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Five Ideas to Change the World (of Orthopedics)

A Sample Problem:

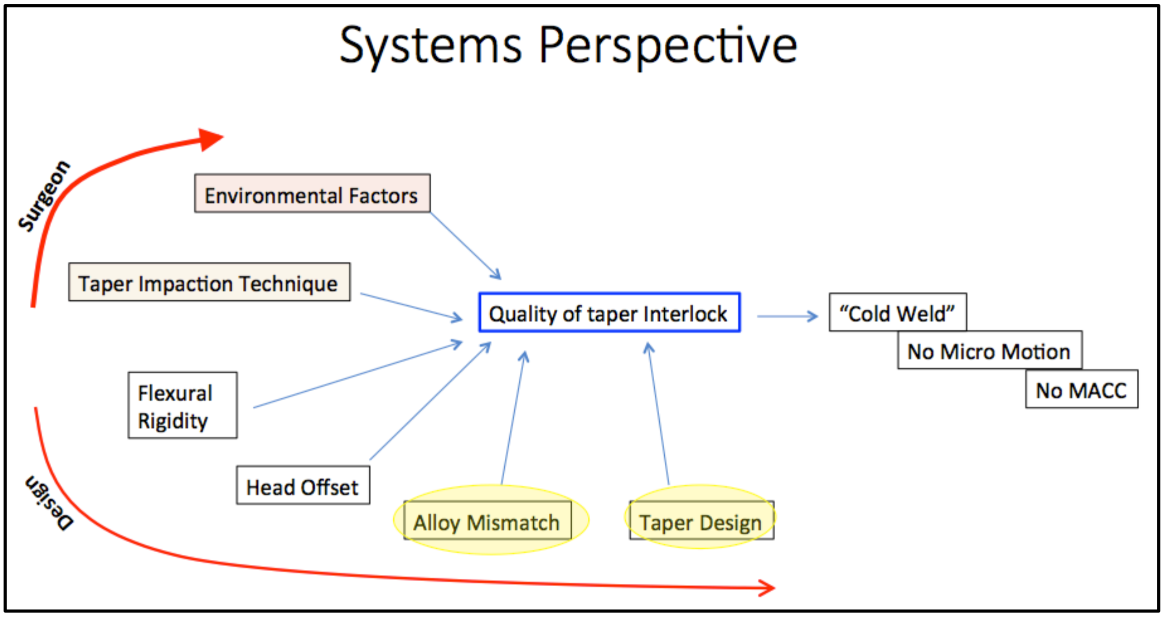
Trunnionosis has been a hot topic issue in orthopedics in the recent years. A recent paper from a prestigious institution evaluated the taper interface of a particular manufacturer. A single surgeon performing over a thousand THR found a 1.1% prevalence of Mechanically Assisted Crevice Corrosion MACC and elevated levels of cobalt associated with metal on metal modular junctions. This paper implicated the manufacture's taper design and cobalt alloy heads as the cause of the problem. The recommendations of the paper are heeded by the industry and academia, which is to use ceramic heads to decrease the incidence of this problem; as well shedding doubt on the manufacturer's taper design.

There is no doubt that mixed alloy use at the taper interface is has a negative influence, however, a variety of factors are proposed to be involved in the causation of MACC and Trunnionosis and include 1. Mixed alloy components 2. Taper design (including geometry, length, diameter, taper angle, taper mismatch, taper roughness, flexural rigidity. 3. Head offset. 4. Femoral head size. 5. *Taper impaction techniques* including assembly force, control of alignment, environmental factors (wet or dry).

Most orthopedic surgeons know that regardless of the design of the taper, including shorter, slimmer and more flexible trunnions, larger heads, varying taper angles (including positive and negative mismatch) there are some universal problems with the process of head impaction onto the trunnion that have to do with "taper impaction technique" and the engagement of the "modular taper interface" that doom the trunnion interface to failure and corrosion, leading to problems discussed above.

From a systems perspective we note a variety of variables that input into the assembly of a head onto a trunnion. These are shown in the figure below.

Figure 1.



The aforementioned paper implicates two of the variables in Figure 1: Alloy mismatch and Taper Design; without awareness or discussion of other confounding variables.

