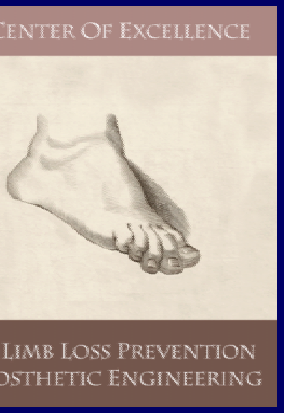


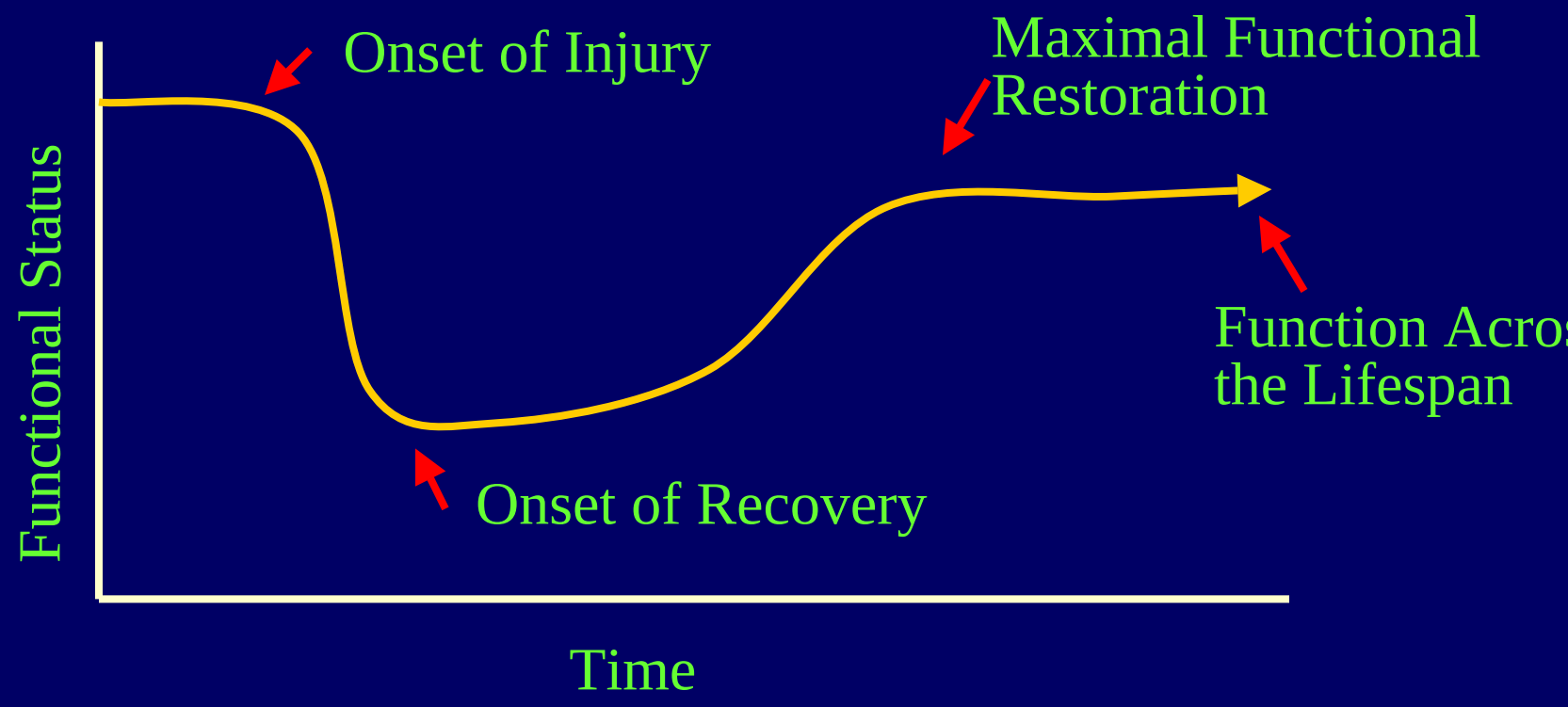
Osseointegration: a Rehabilitation Perspectiv

