Finally an orthopaedic test substrate that is undeniably the real thing!

BoneSim™
Pat. Pend.
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• Background
• History of Bone Analogs
• Use of Bone Analogs
• Problems with current analogs
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• Current Marketing
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• Future of BoneSim
• FAQ’s
Background

• Company name – BoneSim™, Warsaw IN

• Company product - BoneSim™ 1800 series


• Chief Scientist - David M. Blakemore. Mr. Blakemore BSME, has over ten years of experience in the testing and evaluation of surgical implants and instruments. At Zimmer Orthopaedics he managed the BioMechanical Testing Laboratory as well as the Anatomical Testing Laboratory. He has published scientific papers ranging from Analysis of Contact Area in UHMWPE to Biomechanical Analysis of the Human Shoulder. Prior to Zimmer Orthopedics he spent six years as Lead Orbiter Test Engineer reporting to the United States Astronaut office for the Space Shuttle Program.

• Advisory Board – Dr. Dean Jansen, Board certified AAOS, Dr Gary Pitts, MD
History of Bone Analogs

• The need to replicate human bone tissue was preceded by a long period of grave robbing and black market body snatching. Early medical schools would finance body snatchers in England who would supply academia with fresh corpses.

• Many common materials have been previously used: wood, polyethylene, polymers, etc. All with varying degrees of success.

• The 1990’s research was carried out primarily with polyurethane foams (construction insulation), cadaver tissue and viable bovine, porcine, deer or sheep bone.

• Cadaveric data is still the “gold standard” in medical research.
Use of Bone Analogs

- Target customers
  - OEM’s – analogs used in instrument and device testing, design process, validation, FDA submittal, teaching, field returns testing, etc..
  - Instrument/device manufactures – analogs used for design and manf. evaluation
  - Surgeons – analogs used in product evaluation, teaching, device efficacy, procedure studies
  - Researchers – analogs used in many phases of project study
Use of Bone Analogs, cont.,

- Implant testing
  - Implant surface against analog comparisons, i.e., press fit, micromotion, pressurization studies
  - Hips, knees, shoulder (micromotion)
  - Trauma products: screws, plates, anchors (torque, pullout)
- Instrument testing
  - Rotating cutters, i.e., drills, reamers, burrs (performance testing)
  - Oscillating cutters, i.e., saws (performance testing)
Use of Bone Analogs, cont.,

- Micromotion – this addresses issues associated with post-op loading of implant and is typically performed with a cancellous or composite cancellous/cortical analog. The objective is to determine the amount of motion that occurs between the implant surface and the mating bone during average or worst case loading scenarios. Too much motion inhibits osteo-integration and leads to loosening.

- Fasteners – screw design is subject to force/torque insertion testing, thread pullout strength, max. torque testing. Also, other specific designs are subjected to thread forming testing, self drilling, self tapping and strip-out testing. The same applies to anchors.

- Instrument testing - Rotating cutters, i.e., drills, reamers, burrs and saws are subject to useful life testing, cutting efficiency (performance testing) and tissue damage testing (localized heating). These items are all under scrutiny in terms of accuracy of preparation, i.e., final hole size, ease of use, etc.
Use of Bone Analogs, Summary

- Trauma device testing
- Instrument testing
- TKR, THR, TSR

Any bone/implant/instrument interaction

- Screws, anchors, fasteners
- Cutting instruments (drills, reamers, saws, osteotomes)
- Cutting blocks, alignment, etc..
- Acetabular cup
- Humeral, glenohumeral
- Small joint replacement (hands, feet, ankle, wrist)
- Dental
- Maxillofacial,
- Cranial
- Spinal (disc replacement, fusion, etc)
- Femoral implant
- Elbow
Problems with current analogs

- Polyurethane foams – these are insulating materials from the construction industry. Low melting temperatures, dusting, inaccurate hole preparation. Low hardness, low density.

