amber implants

3D printed customized spinal implants

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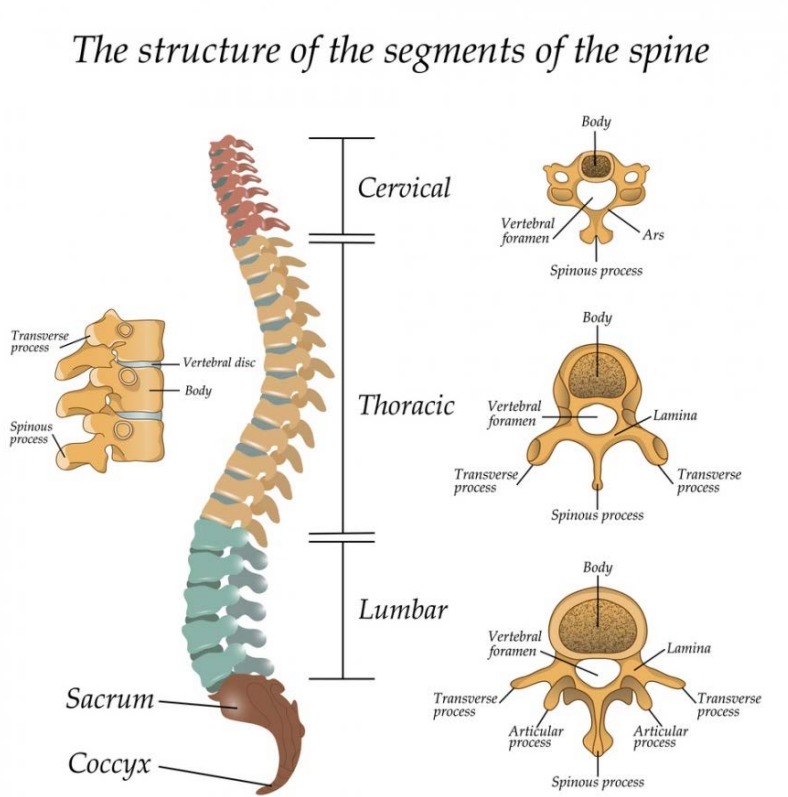
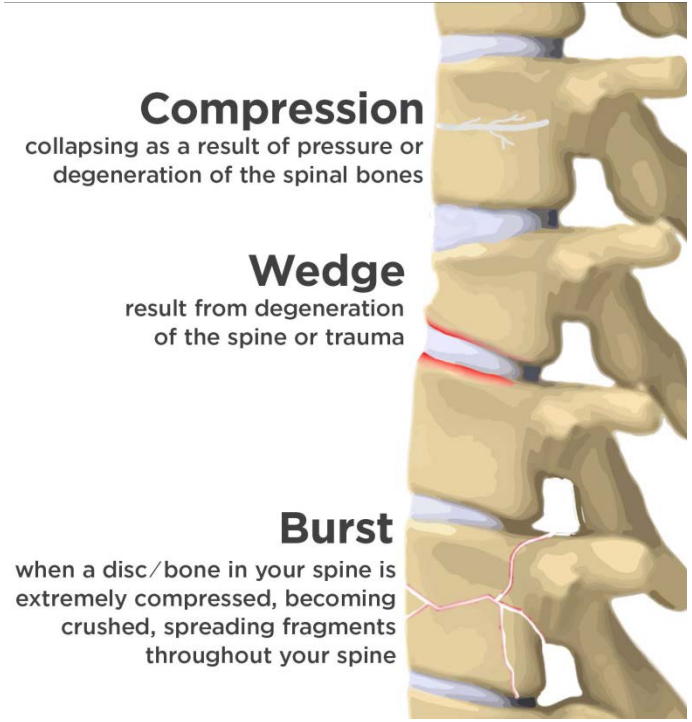
Spinal columns and clinical needs