Is it possible that the 1.1% incidence of MACC in this cohort of patients may be directly related to the surgeon's own "taper impaction technique", <u>since we know there is currently no standardized method or technique to apply a head onto the trunnion.</u>

There are several factors are under the surgeon's control including assembly force (magnitude), assembly force (direction), and environmental factors (keeping the taper interface dry). Given the right tools and standardized techniques, surgeons can obtain a "cold weld", where a perfect interlock with no micro motion and therefore no mechanically assisted crevice corrosion is possible. Figure 2.

Figure 2

Cold Weld → No Micro Motion → No MACC (No Trunnionosis)

Without a standardized impaction technique, no surgeon could have reliably applied the more than 1000 femoral heads onto the trunnions exactly the same way. We ask therefore, if there is enough information in this paper to change the behavior of orthopedic surgeons and the industry? The obvious answer is no.

Over the years some have argued that there are large disconnects between the industry, which drives innovation, and the surgeons who perform the surgeries. For example, regarding trunnionosis, some papers have suggested that surgeons should apply 4000N of force to the taper interface in order to obtain a 2000N pullout force, possibly a "cold weld". Most surgeons tap lightly on the head to insert on a trunionn, but no one would dare to apply 4000N or (1000lbs) of force to the taper interface of a stem already implanted in bone, hence the disconnect between the engineers and the surgeons. In contrast, we have proposed a pragmatic solution from the surgeon's perspective, which primarily focuses on "the surgeon controlled factors". This method is described in project #3 (A Method to Control Trunnionosis Project).

This is an example that brings attention to a bigger problem in orthopedics.

We believe orthopedic surgery is best described as a *"multi-disciplinary "clinical science,* which is best approached from a *systems perspective*. Focusing on a single aspect of a multi-faceted system frequently provides poor information for the surgeons, limiting their ability to do a good job. Without proper techniques and tools to perform the surgeries, the odds of errors and mistakes are increased, with attendant huge cost to patients and society in general.

During orthopedic surgery, the surgeon's job can be broken down into four simple phases: 1. Soft tissue Preparation 2. Bone preparation 3. Application of Force (a cause) 4. Assessment of the (effect) of Force.

1. The soft tissue part of the operation is more of an art, and the surgeon, as an artisan, has to learn soft tissue surgery through a process of apprenticeship.
2. The bone preparation is done with tools, and our contention is that we are still using primitive tools, similar to ones we find in our kitchens and garages. We have proposed concepts to make bone preparation a more sophisticated and technological process.
3. Application of force, with components of *directions* and *magnitude*, is done with a mallet, and current techniques do not allow the surgeon to control either, in order to apply force intelligently and incrementally. We have proposed standardization of force application in orthopedics and elimination of the use of the mallet.
4. Assessment of the *strength of fixation* (the effect force) is done by the surgeon's auditory, tactile and visual senses; with no attempt at standardization. This process is subject to the labile emotions and physical

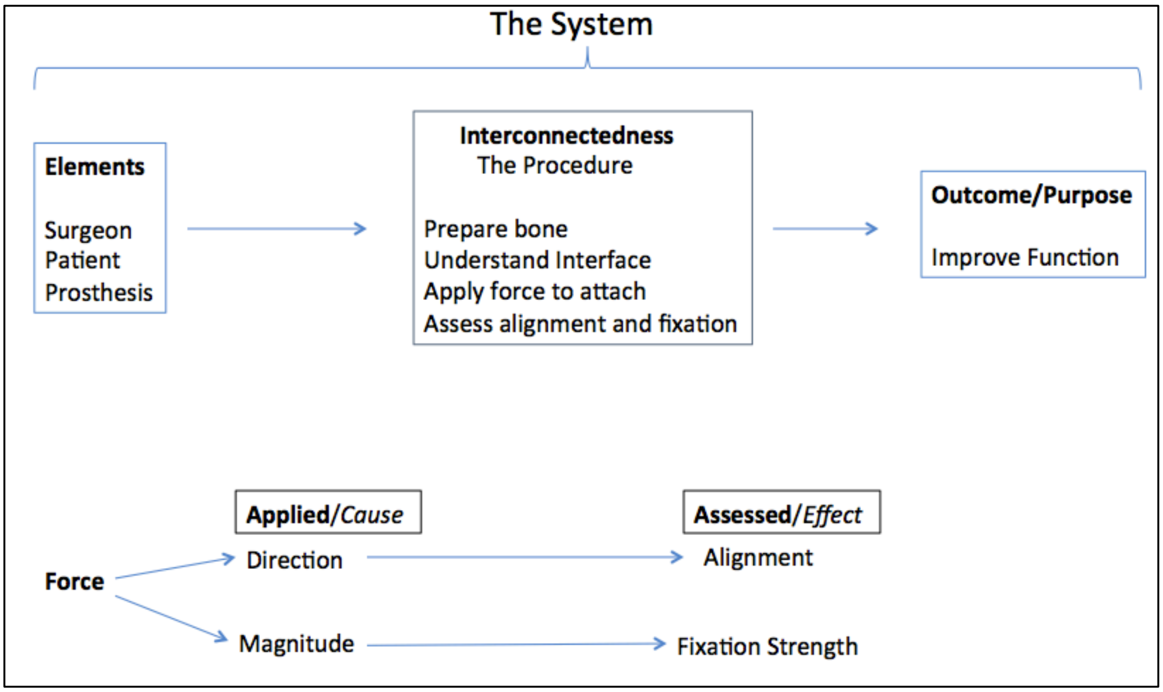
strength of the surgeon, therefore unreliable and primitive. We have proposed the Invasive Sensing Mechanism ISM, and various other ways to technologically assess the *quality of fixation*.

