The Next Generation of 3D-Printed Implants Leverages Computational Design

Matthew Shomper, Not a Robot Engineering

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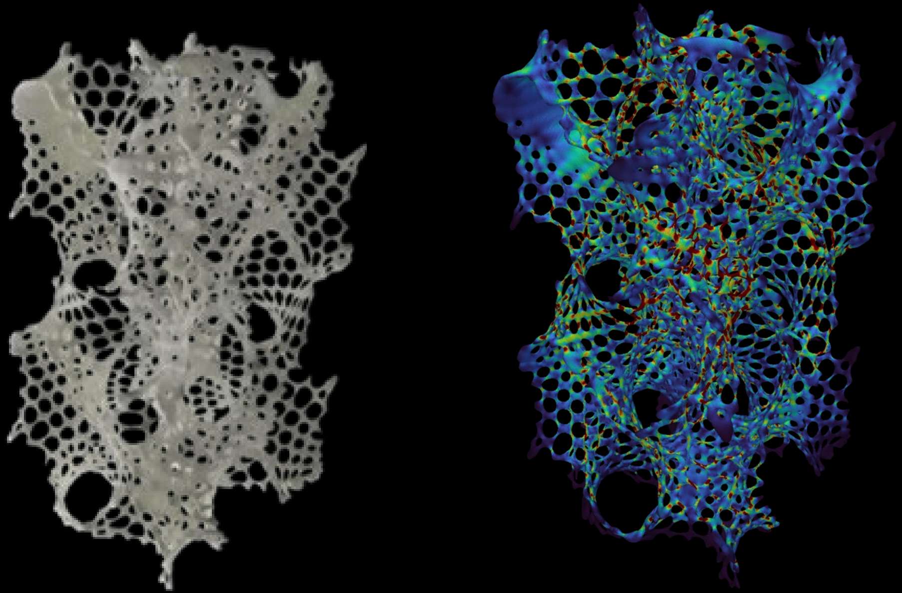

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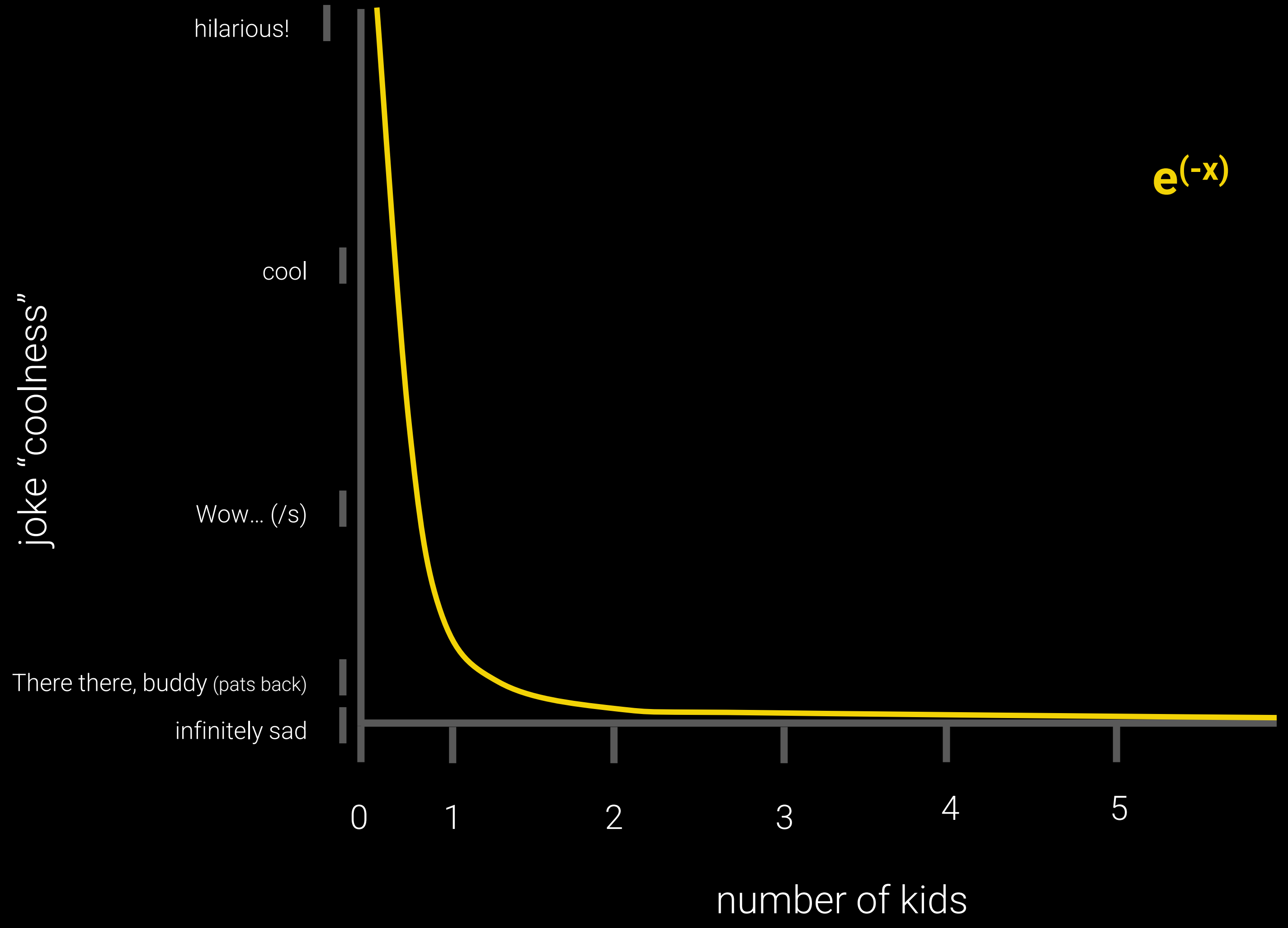
OMTEC | Matt Shomper | Principal Engineer


hilarious!
cool
Wow... (/s)
There there, buddy (pats back)
infinitely sad
joke "coolness"
$e^{(-x)}$
0
1
2
3
4
5
number of kids

OUTLINE | AGENDA

- A Little About Me - *coffee and computational design*
- What is Computational Design - *(hint… not AutoCAD)*
- Balancing Act of Bone - *fragile ecosystem with high stakes*
- Reducing Stiffness - *a general strike on hunks of metal*
- History of Additive Ortho - *a sprint to the next-gen*
- Design Limitations - *how printing got ahead of the curve*
- Computational Modeling - *a new solution for unmet needs*
- Navigating the Design Landscape - *so many options, so little time…*
- Case Study 1 - *patient-specific geometry*
- Case Study 2 - *simulation-informed structures*
- Wrap-up - *Questions*

A LITTLE ABOUT ME

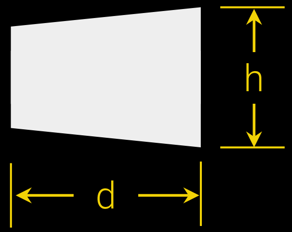
- 4 kiddos *(+1 on the way…)*
  - *Stasia, Mo, Arrow, Tobias*
  - *(why do we do this to ourselves…)*
- musical family
  - *Over 50 years combined piano experience*
- coffee obsession
  - *green bean > perfect espresso*
  - *9 coffee brewing methods*
- expert in biomimicry for human-use products
  - *orthopedic implants*
  - *filtration systems*
  - *heat transfer systems*
  - *consumer goods (earbuds, padding, wearables)*

FOUNDED COMPANIES

LATTICE ROBOT | NOT A ROBOT | uniphorm | LIMBOLOGY

WHAT IS COMPUTATIONAL DESIGN?