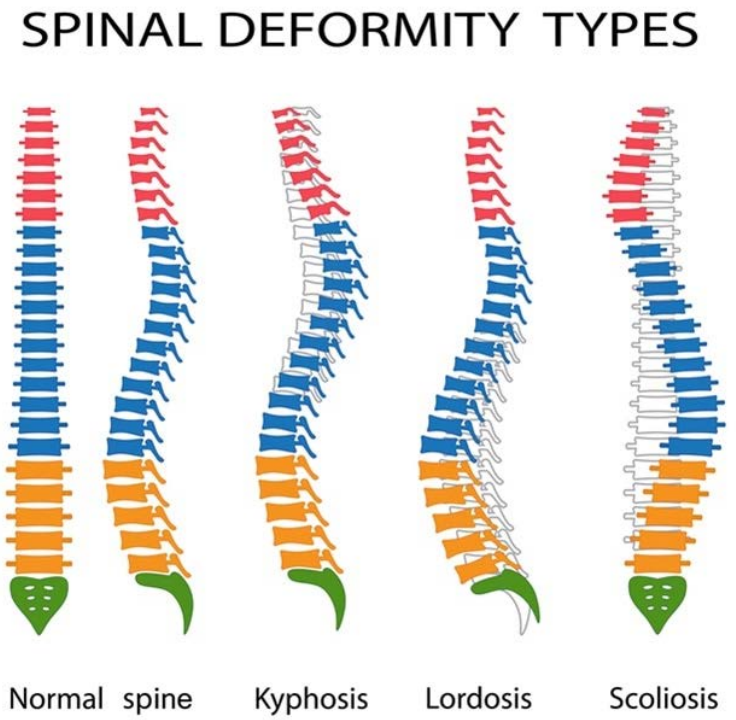
80% of adult population will experience back pain at some point in their lives

