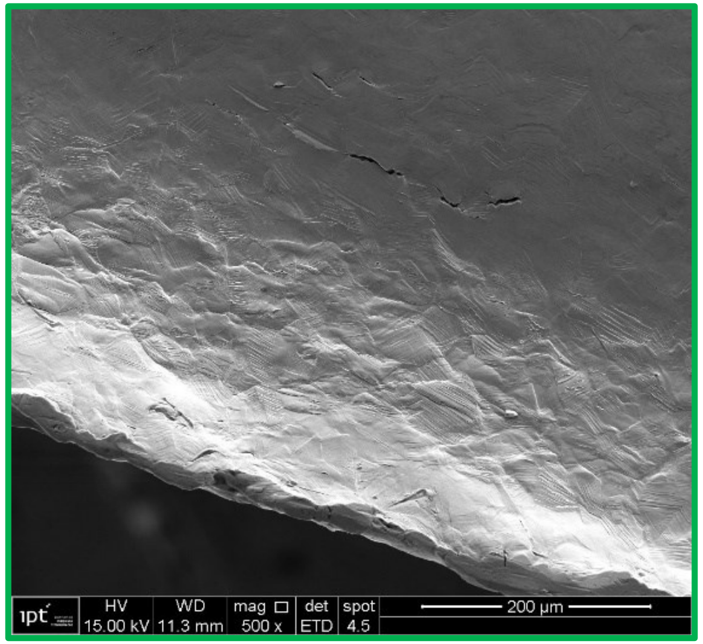


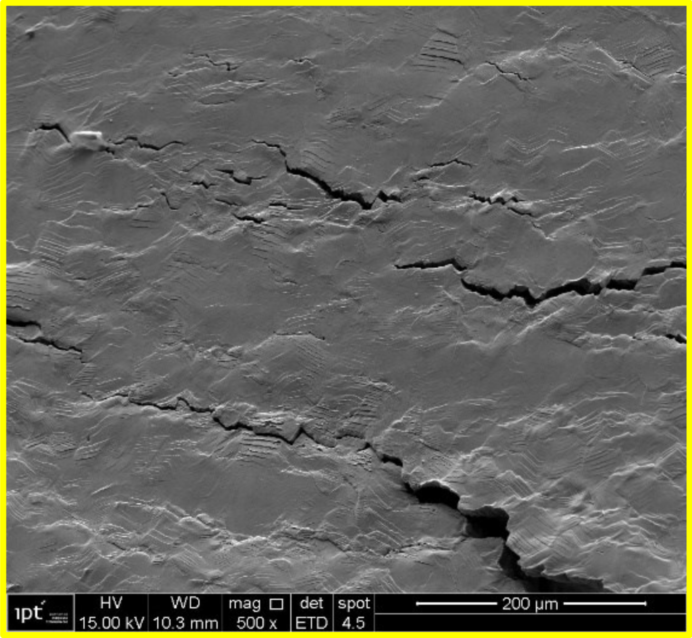


Secondary cracks on the top surface of the implant (away from the bone)