- Computational Design ≠ Computer Aided Design (sorry AutoCAD…)
- Computational Design ≠ Parametric Design
- Computational Design == **Algorithmic** Design
- Computational Design == Systems Design



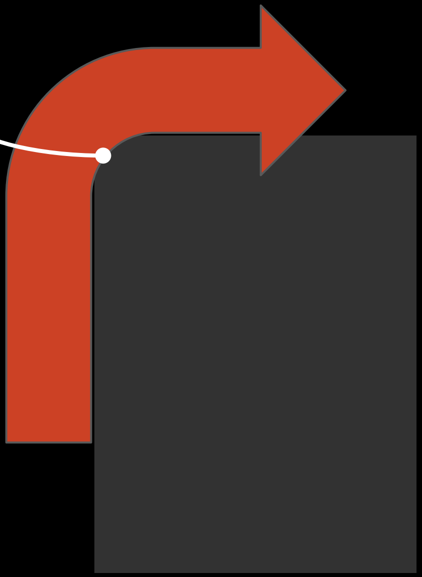
Computational design is a field that involves the use of computer algorithms, simulations, and data analysis to support and enhance the design process

How about an illustration!

WHAT IS COMPUTATIONAL DESIGN?

No zero-turn mower.

Suburban dad fail



WHAT IS COMPUTATIONAL DESIGN?

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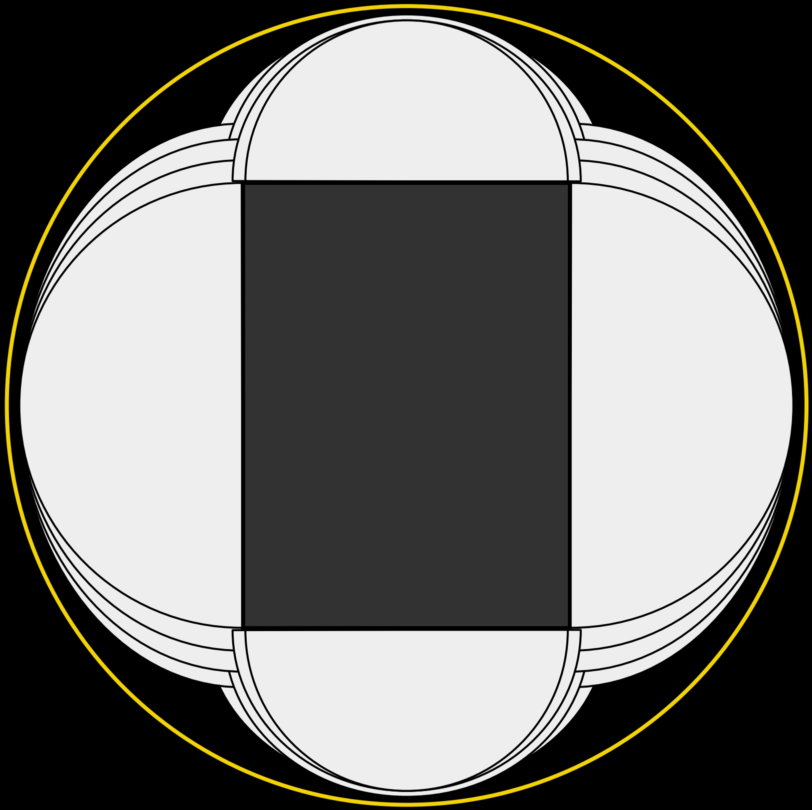


Let's take this to 3D!

WHAT IS COMPUTATIONAL DESIGN?

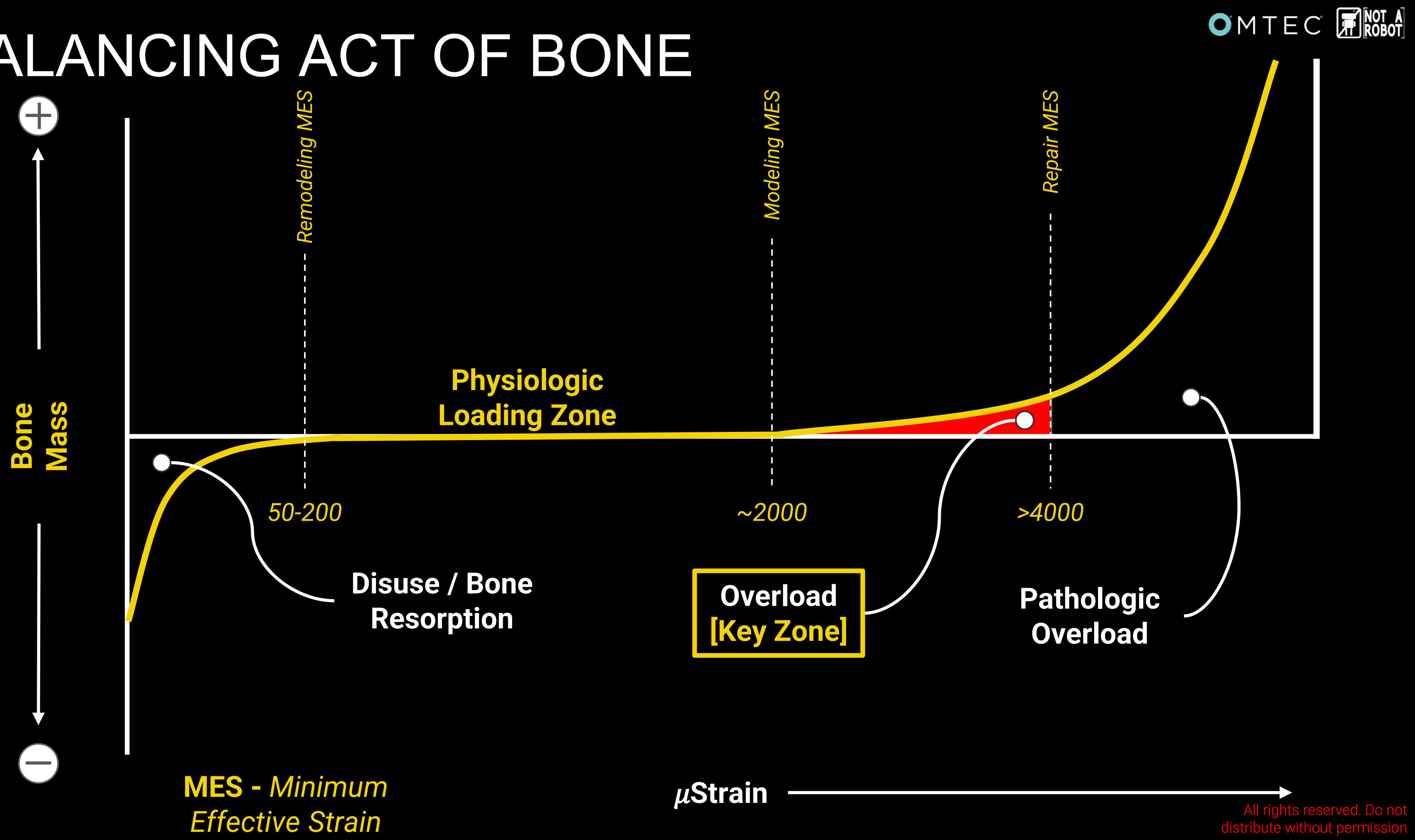
I’m ambiguous **and** conflicting!