2 million people in the Netherlands suffer from either neck pain or back pain

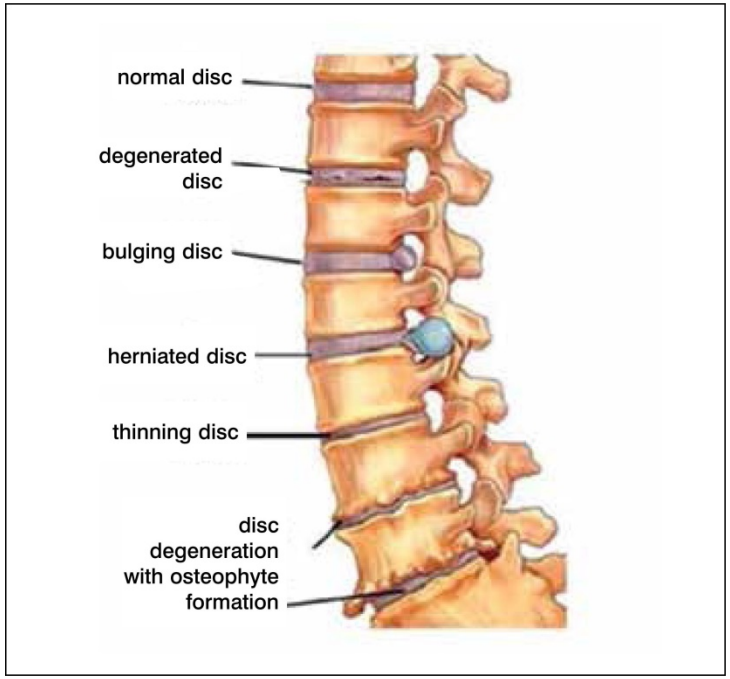


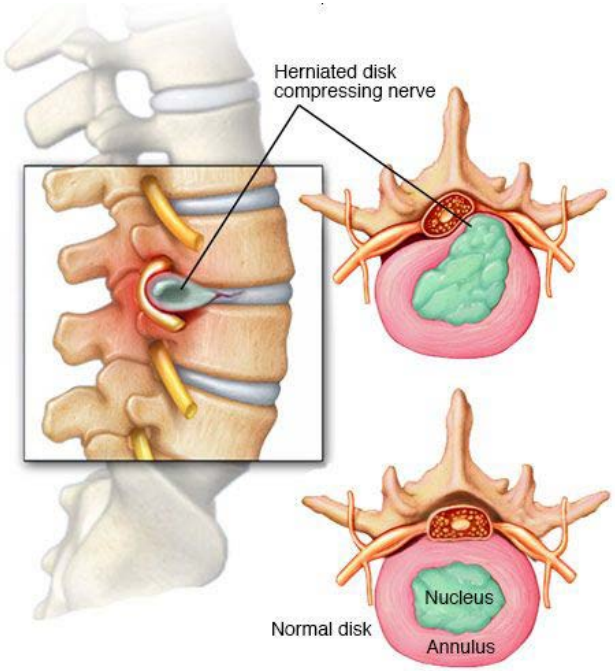
Spinal disorders: Vertebral fracture and curvature deformity





Spinal disorders: Intervertebral disc related





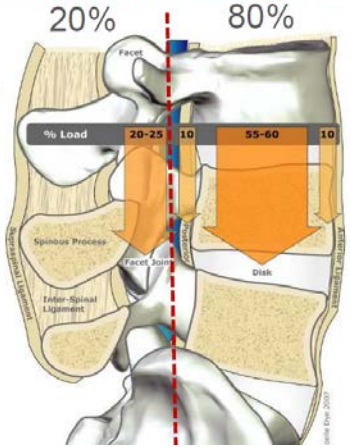
Disc degeneration: Adjacent disease

LOAD BALANCE (STRESS TRANSFER) – HEALTHY

- Vertebra + Disc = 55 - 60%
- Cortical shell = 10%
- Posterior Ligaments = 10-15%

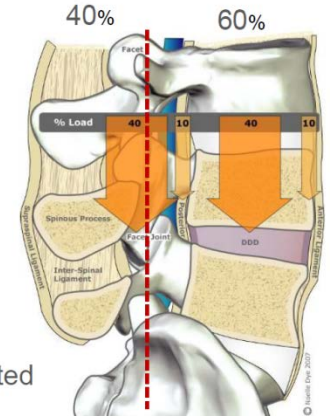
} 80%

- Facets = 20-25% Load transmitted uniformly across endplates & disc
- Uniform load transmits to annulus
- Isotropic stress profile
- Ligaments pull stress away from disc
- 80% Anterior : 20% Posterior