Results

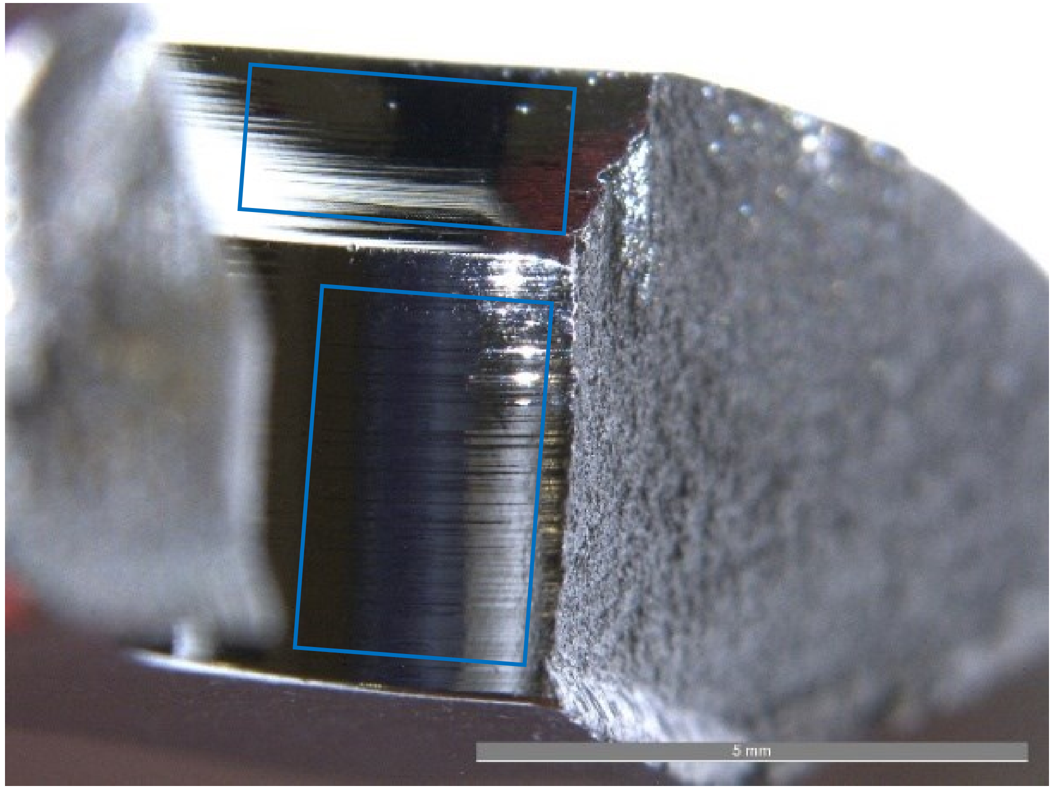






Secondary cracks on the bottom surface of the implant (next to the bone)

Results



All compression holes had tool marks

Although we could not find evidences directly relating them to fatigue crack nucleation, they are not allowed by:

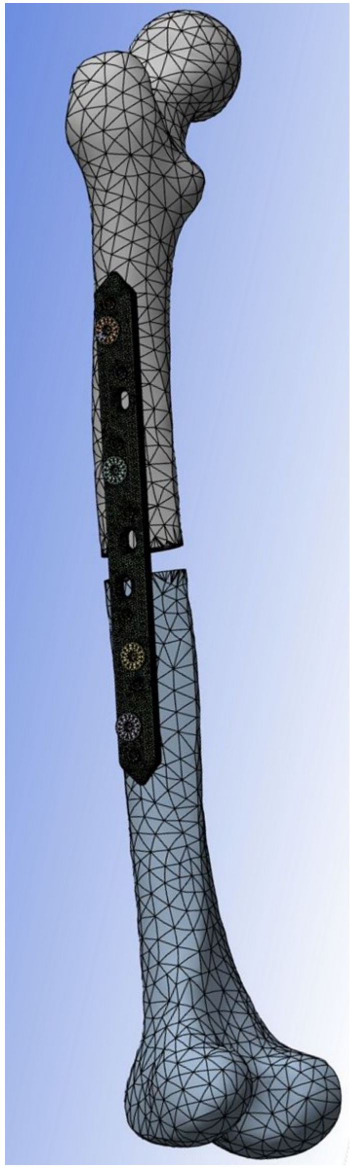
- ABNT NBR 12932/ASTM F86 (Surface Preparation and Marking of Metallic Surgical Implants)
- ABNT NBR 15676-1/ASTM F382 (Metallic bone plates - Part 1: Requirements).