We believe that beyond the soft tissue preparation, all other aspects of the orthopedic surgery can be dramatically modernized and standardized to make the operations safer for the patient, more efficient for the surgeon, and less expensive for third parties, including the insurance companies and the government.

With respect to application of force in orthopedics, the mallet is a tool, which is used by the orthopedic surgeons to apply force. The mallet (essentially a 2lb hammer) is no different than the rock used over three million years ago by our prehistoric predecessors. Our contention is that the use of the mallet in orthopedics is directly related to many of our current day orthopedic problems including: mal-alignment, instability, poor fixation, loosening, fracture, ostoelysis, wear, metallosis, trunnionosis etc. We are just not willing to admit this fact as an industry.

Briefly, to demonstrate this point, we can view total hip replacement THR from a systems perspective. The elements of this system are the patient, the surgeon, and the prosthesis. The interconnectedness of the system is the procedure itself where the bone is prepared, the prosthesis is applied, and the outcome is assessed. More specifically, the prosthesis is applied to the bone through application of force (a cause), and the (effect) of force is assessed by checking the quality of alignment and fixation. The outcome and purpose of this system is improved function. Figure 3.

Figure 3



When we evaluate this system critically as in figure 4, what we see is that the infusion of technology has been primarily limited to the development of the prosthesis (design), and to assessing the quality of alignment (i.e. navigation, fluoroscopy, IMUs etc.) represented in orange.

Figure 4

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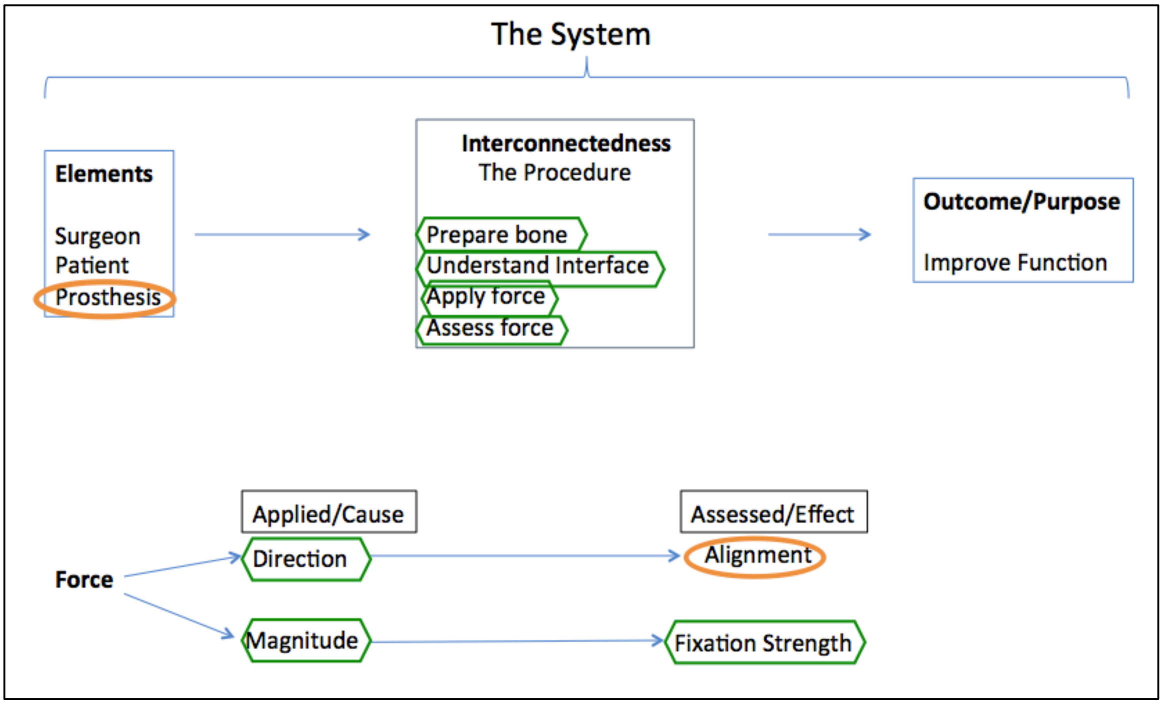