cubesphere

BALANCING ACT OF BONE

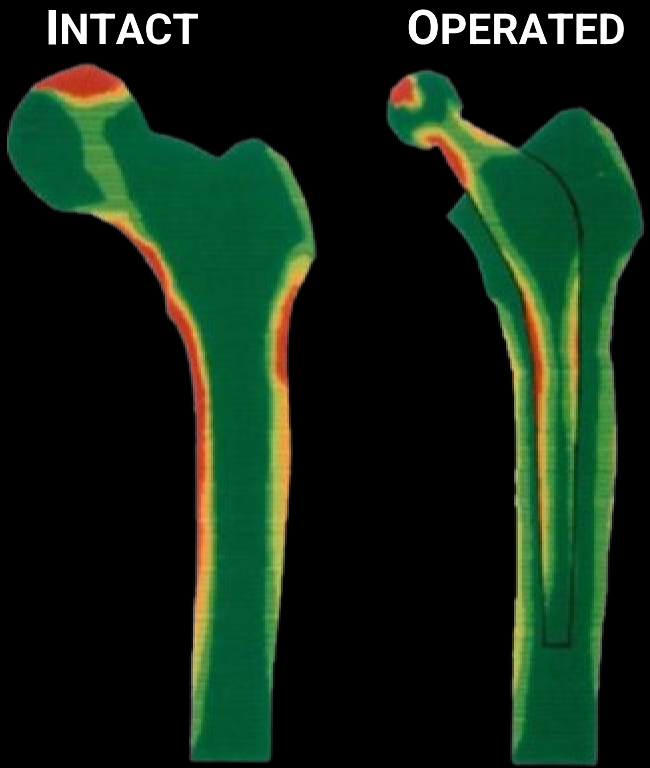
- **Julius Wolff (19th Century)**
  - *Wolff's Law states that bones will adapt to the degree of mechanical loading, such that an increase in loading will cause the architecture of the internal, spongy bone to strengthen, followed by the strengthening of the cortical layer. Furthermore, a decrease in stress on the bone will cause these bone layers to weaken.*
- **Harold Frost (1960s)**
  - *There exists a mechanism that monitors bone metabolism (longitudinal growth, bone modeling, and remodeling activities) in relation to mechanical usage, the "mechanostat." [4]*
  - *Modeling adapts bone to overloads, by enhancing additions of new bone and by changing bone architecture, and remodeling adapts bone to underloads by removing bone next to marrow and conserving normally used bone [4]*
- Recent Literature has affirmed the mechanostat theory and the importance of targeted microstrain for bone remodeling

BALANCING ACT OF BONE



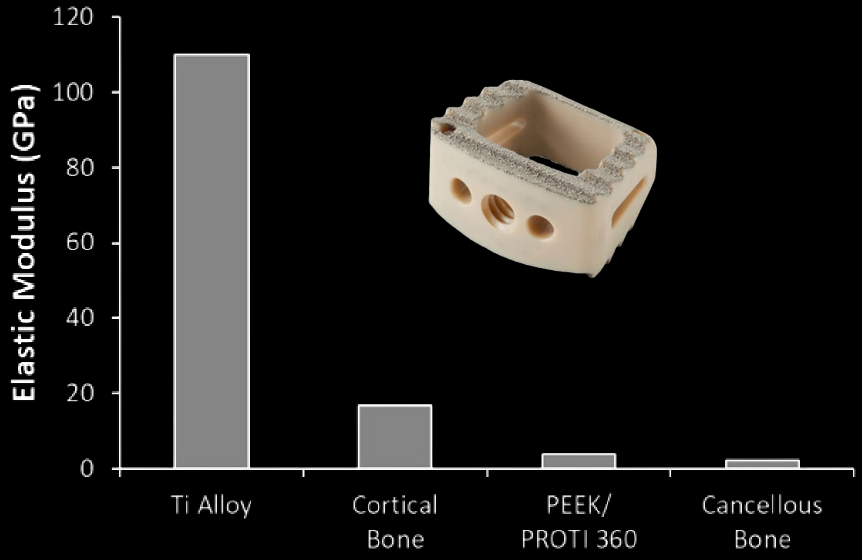
BALANCING ACT OF BONE

- When metals are used, the higher stiffness of the implant results in bone loss as a result of decreased physiologic loading of the bone [5]
- Changes in cyclic bone stresses of less than 1% of the ultimate strength can cause measurable differences in bone remodeling after a period of a few months [6]
- Low-stiffness stems alter this pattern, leading to reduced proximal bone loss, increased proximal medullary bone hypertrophy, and no distal cortical hypertrophy, suggesting that stem stiffness has a profound effect on stress shielding. [7]



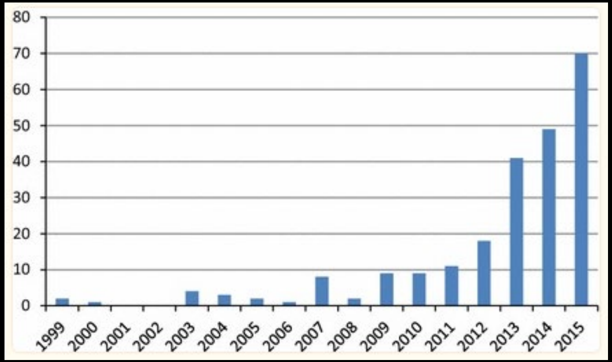
REDUCING STIFFNESS

- The early 2000s saw the rise of PEEK (polyether ether ketone), a bioplastic with a much closer modulus to that of bone
- Stiffness reduction in Ti implants was limited by traditional CAD and machining techniques
- Although PEEK was biocompatible, it lacked the osteogenic capabilities of titanium
- This was rectified with a titanium plasma spray, with mixed success