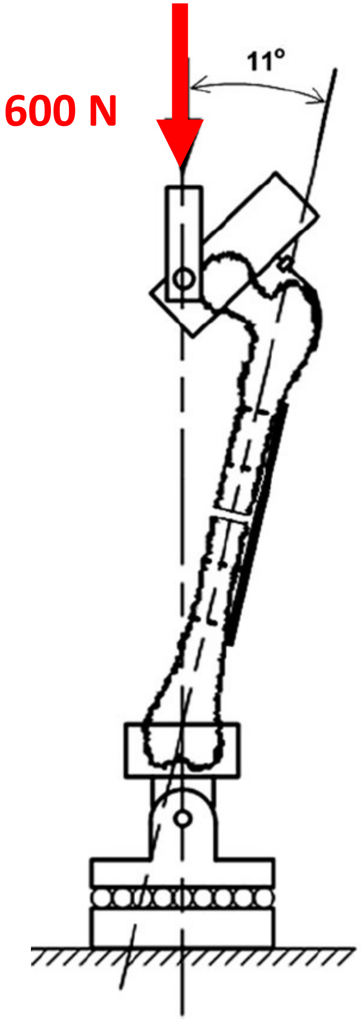
Exploratory Finite Element Analysis

Based on references [1] and [2]

Holes #6, #7 and #11: no screws
Bone fracture region = gap

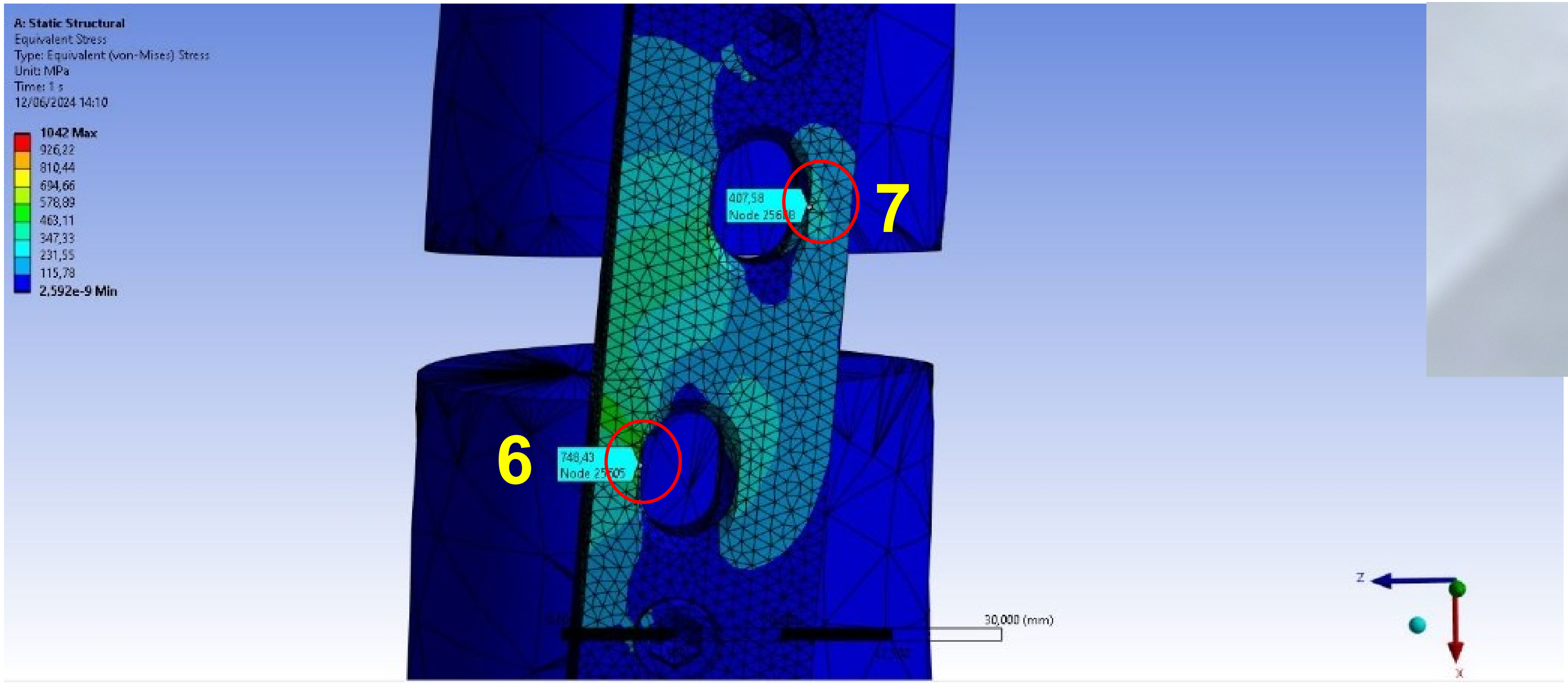
Loading: 600 N at 11° angle to simulate weight bearing (leads to bending stresses)