Over the last thirty years, there has been no attention paid to the other parts of this system, represented in green. The application of force is with a *mallet* where the surgeon has no control over the magnitude or the direction of force. The assessment of the effect of force (fixation strength) is done by *human auditory, visual and tactile senses*, without any standardization. No reliable methods or tools are provided for the *delivery of force*. No methods or tools exist to *assess the quality of fixation*. Similarly the interface of bone and prosthesis is poorly studied and understood; and finally, bone preparation is crude using tools similar to cheese graters in the kitchen. There are multiple aspects to this system that can be improved, modernized, and standardized with simple attention to basic engineering principles and analog technology.

A system is as strong as it's weakest link. As we can see, multiple aspects of hip replacement surgery are primitive. Regardless of how much technology is infused at various stages of the procedure, if the final stage is primitive the whole procedure is subject to errors. The MAKO hip replacement uses a million dollar robot to prepare the bone and at the end the surgeon uses a mallet to impact the prosthesis, which invites inaccuracies. This method invokes the admonition not to measure with a micrometer, mark with a chalk, and cut with an ax.

Donald Coduto, professor of geotechnical engineering points out in his book "Foundations of Design" that one should maintain consistent degree of precision through out the analysis, design, and construction phase of a project. This concept applied to surgical procedures demands that the same level of precision be carried out through out the different phases of the operation

Please see project#1 (The Problem with Total Hip Replacement and the Solution: Controlled Impaction and Invasive Sensing Mechanism).

Questions for the Industry:

What do surgeons need? We understand that the future of orthopedics is focused on biologics, however, for the foreseeable future, as long as press fit joint replacements are done, we believe the following concepts can dramatically improve orthopedic care. We ask the following questions:

1. Can we have tools that allow *Application of Force* to be precise and controlled, with respect to *magnitude* and *direction* of force, when attaching prosthesis to bone? Can we, as an industry, define a *more precise endpoint* of prosthesis to bone fixation, and provide tools to technologically achieve it? How do we apply just the right amount of force to get good fixation but avoid both fracture and poor seating? Is there a technological means to *assess the quality of fixation* that is more reliable than our own senses? Additionally, can we have tools that allow us to place the prosthesis in the exact desired alignment, and NOT JUST in some "acceptable range"?

2. Can we have tools that allow us to better prepare bone in order to harness its amazing spring like qualities?

3. Can we have the same sophisticated tools (described in 1) that allow technological application and assessment of force for prosthesis-to-prosthesis attachments, in order to eliminate fretting and corrosion?

4. Can we have prosthesis that is more intelligent (function built within their structure), such as **A.** A prosthesis "that wants to insert easily" **B.** A prosthesis that wants "not to bone resorb" and "not to stress shield" **C.** A prosthesis that wants "not to corrode", and **D.** A prosthesis that "wants to allow easy fracture healing".

5. Is there a more technological (easier) method to reduce and stabilize fractures with less dissection that allows faster and more reliable healing, with robotics and anisotropic metals?

The industry and academia may answer no to these concepts, and alternatively suggest more training for the surgeons (an old story). We have no qualms with additional training; however, we believe attention to these concepts will lead to the development of enhanced tools and methods that can modernize orthopedic surgery with improvements an order of magnitude. We strongly believe this is the *white space in orthopedics,* where medical device companies can make the biggest difference.

We point out that the orthopedic industry has over focused on products, as it is more natural to claim value in better designs, however, at this point, tweaking the products will only provide incremental improvements, for which no one is willing to pay extra. The companies with the foresight to act on this paradigm can achieve a competitive advantage.

Proposed Solutions:

We have contemplated five basic concepts that can change the world of orthopedics for the better.

