

Cell based applications are the future of biologic augmentation in orthopaedic surgery

A voice in dissent

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The Holy Grail Or A Passing Fad?

- Not an ethical debate
- Does the data live up to the hype?
- Burden of proof – other biologic alternatives
- Bench to bedside or bench to vivarium?
- Stringency of (potential) Level I evidence

BIG BUN

“WHERE’S THE BEEF?”



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Question #1: What are the indications?

- Biologic enhancement should be indication specific
- Undetermined injury patterns – preclinical work simplifies the clinical condition
- Art of orthopaedics is older than the science

Question #2: What is the availability?

- Isolation, characterization and expansion – off the shelf?
- “Ideal” implantation conditions – clinical relevance?
- Patient characteristics – hostile environment

Question #3: What is the toxicity?

- Allogenic stem cells – immunogenic reactions?
- Genetically engineered “factory” cells – viral vectors
- Uncontrolled expression in a receptive host
- Lessons learned from rhBMP-2 FDA IDE trials

Question #4: What is the quality?

- Criteria to assess that repaired tissue is a direct result of cellular applications
- Long term stability of the repaired construct?
- Phylogenetically advanced animal models have a different healing response

Question #5: What is the dose and carrier?

- Will dose and carrier change for each indication?
- Method of delivery indeterminate
- Will the construct meet the biomechanical challenges?
- Off the shelf?

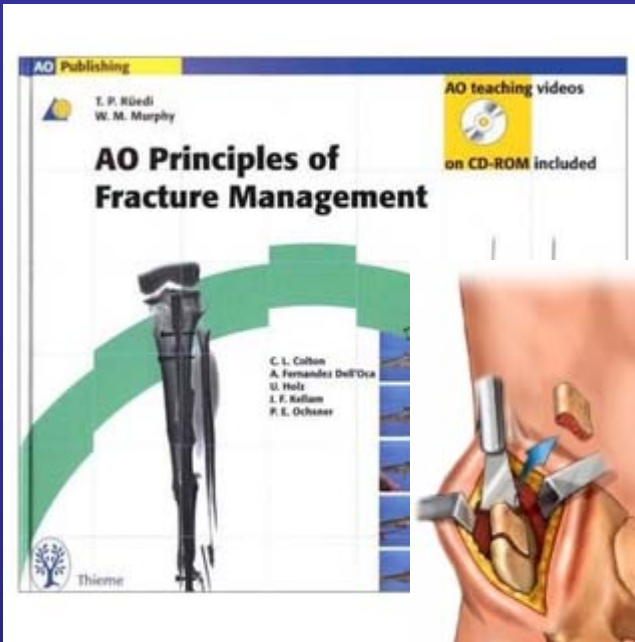


COLUMBO

“JUST ONE MORE THING...”



By AZEEMALIM 2007



- Anatomic reduction
- Stable internal fixation
- Preservation of blood supply
- Early mobilization
- **Biologic enhancers that have met burden of proof**

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Thank You