Joseph M. Czerniecki, MD,
Associate Director, VA Center of Excellence

Professor, Department of Rehabilitation Medicine,
University of Washington

Setting the Stage

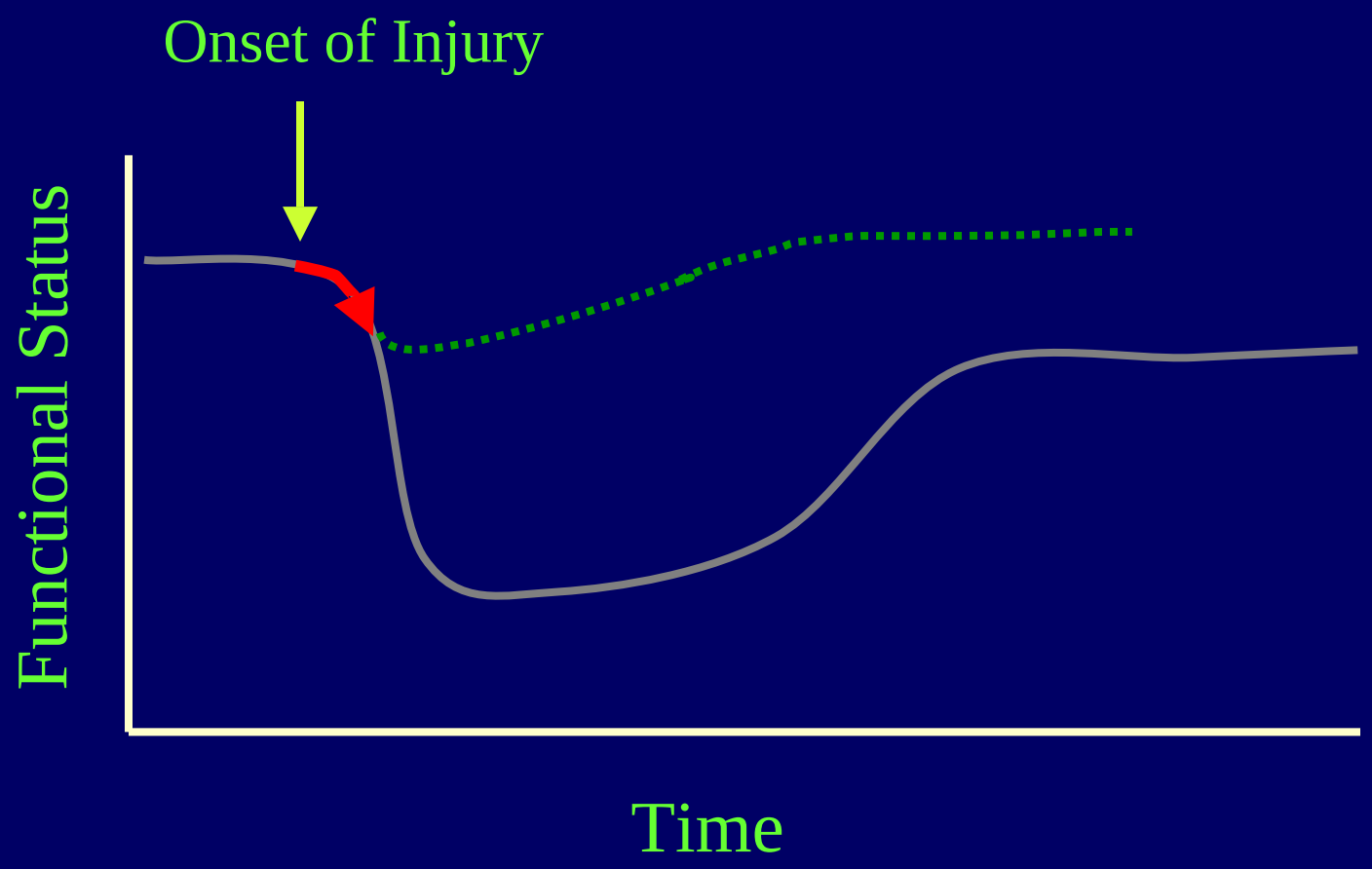
eneral Model of Functional Recovery after Illness or Inju



The Goal of Rehabilitation is the Enhancement and Preservation of Function.