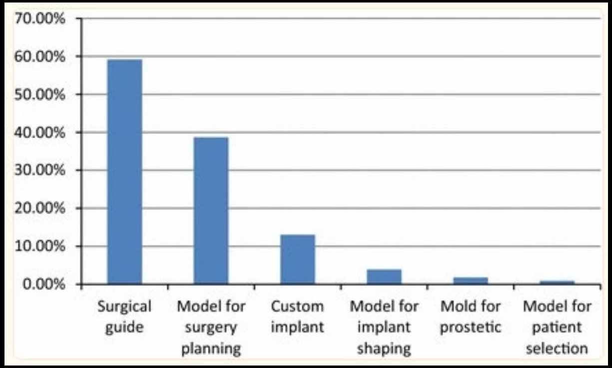


HISTORY OF ADDITIVE ORTHOPEDICS

- Early 1980s - Chuck Hull invents stereolithography [1]
- Late 1980s - Joseph Beaman and Carl Decker invent SLS [3]
- 1999 - Earliest description of the use of 3DP in spine surgery [1]
- 2007 - Earliest Patient-Specific implants being manufactured via AM [2]
- 2010 - One of the First FDA approvals for an AM Implant [2]
- 2010 - 2015 - Era of Research / Medical Modeling / PS Guides
- Insertion of Laminar Screws (2010)
- Cervical Pedicle Screw Placement (2011)
- Screw Jigs for Complex Deformities (2015)
- 2015 - Stryker Tritanium / K2M Cascadia - PLIF Cage 510k
- 2016 - Stryker Tritanium Acetabular Shells
- 2017 - Paragon 28 Titan 3D Wedge
- 2017 - Centinel STALIF FLX Interbody Lines (Cerv / ALIF / LLIF)
- 2019 - Genesys Spine Sacroiliac Joint Fixation Screw
- 2020 - Carlsmed aprevo Patient-Specific Deformity System
- 2022 - Redpoint Medical Patient Specific Titanium Guides (Full Foot)



3DP Papers in Orthopedics from 1999 to 2015



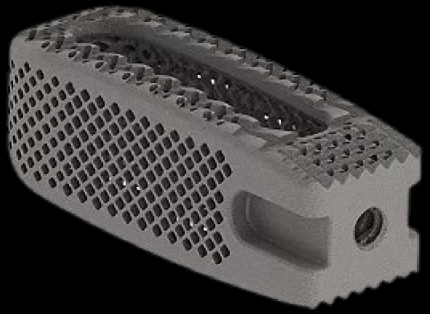
3DP Topics in Orthopedics from 1999 to 2015

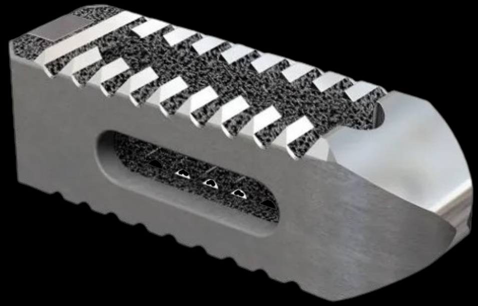
DESIGN LIMITATIONS - SOFTWARE

- By 2014, AM Metal Technology output had outpaced what designers could easily create
- Design Tools Remained Largely Parametric - Solidworks, PTC Creo, NX
- Early Softwares [Grasshopper (2014), Within Medical (2014), nTopology Element (2016)]
  - *Basic Latticing*
  - *Limited Toolsets*
  - *Hindered by Interoperability / Meshing*
- nTopology Platform [2018] was introduced with implicit modeling, a kernel based off of SDF (signed distance fields), allowing for computational design to enter the “engineering” mainstream

DESIGN LIMITATIONS

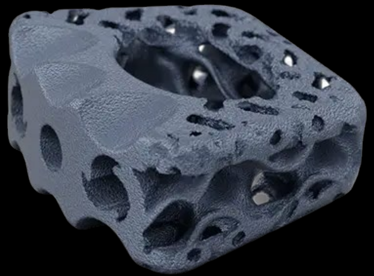
DESIGN LIMITATIONS

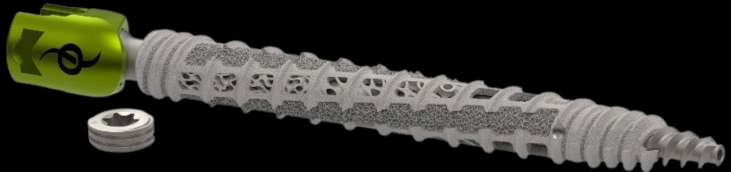


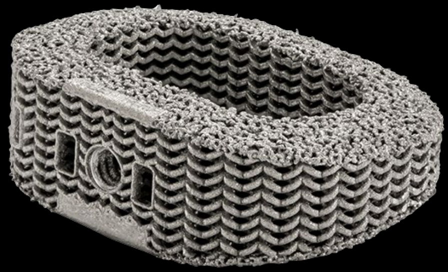


State of Market pre-2020

New Innovations







DESIGN LIMITATIONS REGULATORY

- **Test Values [Preliminary Guidance for Safety and Performance Based Criteria / Bottom 25th percentile of mechanical characteristics chosen]**
  - **ASTM F2077 - Test Methods for Intervertebral Body Fusion Devices**
    - 2% Compressive Yield - 5000 N
    - Dynamic Compression - 2000 N @ 5 Million Cycles
  - **ASTM F2267 - Measurements of Load-Induced Subsidence of Intervertebral Body Fusion Device under Axial Compression**
    - System Stiffness - 1500 N/mm (Foam Stiffness 1525 N/mm)
    - Device Compressive Stiffness - 45000 N/mm

High stiffness devices are often given a "pass" as long as they meet the structural requirements

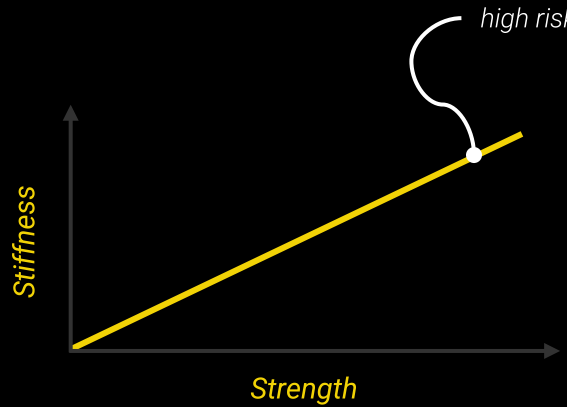
- **Regulatory Requirements**
  - **Equivalence** - strength requirements predicated on some already existing devices

    devices that "were legally marketed prior to May 28, 1976
  - **Guidance** - FDA's Technical Considerations for Additive Manufactured Medical Devices
  - **Standards**
    - ASTM F3001: Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
    - ASTM F2924: Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion

DESIGN LIMITATIONS

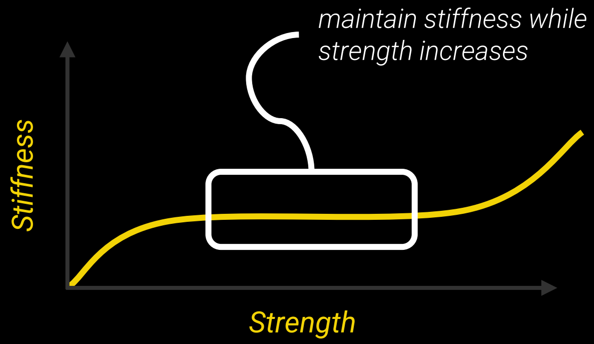
REGULATORY

- Design of functional structures requires a careful balancing of strength and flexibility
- High stiffness is correlated with subsidence and failure of fusion
- Insufficient strength may cause device breakage, expulsion, or too high of micro-movement
- **An appropriate implant stiffness range will reduce the implant's "biological footprint" inside the body**