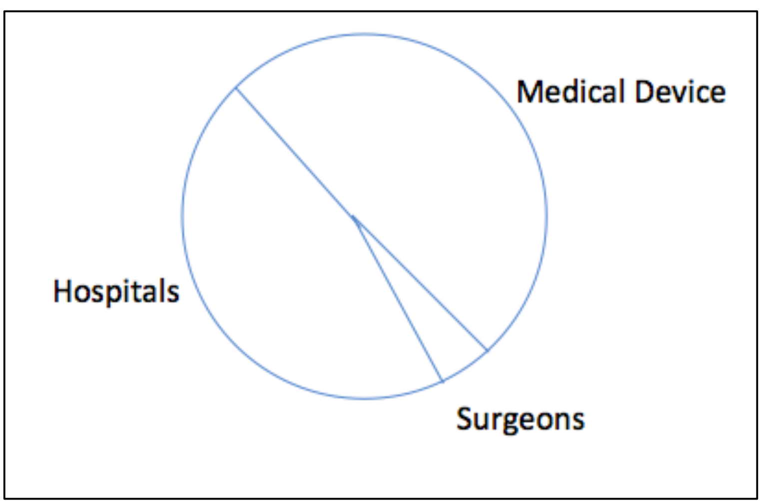
1. We have proposed better ways to:
    - A. *Apply (cause) force* so that the direction and magnitude of force are brought under control. These include controlled impaction, vibratory insertion, and constant insertion.
    - B. We have proposed better ways to *Assess the (effect) of force* in *alignment* and *fixation strength*. This includes the Invasive Sensing Model (ISM).
    - C. We have proposed a *clear endpoint for press fit fixation of prosthesis to bone* (Best Fixation Short Fracture BFSF).
2. We have proposed better ways to prepare bone in order to *access the inherent spring like qualities of bone*.
3. We have proposed better *Taper Impaction Techniques* to minimize/eliminate the plague of Trunionnosis.

4. We have proposed *incorporation of function within the crystalline structure* of prosthesis to allow better healing of prosthesis to bone, better bonding of prosthesis-to-prosthesis, and better fracture healing.
5. We have proposed novel methods for fracture reduction and stabilization with robotics, anisotropic metals, and external fixators.

The Business Model:

The current health care environment is constrained. The money available for joint replacement is divided between the hospitals, medical device industry and the surgeons, with the lion's share of the money being divided between the hospitals and the industry, figure 5. With any new innovation the industry wants to know how they can increase their piece of the pie, as the current business model is "distributive" and not "creative" with respect to value. It is noteworthy that over the last decade, the innovations in orthopedics have all been marginal in nature. The surgeons are no longer interested in risking big changes for marginal gains, and the hospital system will not relinquish a slice of their pie for marginal improvements. Some medial device companies have resorted to eking a small profit by providing marginal improvements in design with lower additive manufacturing costs.

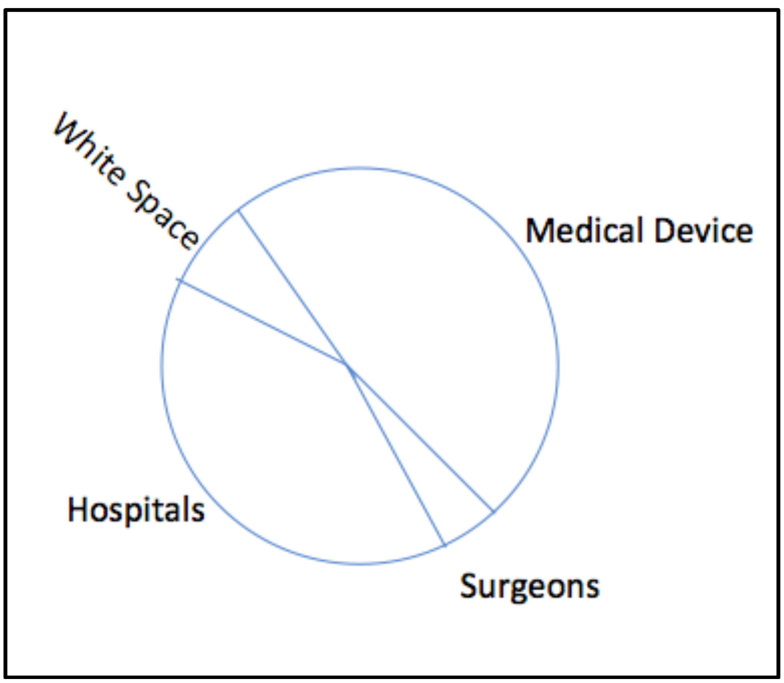
Figure 5



We believe there is significant room for *innovation,* an order of magnitude higher than what is currently available. Hhowever, this advancement is not in another new and improved product, but rather in *the processes* described above.