- Minimize the functional decline associated with illness or injury.
- Prevent additional disability during the acute care episode.
- Shorten the time course of recovery.
- Increase the ultimate functional outcome.
- Preserve the functional status across the lifespan of the individual.

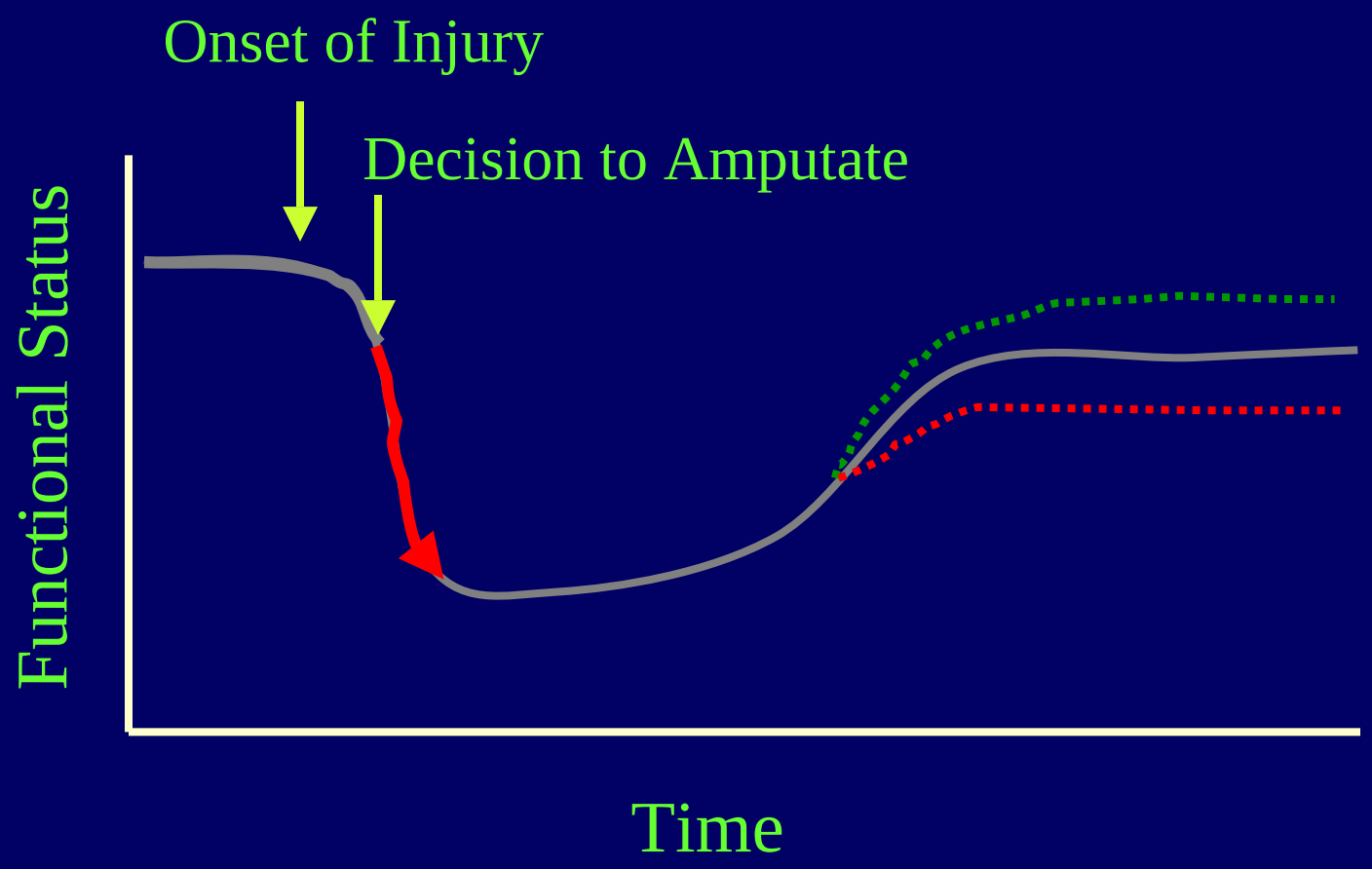
Prevention of the Need for Amputation



Prevention of Need for Amputation

Continued research on the development of predictive lim
injury scales that not only predict salvage but the extent t
which salvage will lead a more functional limb than
amputation