NOT Ideal

THE BEST IMPLANT IS ONE THAT IS "FORGOTTEN" BY THE BODY'S BIOLOGICAL SYSTEMS



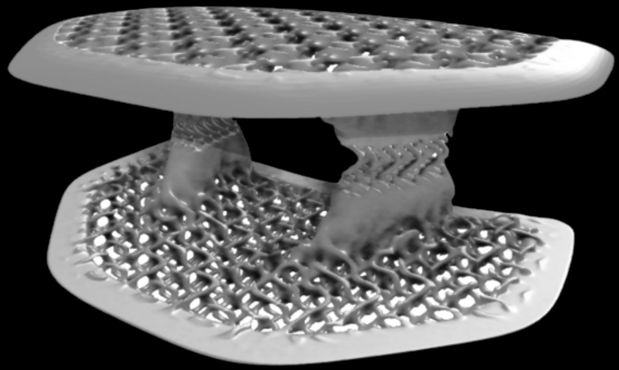
Ideal

DESIGN LIMITATIONS / REGULATORY

OLD

VS

NEW



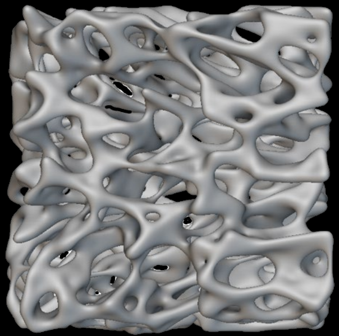
21,786 N - 50th percentile compressive force of 510k submitted devices reviewed by FDA [8]

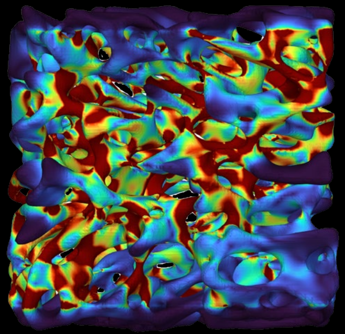
500 N - Clinically-Relevant Lumbar Intervertebral Load [9]

NO TWO ANATOMIES ARE THE SAME, SO WHY SHOULD IMPLANTS BE?

COMPUTATIONAL MODELING

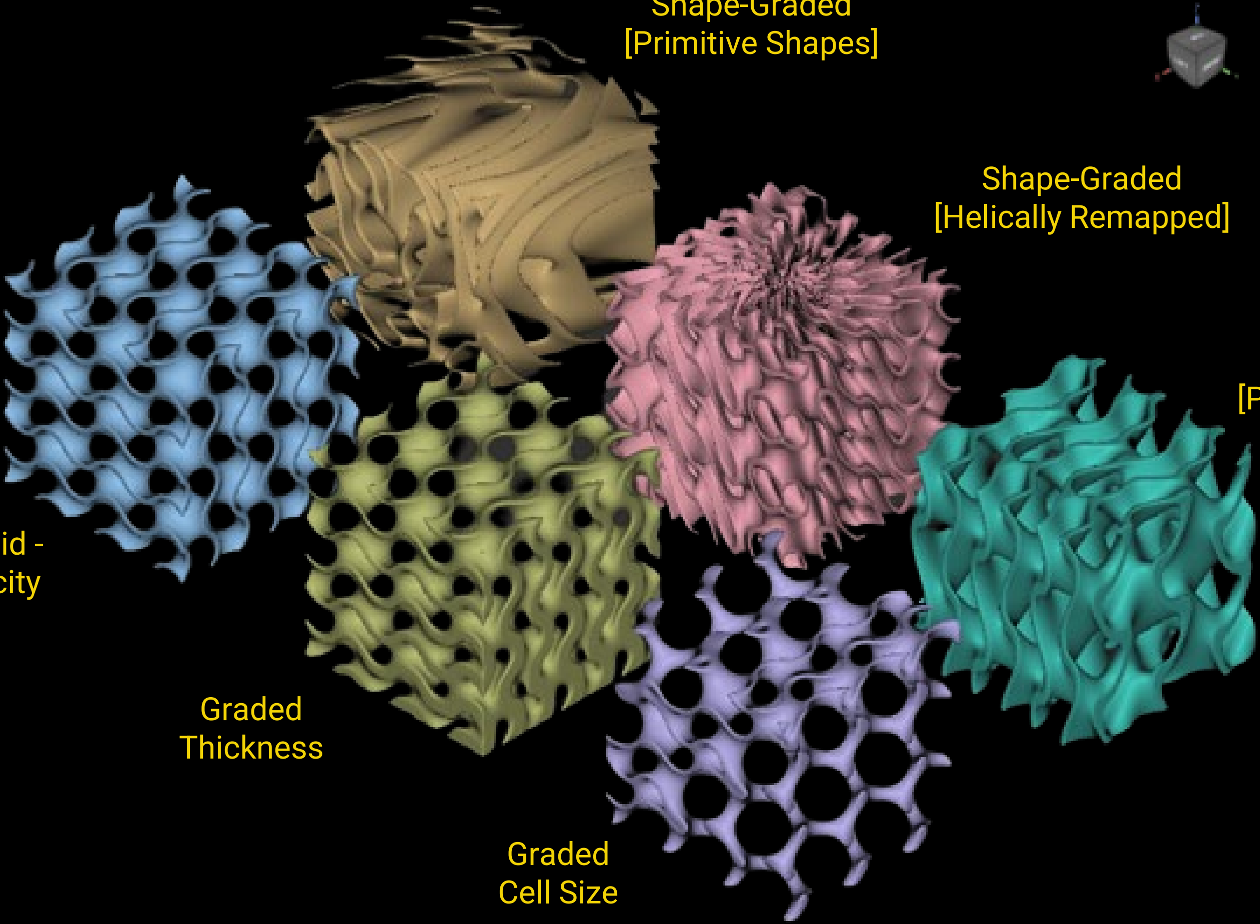
- **Solution:**
  - **Computational Modeling** allows for the creation of both ordered and random structures that weren't before possible.
  - Computational Modeling allows for further manipulation of said structures with functional grading (density, morphology, etc.)
  - Computational FEA allows for analysis of complex structures in ways not previously possible
  - Computational Modeling allows for the use of large data sets from said analyses as a feedback mechanism into the structure



