A New Faster-Absorbing Biocomposite Material: *Long-Term In-Vivo Tissue Reaction and Absorption*

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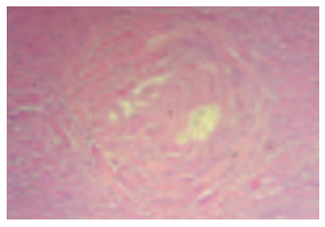
OVERVIEW OF MATERIAL PROCESSING

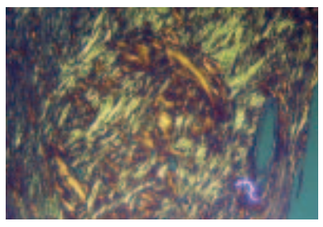
DePuy Mitek utilizes only the purest medical grade ß-tricalcium phosphate for its Biocryl Rapide material. Biocryl Rapide does not contain fillers, such as magnesium oxide, which may be present in other composite materials. This ensures that the implant contains the highest percentage of osteoconductive TCP.

A proprietary manufacturing process known as Micro Particle Dispersion (MPD) Technology makes Biocryl Rapide material a homogeneous blend of PLGA and TCP particles. Dispersion of the composite particles is critical to the material properties. Non-homogeneous composites may result in a material with compromised or variable strength properties due to stress risers within the material.

Rapid Absorption and Long-Term Compatibility



Newly Formed Bone



Under Polarized Light

Cortical Bridging at Entry Site

By 24 months, nearly the entire cross-section of the Biocryl Rapide test rods in cortical bone had been absorbed and replaced by either normal bone or bone with fibrous or adipose tissue. The circular orientation of new osseous tissue was clearly apparent under polarized light.

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OBJECTIVE

To evaluate the in-vivo tissue response and long-term (24-month) bioabsorption of a new ß-TCP/PLGA biocomposite material for potential use in bone fixation implant applications.

MATERIALS & METHODS

Animal Model:

Canine transcortical femur, using skeletally mature male and female beagles

Methods:

Lateral unicortical implantation in 4 sites in the right and left femur bones

Materials:

30/70 w/w ß-TCP/PLGA (Biocryl Rapide™) & L-PLA

Specimens:

3mm diameter X 10mm long rods, EO-sterilized

Time Periods:

3,10,18 and 24 months post-implantation

Evaluations:

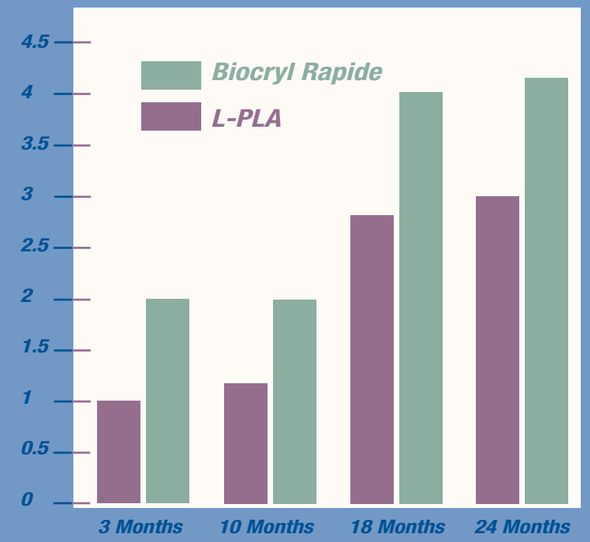
Undecalcified transverse section histology and radiographic

GLP Test Site:

MPI Research LLC, Mattawan, MI

RESULTS: ABSORPTION

Absorption Score Averages in Cortical Bone[1]