Any company with the foresight to see the potential in our concepts can demand a larger piece of the pie from both medical device industry and the hospital systems. A better method of bone preparation, force application, and force assessment in orthopedics can be analogous to a better breaking system (antilock breaks) in the automotive industry, figure 6.
Our concepts manifest in more sophisticated tools with adaptors and disposables, which initially justify an increased charge. However, ultimately if one can teach all surgeons to better surgery, resulting in less harm to patients, with dramatic cost saving to society, one can demand a higher premium from all parties involved.

Figure 6.



Currently, certain ingrained attitudes in orthopedics are contrary to advancement. As junior residents we have all been told to bang harder on the prosthesis, and that unless you "break a femur or two" you will never be an orthopedic surgeon. This is a mentality that does damage to all patients and surgeons alike, and has to be countered as nonsense.

In the orthopedic world the industry innovates, the academia validates and the surgeons dutifully perform the surgeries. We believe the surgeons should be more involved and ask more questions (especially on behalf of their patients), and demand more from the industry.

The Proposal:

We have contemplated five concepts to change the world of orthopedics. These have further been categorized in 10 different projects. Some of these concepts have been flushed out (significantly de-risked) with prototypes and basic science experiments. Some of the concepts require further validation. Finally we have made attempts to protect all our concepts in patent applications, with some issued patents and many pending examination. We are seeking private, industry, university and government involvement to further these ideas, as we strongly believe it would allow us to do better job for our patients.

Five Distinct Concepts

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- Technological Application of Force (Prosthesis to Bone)
  - Controlled Impaction
  - Vibratory Insertion
  - Constant Insertion
- Technological Assessment of Force (Prosthesis to Bone)
  - Invasive Sensing Mechanism (ISM)
  - Vibrations in Bone
  - Vibrations in Air (Pitch)
- Technological Application and Assessment of Force (Prosthesis to Prosthesis)
  - Solution to Trunionnosis Problem
  - Prototypes (Video)
- Better Fine Tuning of Bone (Amazing Spring)
  - Ultrasonic Machining of Bone
    - Faster Material Removal Rate
    - Tighter Tolerances
    - Haptic Window Protection of Robotics
- Alteration of Crystalline Structure of Metal
  - *Two Dimensional Stiffness and Bias for Insertion*
    - A Prosthesis with Macro- and Micro-Structure Bias for Insertion
    - Genetic Predisposition for Insertion in Implant (Expressed with Vibration)
  - *Variable Material Prosthesis*
    - Wants Not to Corrode (Prosthesis to Prosthesis)
    - Wants Not to Bone Resorb or Stress Shield (Prosthesis to Bone)
- Fracture Fixation with Robotics
  - *Anisotropic and Viscoelastic Metals*
    - Wants to Allow Bone to Heal
    - Design Studies to determine optimal combination physiological loads for callus formation & fracture healing (Compression, Tension, Bending, Torsion, Shear)
    - Design various Anisotropic/Viscoelastic metals
    - Compare Fracture healing with:
      - Isotropic Metals
      - Various Anisotropic Metals
      - Various Physiological Loads
  - Reduce with Robotics
  - Stabilize with Anisotropic Metals
  - Plate and Rod Fixation Obsolete

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Ten Distinct Projects

1. **Technological Application of Force**
   a. **Controlled Impaction**
   b. **Vibratory Insertion**
   c. **Constant Insertion**
2. **Technological Assessment of Force**
   a. **Invasive Sensing Mechanism (ISM)**
   b. **Vibrations in Bone**
   c. **Vibrations in Air**
3. **Controlled Impaction + ISM**
4. **Vibratory Insertion + ISM + IMU (Mechatronic Handle)**
5. **Constant Insertion + ISM**
6. **Trunionnosis: How to Achieve a Cold Weld**
7. **Technological Machining of Bone + ISM**
8. **Two Dimentional Stiffness and Bias for Insertion**
9. **Variable Material Properties Prosthesis**
10. **Anisoptropic Metals and Fracture Fixation with Robotics**