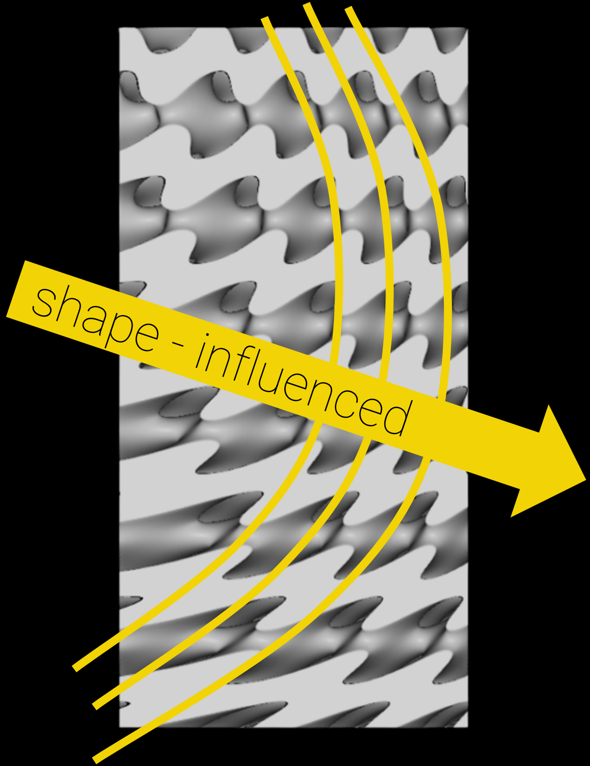


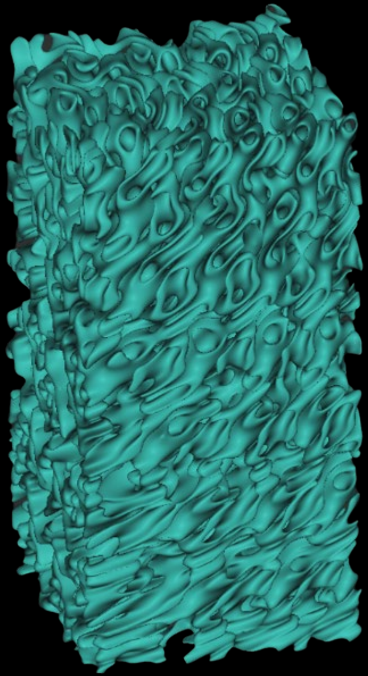
From ideation
to initial analysis:
*Less than **10** minutes*

COMPUTATIONAL MODELING

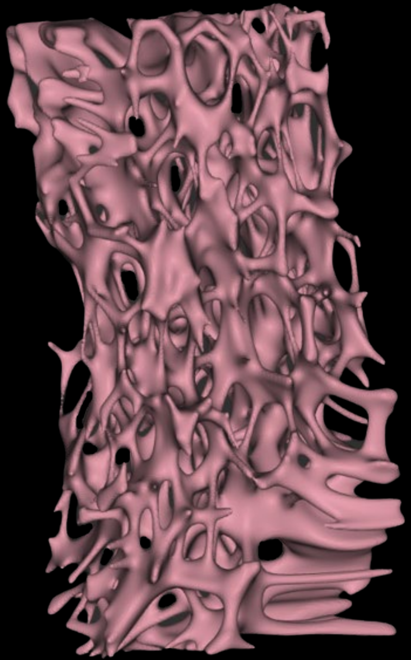


COMPUTATIONAL MODELING





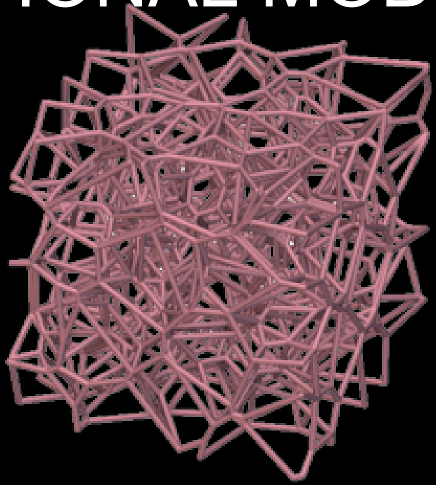
Oriented
Perforated
Strands



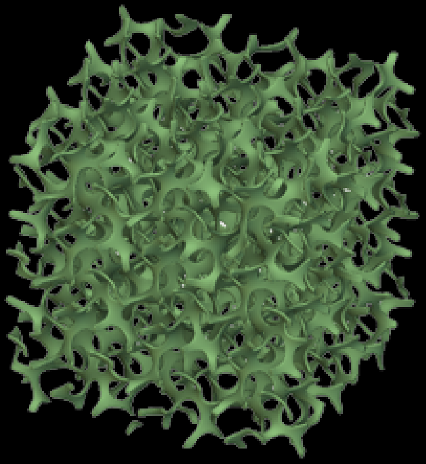
Radially-Mapped
Sheet-Strut
Hybrid

COMPUTATIONAL MODELING

For Lattices with the same volume fractions, intentional structural design can almost ***halve*** *the stiffness while maintaining the same loading*

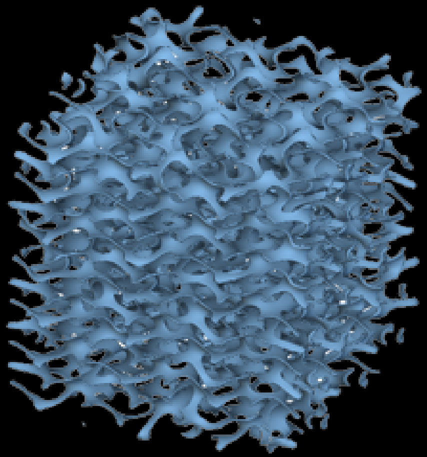


Stochastic Lattice:
Vol. - 486 mm^3
Displ. - 7.5 μm
Stiffness - 66 kN/mm
Avg. Stress - 8.06*e+07*
Peak Stress - 8.06*e+07*



Perforated TPMS:
Vol. - 478 mm^3
Displ. - 9.3 μm
Stiffness - 54 kN/mm
Avg. Stress - 9.65*e+07*

18% reduction
in stiffness



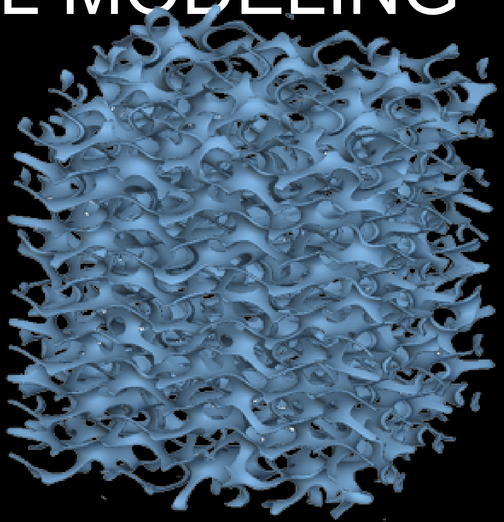
Remapped Perf. TPMS
Vol. - 476 mm^3
Displ. - 36.53 μm
Stiffness - 13.78 kN/mm
Avg. Stress - 1.66*e+08*

