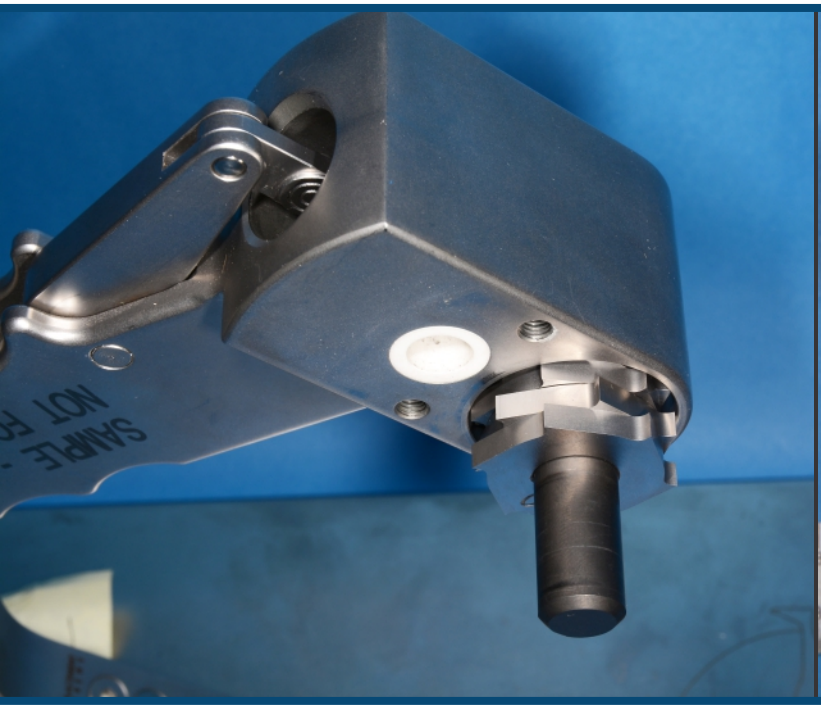
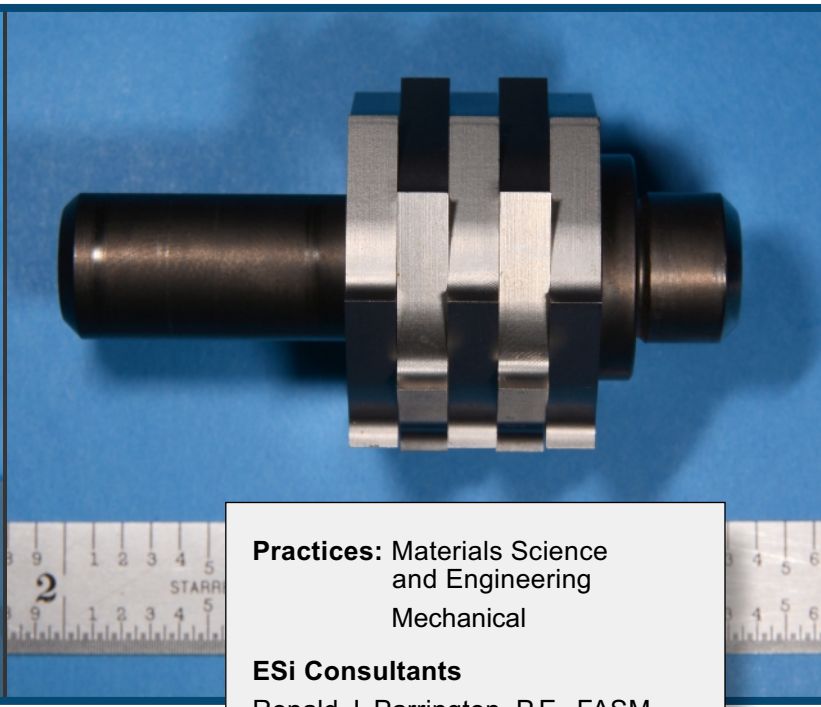
ESi

CASE STUDY





SPINAL FUSION BONE MILL ANALYSIS

Metal fragments were found in the milled bone used for spinal fusion surgeries. ESi's in-depth metallurgical and design analysis cleared the OEM of breach of contract and anti-competitive practice lawsuits brought by the bone mill subcontractor.

SITUATION

Three complaints were received from physicians using a bone mill designed for spinal fusion surgeries, when metal fragments were found mixed in with the milled bone. The subcontractor of the bone mills brought breach of contract and anti-competitive practice lawsuits against our client, the OEM, who refused delivery of additional bone mills and turned to another bone mill design.

Bone mills are operated by inserting small pieces of bone into a chute, applying moderate pressure on a plunger trigger to cause the bone to engage the cutting blades, and then cranking the handle clockwise to mill the bone material which exits the mill through a chute at the bottom of the bone mill housing.