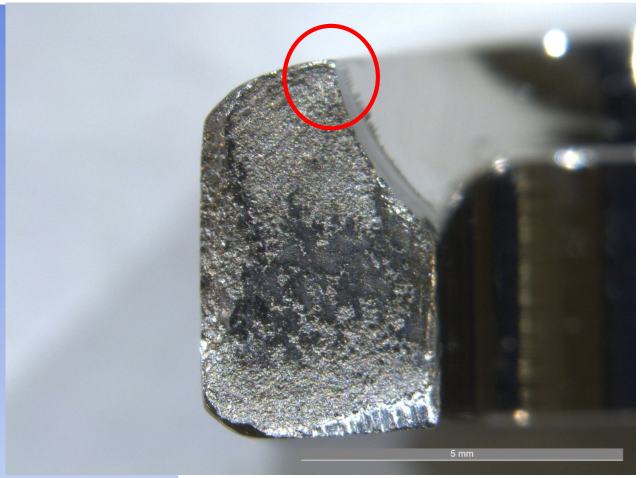




Source: [1]

[1] C. Kanchanomai, V. Phiphobmongkol, P. Muanjan, Fatigue failure of an orthopedic implant – A locking compression plate, Engineering Failure Analysis 15 (2008) 521–530. https://doi.org/10.1016/j.engfailanal.2007.04.001
[2] B. Gervais, A. Vadean, M. Raison, M. Brochu, Failure analysis of a 316L stainless steel femoral orthopedic implant, Case Studies in Engineering Failure Analysis 5–6 (2016) 30–38. https://doi.org/10.1016/j.csefa.2015.12.001.





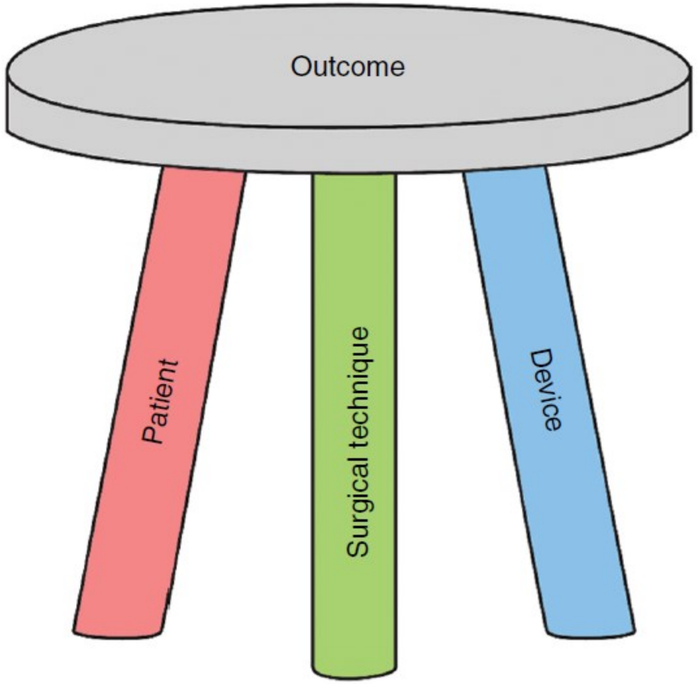
Hole #6: 748 MPa
Hole #7: 408 MPa

Fatigue limit = 394 MPa [2]
(cold-worked 316L, R = 0)

Fatigue failure due to excess loading (without bone healing) seems possible

What can lead to implant failure?