45% reduction
in stiffness

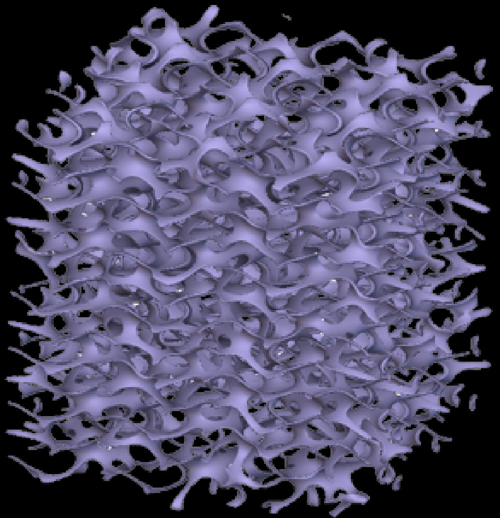
Step 1: Intentional Structure Design

COMPUTATIONAL MODELING

*By functionally grading with the von Mises stress field, we can further thin low stress areas and bolster the high stress ones. This allows us to maintain the same load without yielding while also decreasing stiffness by **more than half** from our already architected structure!*



Remapped Perf. TPMS
Vol. - 476 mm^3
Displ. - 36.53 µm
Stiffness - 13.78 kN/mm
Avg. Stress - 1.66*e+08*
Peak Stress - 1.72*e+09*



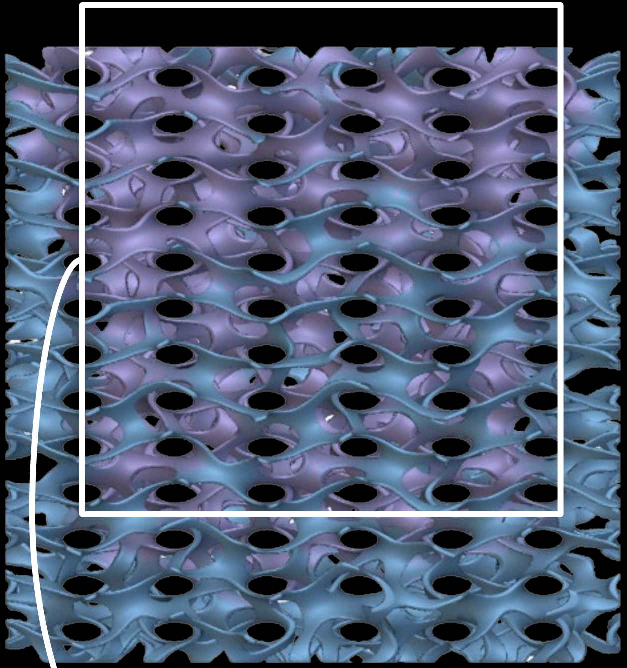
Functionally Graded
Vol. - 276 mm^3
Displ. - 95.25 µm
Stiffness - 5.25 kN/mm
Avg. Stress - 3.30*e+08*
Peak Stress - 3.6*e+09*