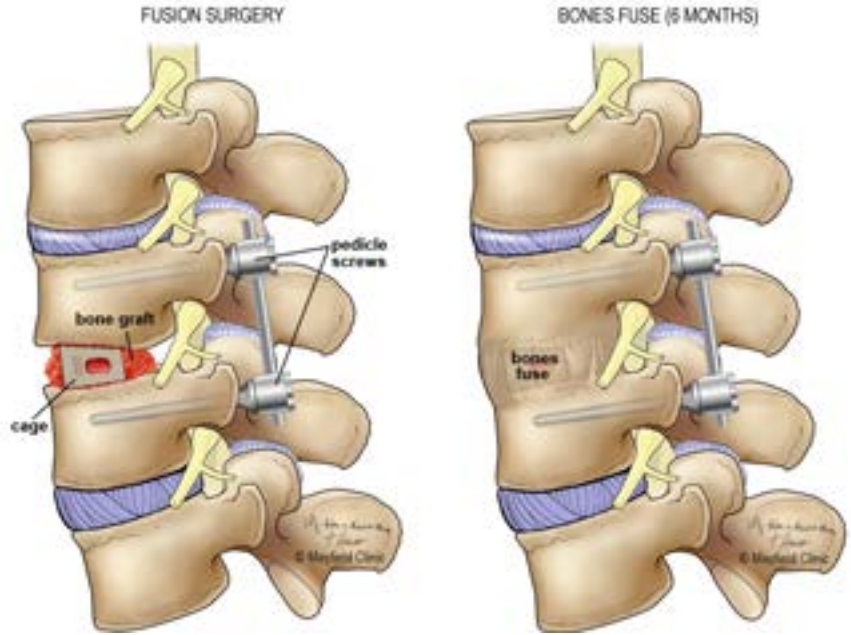


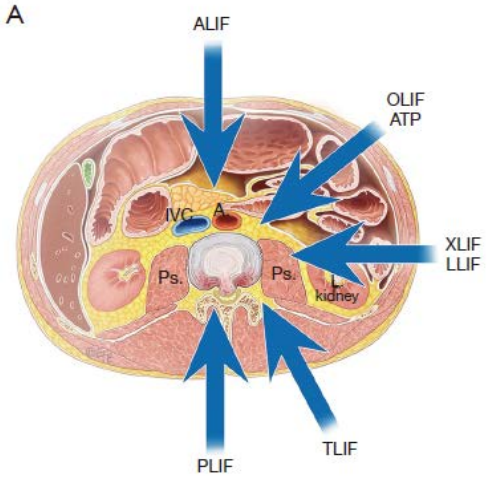
LOAD BALANCE - DEGENERATIVE

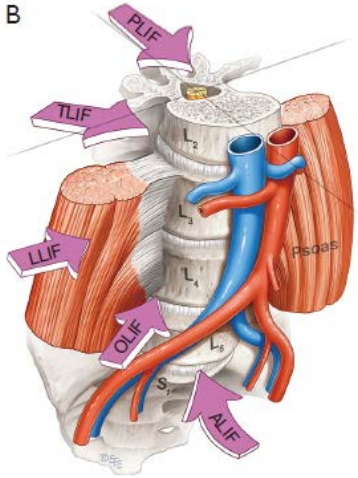
- Less Efficient
- Vertebra + Disc = 40%
- Cortical shell = 10%
- Posterior Ligaments = 10%
- Facets = 40%
- Facets > load transmission
- Stress profile anisotropic
- Excessive stress & COR transmitted posteriorly



Treatment of the unhealthy disc

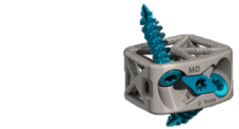






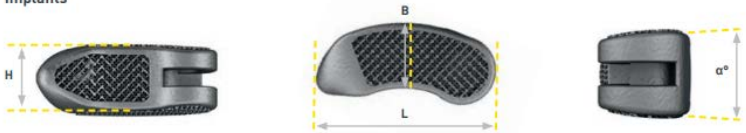
Type of cages

Titanium, PEEK, Porous Titanium



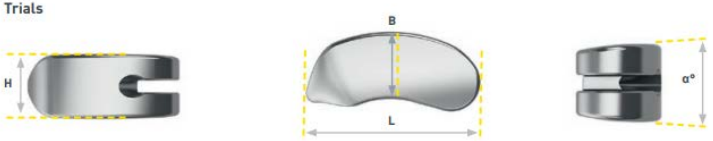
Mass produced implants

Implants



EIT TLIF Implants									
	10 mm x 28 mm (Width x Length)			10 mm x 32 mm (Width x Length)			12 mm x 32 mm (Width x Length)		
Height	Lordosis			Lordosis			Lordosis		
	0°	8°	12°	0°	8°	12°	0°	8°	12°
7 mm	TEI00728			TEI00730			TEI00732		
8 mm	TEI00828	TEI80828		TEI00830	TEI80830		TEI00832	TEI80832	
9 mm	TEI00928	TEI80928	TEI30928	TEI00930	TEI80930	TEI30930	TEI00932	TEI80932	TEI30932
10 mm	TEI01028	TEI81028	TEI31028	TEI01030	TEI81030	TEI31030	TEI01032	TEI81032	TEI31032
11 mm	TEI01128	TEI81128	TEI31128	TEI01130	TEI81130	TEI81130	TEI01132	TEI81132	TEI31132
12 mm	TEI01228	TEI81228	TEI31228	TEI01230	TEI81230	TEI31230	TEI01232	TEI81232	TEI31232
13 mm	TEI01328	TEI81328	TEI31328	TEI01330	TEI81330	TEI31330	TEI01332	TEI81332	TEI31332
14 mm	TEI01428	TEI81428	TEI31428	TEI01430	TEI81430	TEI31430	TEI01432	TEI81432	TEI31432
15 mm	TEI01528	TEI81528	TEI31528	TEI01530	TEI81530	TEI31530	TEI01532	TEI81532	TEI31532