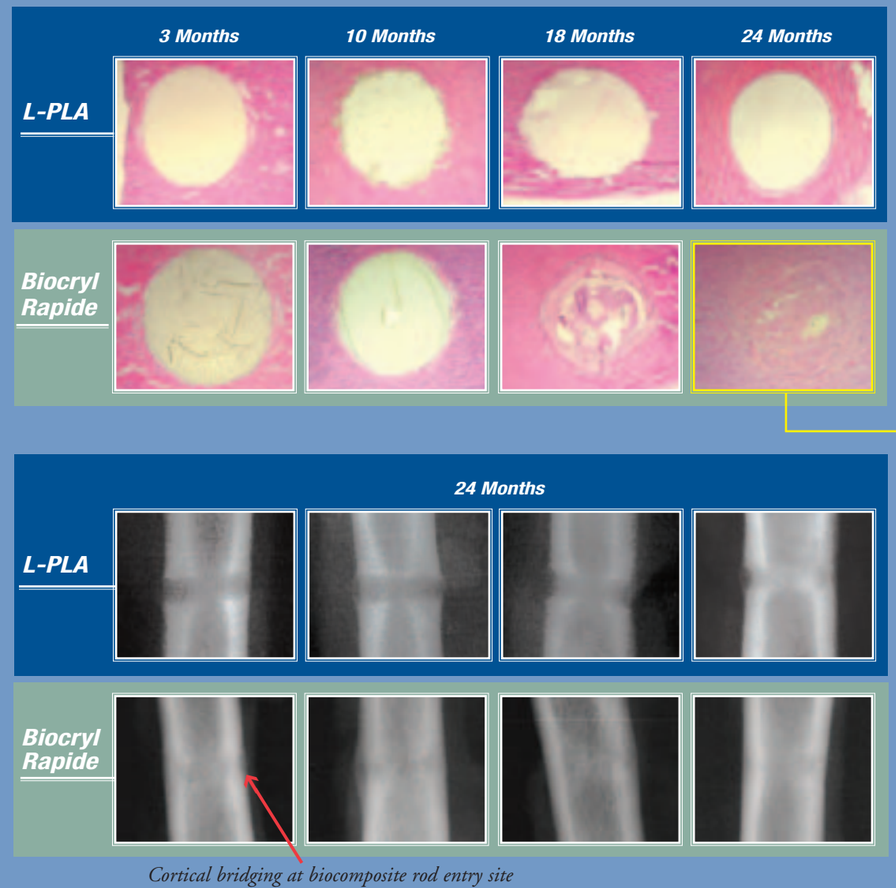


Grading Scale:

1- No apparent change
2- Minor CIEF
3- Moderate CIEF
4- Marked CIEF
4.5- Only trace amounts remain
5- No recognizable material remained

CIEF = cracks, cell infiltrations, erosions and/or fragmentation

[1]Data on file from pre-clinical evaluation



Cortical bridging at biocomposite rod entry site

In the image below, viewed under polarized light, newly formed bone can be seen as the cells begin to align in patterns similar to native bone.

All images obtained from the e-poster presented at the Spring 2005 meeting of the Arthroscopy Association of North America.

DISCUSSION & CONCLUSIONS

Biocomposite rods of ß-TCP/PLGA are biocompatible in beagle femoral bone out to 24 months, with only minimal-to-slight tissue reaction peripheral to the rods and without necrosis.

The ß-TCP/PLGA material exhibited marked absorption from 18-24 months[1], accompanied by a gradual increase in the proliferation of mesenchymal cells that differentiated toward the osteoblastic line.

By 24 months, nearly the entire cross-section of the Biocryl Rapide test rods in cortical bone had been absorbed and replaced by either normal bone or bone with fibrous or adipose tissue. The circular orientation of new osseous tissue was clearly apparent under polarized light.

During the same duration, L-PLA test specimens showed only minimal absorption in comparison.

SUMMARY & SIGNIFICANCE OF FINDINGS

Biocryl Rapide, a new ß-TCP/PLGA biocomposite material, has demonstrated long-term compatibility in the canine transcortical femoral rod model.

When compared to L-PLA, the new biocomposite material offers a more rapid absorption profile with the possibility of more rapid infill, and it may be well-suited for bone fixation device applications.