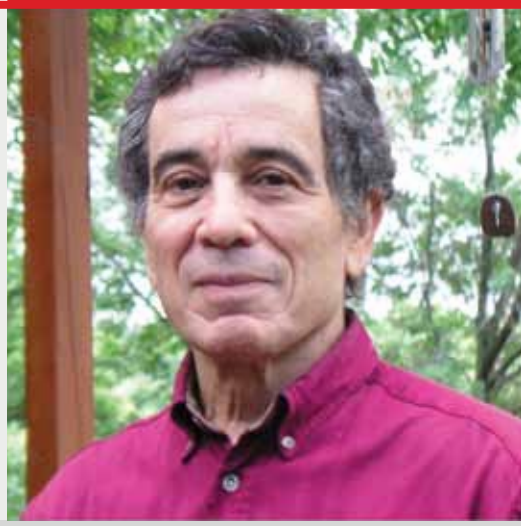
USER CASE STUDY

Diagnostic Simulations, Inc.

Customer Profile: Paul Buscemi, Ph.D.



Dr. Paul Buscemi was the VP of Research and Development at Restore Medical Inc. in Medina MN, now a part of Medtronic. Paul and his team were responsible for conceptualization and realization of a new tongue implant to treat sleep apnea.

Challenge

Restore Medical's challenge was to build a simple, innovative, minimally invasive, palatal implant. The R&D group needed to get insights beyond airway closure to study the effect of the implant on critical tongue functions such as speech and swallowing.

Solution

Marc, Patran.

Benefit

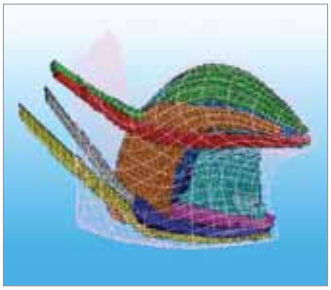
Using MSC.Software technology, Paul's R&D team created an accurate model of tongue musculature and motion. The model was used to design and test a virtual prototype for a new tongue implant and its effects.

Case Study

Obstructive sleep apnea (OSA) is a sleep disorder characterized by pauses in breathing during sleep. It is estimated that 18 million or roughly 20% adult Americans are affected by sleep apnea. This occurs when soft tissue in the back of the throat collapses and closes during sleep causing blockage of airways. Its symptoms include memory problems, weight gain, job impairment and vehicle crashes.

Mesh generated in Patran using the Marc Hex Mesher

Paul said, "We needed to use analysis to understand the causes of the condition and optimize the design of the implant while minimizing deleterious effects to critical tongue functions. Human tongue is one of the complex muscle systems in the human body consisting of 16 individual and distinct contracted sets of fibers. The behavior of biological muscle is a dynamic and sophistically interconnected physiological phenomenon. As more intricacy is demanded from implantable medical devices and precision required from the surgical procedures which place them, it has become imperative that methods exist for predicting how these bodies generate loads, effect device lifetime performance, and influence patient comfort and recovery."



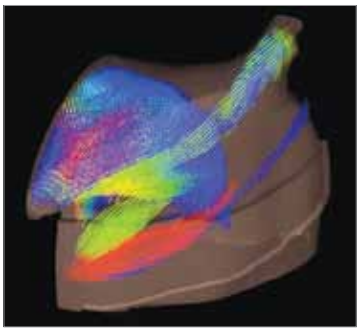
Finite Element Mesh for Internal Muscular Regions

The team came up with a generalized approach for modeling muscle behavior via the finite element method using Marc. A finite element model was built specifically for analyzing passive and active muscle tissues and custom tools developed for creating, activating, and visualizing muscle fiber activity. The model helped understand how surgical sleep apnea procedures may affect critical functions such as speech and swallowing.

> "MSC provides a comprehensive library of sophisticated products that allow researchers to approach and solve difficult problems in the biomechanical arena."

Paul and his team evaluated MSC.Software's Marc for its superior material modeling capabilities. Patran's hexahedral mesh generator was used to generate high quality hex meshes. "MSC provides a comprehensive library of sophisticated products that allow researchers to approach and solve difficult problems in the biomechanical arena. They also have gifted technical resources for those who are less or unfamiliar with the capabilities of computational analysis."