Trials



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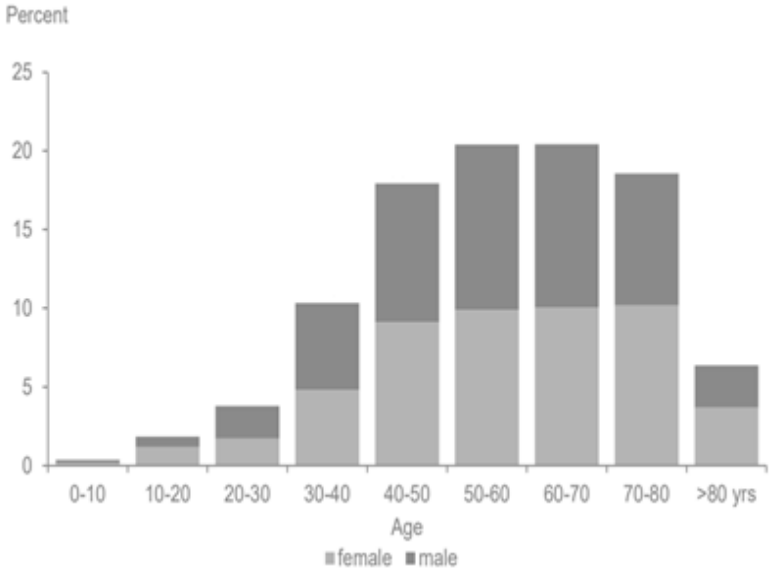
8 mm	TET00828	TET80828		TET00830	TET80830		TET00832	TET80832	
9 mm	TET00928	TET80928	TET30928	TET00930	TET80930	TET30930	TET00932	TET80932	TET30932
10 mm	TET01028	TET81028	TET31028	TET01030	TET81030	TET31030	TET01032	TET81032	TET31032
11 mm	TET01128	TET81128	TET31128	TET01130	TET81130	TET81130	TET01132	TET81132	TET31132
12 mm	TET01228	TET81228	TET31228	TET01230	TET81230	TET31230	TET01232	TET81232	TET31232
13 mm	TET01328	TET81328	TET31328	TET01330	TET81330	TET31330	TET01332	TET81332	TET31332
14 mm	TET01428	TET81428	TET31428	TET01430	TET81430	TET31430	TET01432	TET81432	TET31432
15 mm	TET01528	TET81528	TET31528	TET01530	TET81530	TET31530	TET01532	TET81532	TET31532

3 (footprints) x 3 (angles) x 8 (heights) x 2 (trials + implants) =144 pieces for one operation!

Mass produced implants, What's missing?



Age distribution of the patients

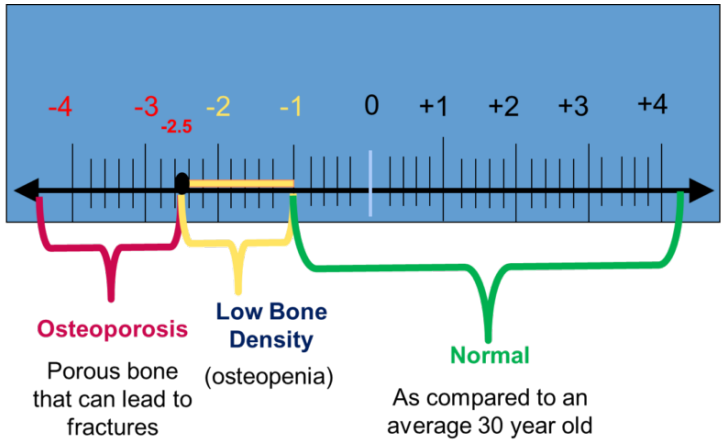
Customized spine Implants: Design criteria