61% additional reduction in stiffness

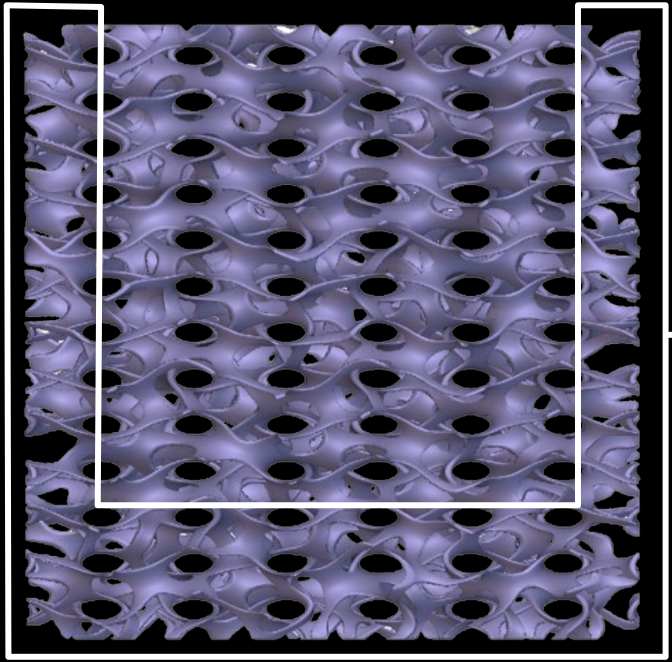
Step 2: Structure Refinement

COMPUTATIONAL MODELING

OMTEC NOT A ROBOT

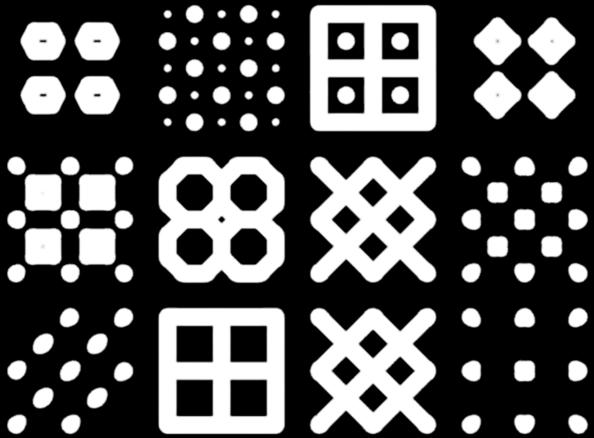


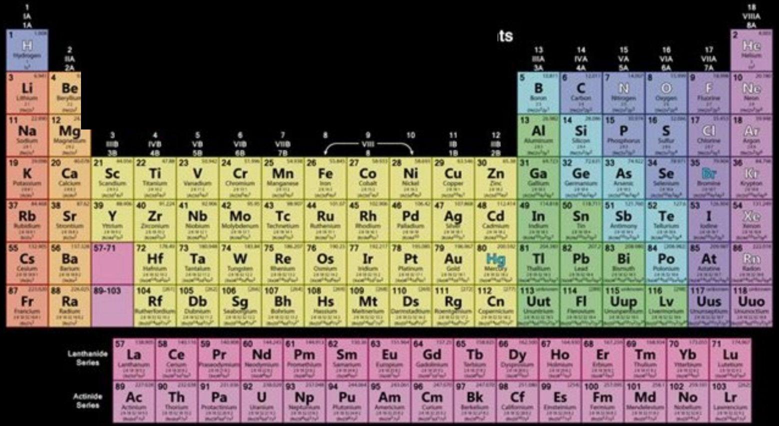
Material Addition in
High-Stress Areas



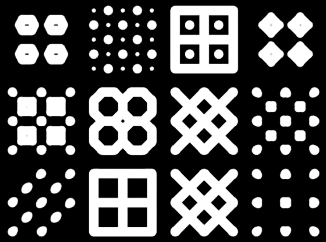
Material Reduction in
Low-Stress Areas

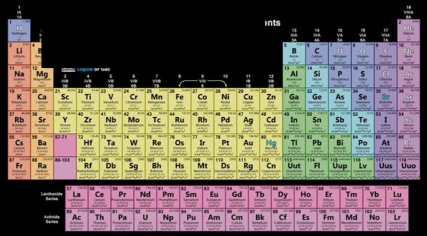
NAVIGATING THE DESIGN LANDSCAPE





NAVIGATING THE DESIGN LANDSCAPE





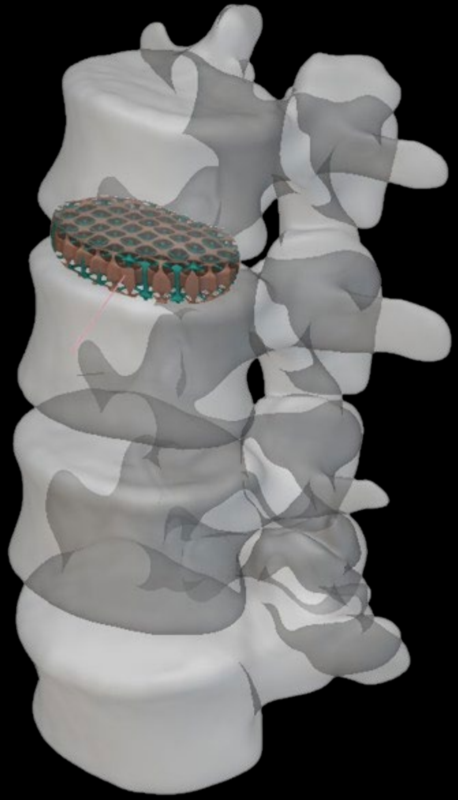
THE PERMUTATIONS ARE MULTI-PLICATIVE AND EXPAND RAPIDLY

NAVIGATING THE DESIGN LANDSCAPE

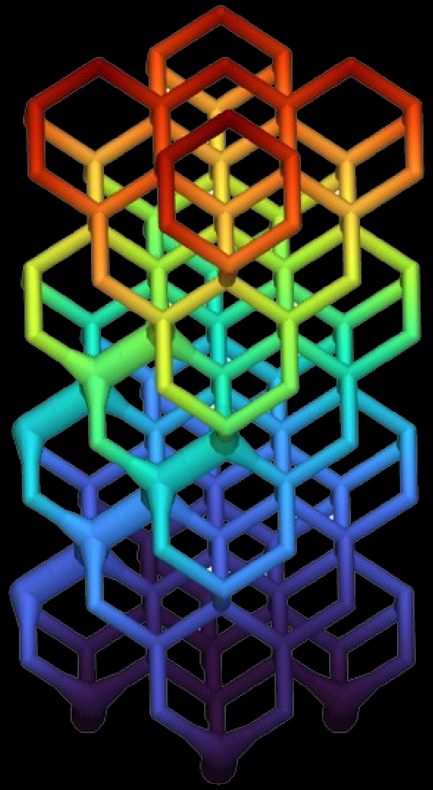
NAVIGATING THE DESIGN LANDSCAPE

NAVIGATING THE DESIGN LANDSCAPE

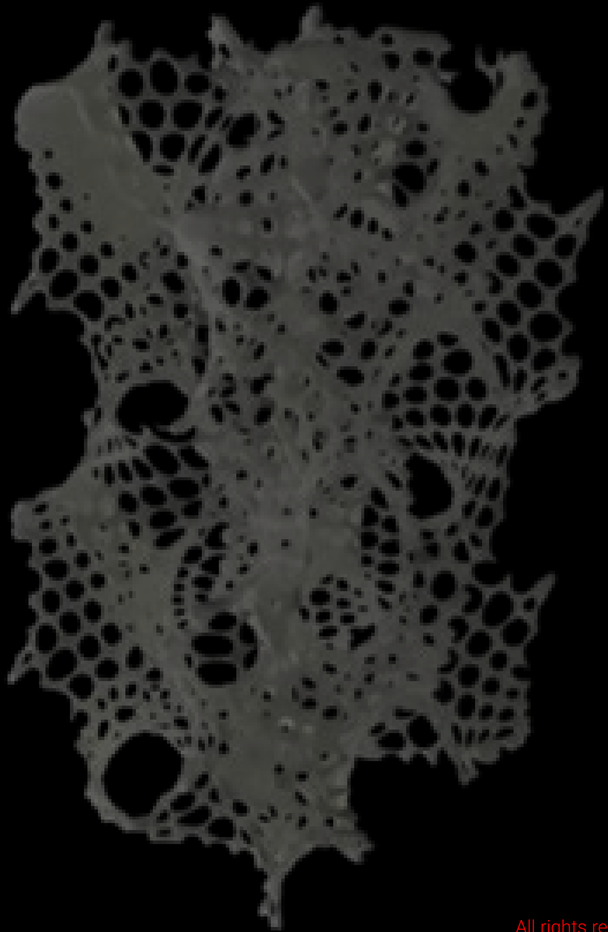
CASE STUDY - PATIENT SPECIFIC



CASE STUDY 2 - ADAPTIVE STRESS STRUCTURE



Thanks for Listening!



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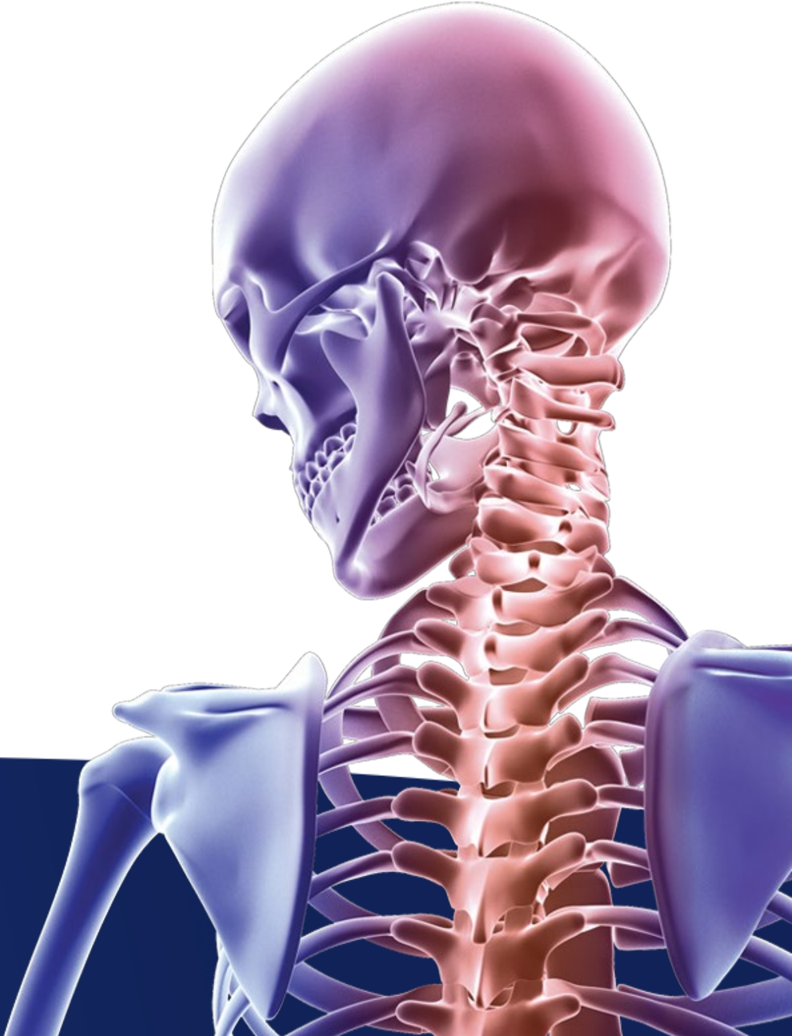

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