Using MSC.Software's CAE products Paul and his team were able to perform a complete analysis of a new human tongue implant design. "While tongue motion is obviously a very individual characteristic and specific muscles within the tongue are responsible for motions in gross deformations. Tongue motion in general recruits several muscles at once. The model allows, for the first time, study of the not only the kinematics but also the kinetics of groups of muscles – e.g. forces during swallowing. The model can be used to address what the effects of an implant might be or the effect of the removal of a section of tissue. In conjunction with a model of the upper airway, the model can show the site of closure during an apneic event, which cannot be easily demonstrated in patients."



Complex Muscle Activations in a Human Tongue

MSC Software

MSC Products Used:

Marc

- Comprehensive Material Model Library
- Adaptive Remeshing/Rezoning Capability
- Automatic Multibody Contact Analysis
- Parallel Processing using Domain Decomposition (DDM)
- Element Property Creation and Edit
- Material Property Creation and Edit
- Load and Boundary Condition and Edit
- Pre-defined User-Subroutines Library
- TABLE Inputs
- Powerful Analysis Capabilities
  - Structural
    - Linear and nonlinear
    - Static and transient dynamics
    - Buckling/post-buckling
    - Modal/Frequency response
    - Creep, relaxation
  - Multi-physics
    - Thermal
    - Thermal-structural-electric
    - Electrostatics and Magnetostatics
    - Electromagnetics
    - Joule heating
    - Piezoelectric
- Structural Material models
  - Linear elastic
    - Isotropic, orthotropic, anisotropic
    - Temperature dependent
  - Elastic-plastic
    - Isotropic, kinematic or combined hardening
    - Multiple yield criteria
    - Anisotropic plasticity
    - Temperature dependent properties
    - Damage models
  - Viscoplasticity
  - Elastomers
    - Generalized Mooney-Rivlin model
    - Ogden model
    - Boyce-Arruda model
    - Gent model
    - Foam model
    - Large strain viscoelasticity
    - Damage models
  - Hypoelastic
    - Nonlinear elastic model
  - Creep
    - Deviatoric or volumetric strains
    - Temperature dependence

Patran

Pre-processing

- Standard Geometry Access from
  - Parasolid
  - STL
  - IGES
  - STEP 203 and 209
  - VDA
  - I-DEAS
- Parametric Modeling Capabilities
- Mesh Generation
  - Hexahedral mesh generator
  - Automatic 2-D surface meshing
  - Automatic solid mesher
  - Generalized mapped mesher
  - Mesh on mesh
  - Mesh editing and modification
- Comprehensive Element Library
- Element Property Creation and Edit
- Material Property Creation and Edit
- Load and Boundary Creation and Edit
- Easy Contact Definitions
- Model Visualization and Verification
- Support for multiple FEA solvers
  - Marc
  - Dytran
  - MD Nastran
  - MSC Nastran
  - 3rd party solvers

Post-processing

- Results Access
  - Marc
  - Nastran
  - Dytran
  - 3rd Party Solvers
- Results Visualization
  - Contours
  - Vector arrow
  - Fringe Plots
  - Isosurfaces
  - Data History/Animation
  - X-Y plots
- Results Templates

Company Profile

Diagnostic Simulations, Inc. is dedicated to simulation of medical devices in use through finite element analysis. Our staff has over 25 years of experience in medical device development and an in-depth knowledge of materials interaction with tissue. Projects are conducted with a thorough understanding of not only the mechanical behavior of the device but also of a realistic interpretation in its intended biological environment.

Diagnostic Simulations Inc. helps medical device companies to verify the device function under several load conditions especially when placed in tissue where ex-vivo mechanical testing simply does not simulate the actual use situation closely enough, or is simply too expensive to conduct multiple scenarios.

For more information visit us online at: http://diagnosticsimulations.webs.com/

Corporate
MSC Software Corporation
2 MacArthur Place
Santa Ana, California 92707
Telephone 714.540.8900
www.mscsoftware.com

Europe, Middle East, Africa
MSC Software GmbH
Am Moosfeld 13
81829 Munich, Germany
Telephone 49.89.431.98.70

Asia-Pacific
MSC Software Japan LTD.
Shinjuku First West 8F
23-7 Nishi Shinjuku
1-Chome, Shinjuku-Ku
Tokyo, Japan 160-0023
Telephone 81.3.6911.1200

Asia-Pacific
MSC Software (S) Pte. Ltd.
100 Beach Road
#16-05 Shaw Tower
Singapore 189702
Telephone 65.6272.0082