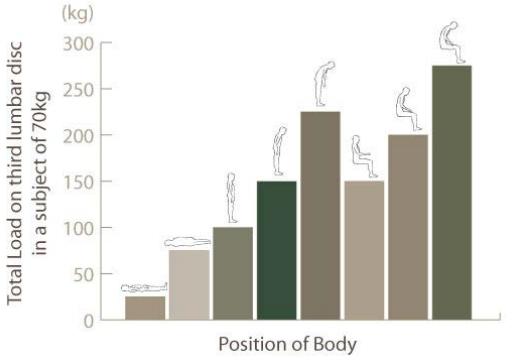
Variables	Values	Parameter
Age	20 – 90 years	Loads T-score Time
Gender	See other parameters	T-score
Peak forces	Force on vertebrae during comfortable lifting Female: 1671 N Male: 2080 N	Loads
Cyclic forces	50 – 150 % body weight	Loads
Bone strength	Female: -99.78x + 11006N (x in years) Male: -76.94x + 8864N	T-score
Bone density	Female: -1.3x + 214 kg/m3 (Ash density) Male: -1.1x + 200 kg/m3 Osteoporotic: Density: 60 – 90 kg/m3 Describing the bone density of males with a linear graph is relatively accurate, but for females this is not the case. Females have a close to linear reduction of bone density until the menopause where a high decrease of bone density is observed. After this large decrease the bone density stays almost stable during aging.	T-score
Bone stiffness	Increases due to mineralization Decreases due to density decrease Increase with increasing force Male ~25% higher than female	T-score

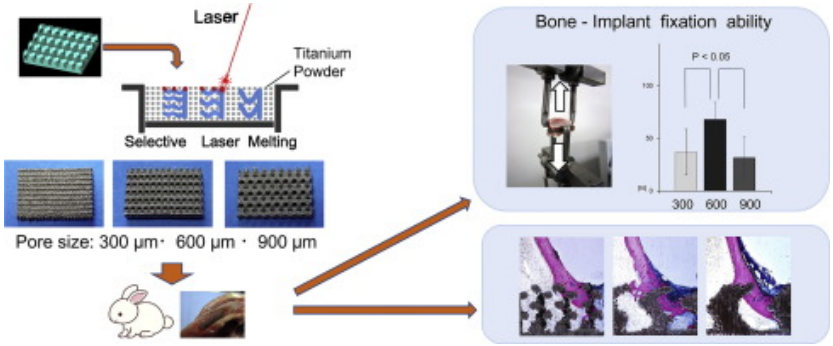
Customized spine Implants: Design criteria

Variables	Values	Parameter
Speed bone ingrowth	3 to 6 months	Time
Product life cycle	After a certain time the bone can support itself, so no mechanical strength from the implant is needed. Corrosion is still a problem which stimulates osteolytic cytokines. Vanadium, Titanium and Aluminum al reach plateau concentrations in the body after 8 years.	Time
Disease	Most common when spinal implant needed: Osteoporotic: See bone density Fracture: See fracture	T-score
Fracture	Maximum recorded density decrease is 13% Fully recovered after 1 year	T-score
Pore size	Optimal pore size age related?	Pore size
Menopause	See bone density and strength	T-score
Body weight	During a study about forces on vertebrae the following formula for bodyweight was found: Female: 0.027x + 56.1 kg Male: -0.257x + 87.1 kg Where x is in years	T-score
Angle	Angle between L2 and L3 is between 0 and 15 degrees Average: 6.89 deg	Design Loads
Vertebrae size	Upper vertebrae width L3 A Female: 40.9 ± 3.6 mm	Design Loads

Customized spine implants: Design criteria







Customized spine implants: Group definition

Group **1**:
Healthy active people
T-score: between -1 and 2.5 with high loads
Bone mineral density: > 0.98 g/cm3
Endurance limit: 2500 N
Percentage of current cases: 26.35%