- Polymers – Acetal copolymers, delrin, UHMWPE. Low hardness, low density, low melting temperature, low frictional coefficient.

- E-Glass Epoxies – Pacific Research (Sawbones) products include anatomically correct simulations. Hardness is better, strength is moderate, constituents, i.e., glass fibers are unlike true bone and react unexpectedly to cutting, drilling and tapping. (elaborate)

- Viable bovine, porcine, etc. – these are the best analogs and widely available, yet they are expensive to prepare, variable in nature, difficult to fixture and not very reproducible.

- Cadaveric – although still the “gold standard”, efficient science can not be carried out due to high variability caused by death, aging, freezing, thawing, embalming, lifestyle, general health, area of interest, etc.
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New Product....BoneSim™

- Scientific merit: Eliminates polymer issues and harvested specimen variability
- Composition: Manufactured from bovine bone, “it’s the real thing”
- Ease of Use: Easily secured in fixture - no prep or messy clean up
- Quality: Manufacturing density and hardness strictly controlled
- Validity: Your test is based on actual bone, not polymers or variable harvested tissue
- Performance: Inherent properties of true bone
- Efficiency: Quick set up, higher statistical power, lowers laboratory overhead
- Value: Data is more usable, costs are lowered

Some of the many uses for BoneSim 1800 series...

- Drill performance
- Rotating cutter performance
- Screw thread and self tapping performance

Other uses:
- Implant interface evaluation
- Recip saw testing
- Burr evaluation
- Rasp evaluation
- Machine to shape
  - metatarsals
  - tarsals,
  - phalanges
  - mandibles, etc.
- Custom molding on request
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BoneSim, cont.

• BoneSim© - 1800 series is an engineered matrix of reconstituted viable bone that replicates the essential mechanical characteristics of human cortical bone.

• The substrate makes possible the standardization of performance testing for rotating cutters, such as drills and reamers.

• Performance indicators (cutting efficiency, heat generation and tool life) are virtually identical to real human bone.

• Equally important, BoneSim -1800 comes in a uniform disk that can be easily and reliably secured for testing purposes.
BoneSim, cont.

Development of cortical analog

BoneSim™ - 1800 series development followed an arduous task of comparative testing and evaluation of harvested bovine, human bone, composites and other analogs. Some of the findings were:

- Drilling resistance in harvested long bones vary substantially through length of bone
- Cortical wall thickness varies substantially
- Cortical densities vary with specimen condition
- Human cortical bone hardness varies slightly through specimen areas but substantially from specimen to specimen
- Bovine bone properties are more consistent as most are fed the same diet and slaughtered prior to 2 years of age

Through careful selection of particle size and density, followed by subsequent testing, BoneSim 1800 series was developed. Particle size is of most importance. Too small of a particle would not retain true bone properties and too large of a particle yielded inconsistent properties.
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Organic Bone Analog

BoneSim, cont.

<table>
<thead>
<tr>
<th>Property</th>
<th>Bovine Cortical Bone</th>
<th>Human Cortical Bone</th>
<th>Polyurethane foam (40 lb/ft³)***</th>
<th>BoneSim 1800</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness (Shore D)</td>
<td>85-95</td>
<td>85-95</td>
<td>60-66</td>
<td>90</td>
</tr>
<tr>
<td>Density, g/cc</td>
<td>1.4-1.9</td>
<td>1.4-1.9</td>
<td>0.64</td>
<td>1.8</td>
</tr>
<tr>
<td>Comp. Strength, Mpa</td>
<td>110-200</td>
<td>100-182</td>
<td>37</td>
<td>110</td>
</tr>
<tr>
<td>Screw insertion torque, Nm*</td>
<td>1.36-1.58</td>
<td>similar to bovine</td>
<td>0.45</td>
<td>1.47</td>
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<td>2.42</td>
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* Tested using 4.5mm self tapping cortical screw w/3.25mm pilot

** Tested using a single 6mm dia. orthopaedic drill, 1000RPM, 90N force

Femoral Cortical Wall Thickness and Hardness Evaluation, K. Calvert, SFB, 2005

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**Organic Bone Analog**

**Compressive strength:** Measure of stress needed to fail material, Mpa (mega pascals, same measure as psi). This is closely related to hardness but is more of a bulk material property.