Individual health characteristics and post-operative behavior
e.g.: bone heals very slowly, patient does not follow post-operative recommendations



Source: [4]

Design and manufacturing issues
e.g.: presence of stress raisers, wrong material, inadequate microstructure

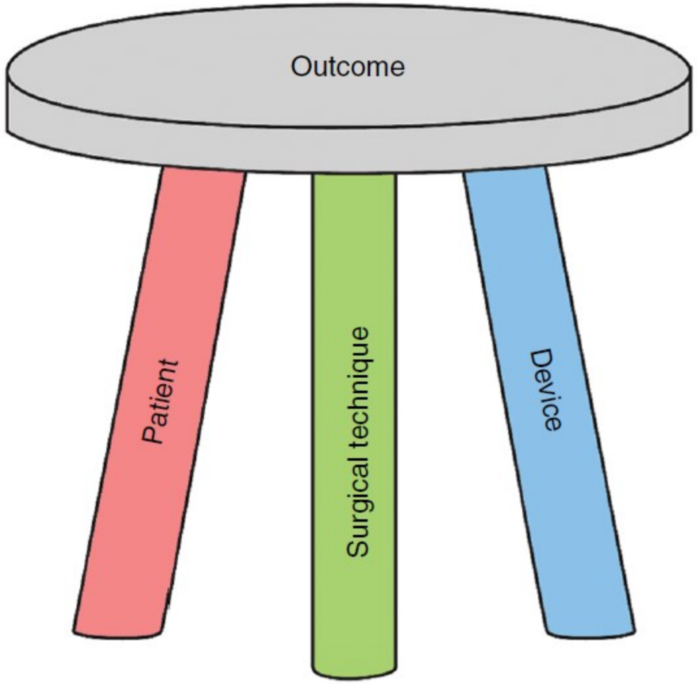
Implant installation errors
e.g.: introducing surface defects while installing the implant, wrong implant positioning

[4] M. Bowers, G. Ganot, L. Malito, B. Kondori, A. Ezechukwu, F. Svedlund, B. James, Failure Analysis of Medical Devices, J Fail. Anal. and Preven. 22 (2022) 154–180. https://doi.org/10.1007/s11668-021-01332-2.

In this case...

- ✓ **Lack of bone healing → mechanical instability**

- **Second failure case for the patient**
- **Multiple crack nucleation**
- **Patient's profile**
- **FEA**



Source: [4]

- ✓ Tool marks on compression holes (maybe)

Not allowed by the relevant standards

- ✓ Outside the scope of this investigation

Previous failure could have called for a different surgical approach?

[4] M. Bowers, G. Ganot, L. Malito, B. Kondori, A. Ezechukwu, F. Svedlund, B. James, Failure Analysis of Medical Devices, J Fail. Anal. and Preven. 22 (2022) 154–180. https://doi.org/10.1007/s11668-021-01332-2.

This failure in the context of Brazil

PERGAMON

Engineering Failure Analysis 9 (2002) 621–633

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Failure analysis of surgical implants in Brazil

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Received 27 May 2002; accepted 23 June 2002

Engineering Failure Analysis 97 (2019) 354–373

Contents lists available at ScienceDirect

Engineering Failure Analysis

journal homepage: www.elsevier.com/locate/engfailanal

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Review

Selected cases of failure analysis and the regulatory agencies in Brazil. Part 1: Aviation, railway and health

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[b] Institute for Technological Research of the State of São Paulo, Brazil

- Unreliable implant certification procedures
- Implant retrieval does not follow ABNT NBR ISO 12891-1 recommendations
- Brazilian Health Regulatory Agency should take immediate actions to monitor and investigate failures of orthopedic implants

In this case:

- The prior failure was not analyzed
- Screws were not available for analysis
- Poor implant retrieval documentation (e.g.: if the device was damaged during explantation)
- Tool marks were not in accordance with the relevant standards

Thank you!

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