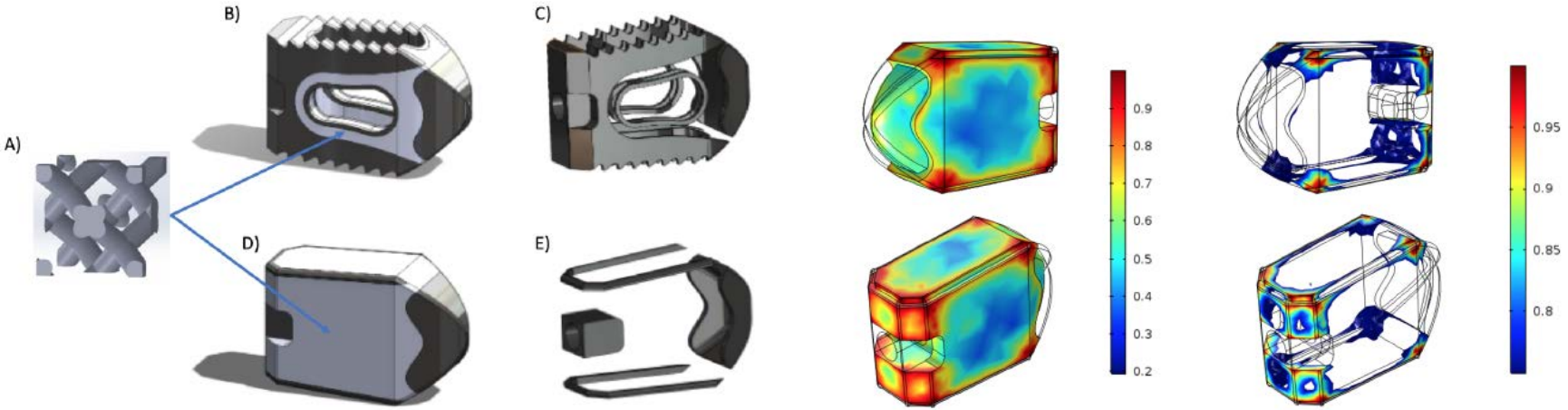
Group **2**:
Healthy – with normal activity
T-score: between -1 and 2.5 with medium loads
Bone mineral density: > 0.98 g/cm3
Endurance limit: 2000 N
Percentage of current cases: 26.35%

Group **3**:
Osteopenia
T-score: between -1 and -2.5
Bone mineral density: > 0.85 g/cm3, < 0.98 g/cm3
Endurance limit: 1500 N
Percentage of current cases: 16.4%

Group **4**:
Osteopenia with low activity
T-score: between -1 and -2.5
Bone mineral density: > 0.85 g/cm3, < 0.98 g/cm3
Endurance limit: 1100 N
Percentage of current cases: 16.4%

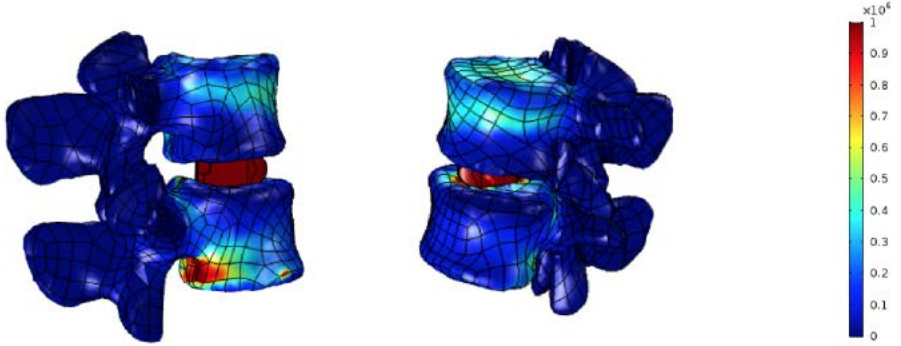
Group **5**:
Osteoporosis
T-score: below-2.5
Bone mineral density: < 0.85 g/cm3
Endurance limit: 800 N
Percentage of current cases: 14.5%

Topology optimization for each group



Conclusion

The developed method showed to be reliable and improved the mechanical performance of the implant.



Through topology optimization the fatigue lifetime of the device was prolonged and the stiffness considerably reduced.