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**Hardness:** Measure of resistance to deformation under load (Shore D). The cortices of harvested bone varies slightly. This variation is due mostly to external (age, health, processing) parameters. Synthetic analogs are typically low in this property.

**Density:** Measure of weight per unit volume, g/cc (grams per cubic centimeter). Water is 1 g/cc, cortical bone will sink in water. Harvested cortical bone varies slightly in nature and due to external factors. Synthetic analogs are typically low in this property.

**Screw insertion torque, NM** (newton-meters, same measure as in-lb). Good indicator of toughness of material. Synthetic analogs are low in this property, typically half.

**Drilling toughness, s/mm**
Time it takes a specific rotating cutter to pass through 1 mm of material at constant speed and load. Most synthetic analogs are low in this property.
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Current Marketing

- Current customers – Medtronic, W. Lorenz Surgical
- Current trials – Depuy, Zimmer
- 2006 AAOS
- 2006 OMTEC – Presentation, Paragon
- Spring 2006 BoneZone article and cover
- Reviewing CE mark requirements
- 2005 Patent

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Pricing

Each BoneSim 1800 series per piece cost is $63.50

Orders 20 pieces and higher will be discounted 20%

Michigan purchases pay 6% sales tax

This pricing is based on a study in which 2 drill bit designs were evaluated in bovine bone. Cost of study included procurement, storage, preparation, inspection, setup, test replicates, cleanup and data reduction.

Final cost using harvested bovine bone - $230.00  BoneSim cost (2 disks) - $120.00

Ordering

Web service to be in place by 4/1/06 accepting all

Samples

Samples available through web service only
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Future of BoneSim

BoneSim will be available in two formulations:

- **Cortical (compact bone) simulation to replicate outer bone morphology.** Max. size is 57mm dia. x 10mm thick (w/current equipment)

- **Cancellous (porous bone) simulation to replicate "joint" end and implant interface**

- **Other products may include custom molding (small bone, hand and foot - tarsals, metatarsals, vertebrae, carpals, metacarpals, phalanx)**
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Frequently asked questions

• What is BoneSim 1800 made from?

  BoneSim is produced from the cortices of long bones from USDA approved cattle. It contains the same rendered high quality raw material used for various consumer products, including food-grade gelatin, photographic film and pharmaceutical capsules.

• Is BoneSim 1800 available in any other shapes or sizes?

  Currently it is available in 57mm dia. x 10mm high disks. This is to replicate the thickest cortices found in the human body. Thinner disks can be made or machined from standard size. Other shapes can be machined from standard size. Custom molding (small bone, hand and foot - tarsals, metatarsals, vertebrae, carpals, metacarpals, phalanx) is available through customer purchased mold agreement.

• Can BoneSim be used for cyclic loading

  Yes, provided loading is predominantly compression in nature. Its hardness, density and frictional properties will closely replicate human cortical bone.

• What is BoneSim best suited for?

  BoneSim 1800 series is originally developed for performance testing of surgical rotating cutters and saws. It also reproduces surface and resistance properties most similar to viable bone for fastener evaluation.

• Are there quantity discounts available?

  Yes, a 20% discount is available for orders 20 pieces and higher

• How soon can I get the product?

  Shipping will occur same day as order. Expedited delivery available. Web order in place 3/17/06
Organic Bone Analog

Frequently asked questions, cont.

• What is the shelf life and storage parameters

  Since BoneSim is an organic substance, it should be kept in vacuum sealed packaging until use. After package is opened, it should be refrigerated in sealed container. Typical shelf life – 6 mos.