ESi was asked to examine four bone mills, including the three bone mills that were used in the procedures where the physicians' complaints were generated, to determine if there were design, manufacturing, service, and/or materials issues that would explain why the bone mills created metallic debris when used to mill bone.

Practices: Materials Science and Engineering

Mechanical

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Services Utilized

- Optical Microscopy
- Scanning Electron Microscopy (SEM)
- Energy Dispersive Spectroscopy (EDS)
- Finite Element Analysis (FEA)
- Design Analysis

About ESi

For over 30 years, ESi has leveraged its multidisciplinary team of engineers, scientists, and professional technical staff to investigate many major accidents and disasters. Our technical expertise, hands-on experience and state-of-the-art facilities, combined with diagnostic, analytical and physical testing capabilities create an ideal environment for quickly identifying and interpreting the facts of a case.

Contact ESi

For more information visit our website or call us toll free at 866.596.3994

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SOLUTION

The bone mill analysis began with macroscale (unaided eye and stereo-microscopy) and microscale (scanning electron microscopy with energy dispersive spectroscopy [SEM/EDS]) examination of the suspect bone mills to identify the failure mechanism and the source of the metallic debris. This step included disassembly of the bone mills and careful examination of the subcomponents as well as microscopic analysis of the metallic particles generated by bone mill usage.

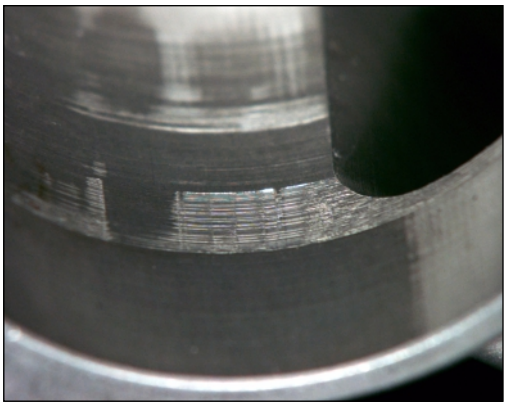
Next, design analysis, finite element analysis (FEA), and coordinate measuring machine (CMM) dimensional analysis were performed to identify any design and manufacturing errors that caused the failure. Design analysis and finite element analysis were able to characterize the intricate interactions between the bone mill subcomponents under various loading conditions, including gravitational loading and the loads applied while grinding bone fragments. The CMM analysis was able to accurately and precisely measure the bone mill subcomponent dimensions for comparison with the design drawing dimensions and tolerances.

RESULTS

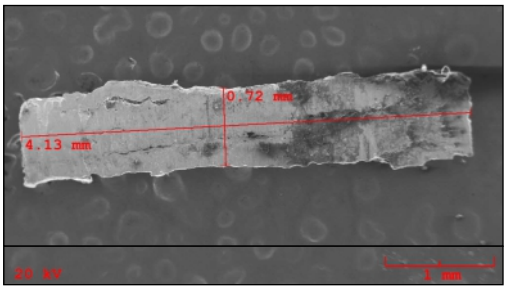
Abrasive wear of the bone mill housing was observed. Abrasive wear is caused when two surfaces in relative motion come into contact and the harder material cuts away the softer material. The locations of the wear scars were similar on all three of the used bone mills. SEM/EDS results indicated that the metallic wear particle widths were consistent with wear scars on the bone mill housing and that the base metal of the metallic particles is consistent with the Type 17-4 PH stainless steel used to make the bone mill housing, rather than the much harder Type 440C stainless steel cutting blades.

Design analysis, finite element analysis, and CMM measurements revealed that the root cause of the abrasive wear is interference between the hard cutters and the bone mill housing due to several design and manufacturing errors. The bone mill design lacked requirements on position control, flatness, parallelism, run out, concentricity, and straightness that enabled cutting plate-to-housing contact and wear. Tolerance stack-up errors exacerbated the severity of the part interference and wear. In addition, the bone mill components were not manufactured to the dimensional specifications which further exacerbated the amount of interference and abrasive wear.

Simple design changes, such as the use of dowel pins to assure alignment of parts and the use of a one-piece integral shaft and cutters, would have remedied many of the issues.



Interference between cutting plates and type 17-4PH SS housing.



The width of the metal debris is consistent with the width of the Bone Mill cutting teeth.

WHY ESi

ESi was able to assemble a multi-disciplinary team of metallurgical and mechanical engineers to determine the mechanism and cause of failure. A comprehensive expert report and trial testimony addressed all aspects of the failure in a compelling manner that ultimately led to a highly favorable verdict for the OEM defendant.

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