Amputation Decision Making

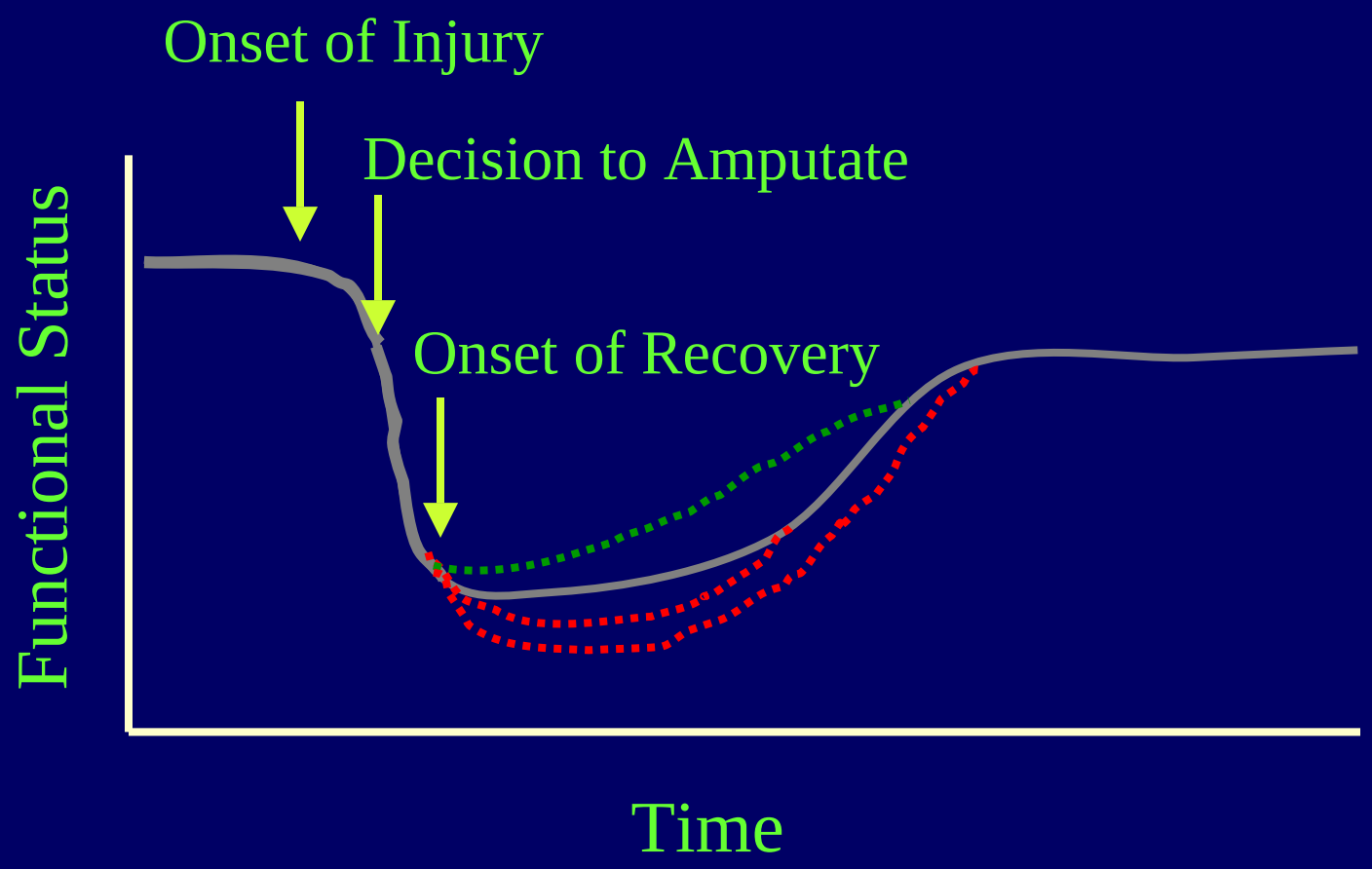


Amputation Level Decision Making; Its Effect on Functional Outcome

- What is the optimum level of amputation?
- When is the outcome of a compromised transtibial residual limb better than a transfemoral amputation?

The Compromised Transtibial Residual Limb

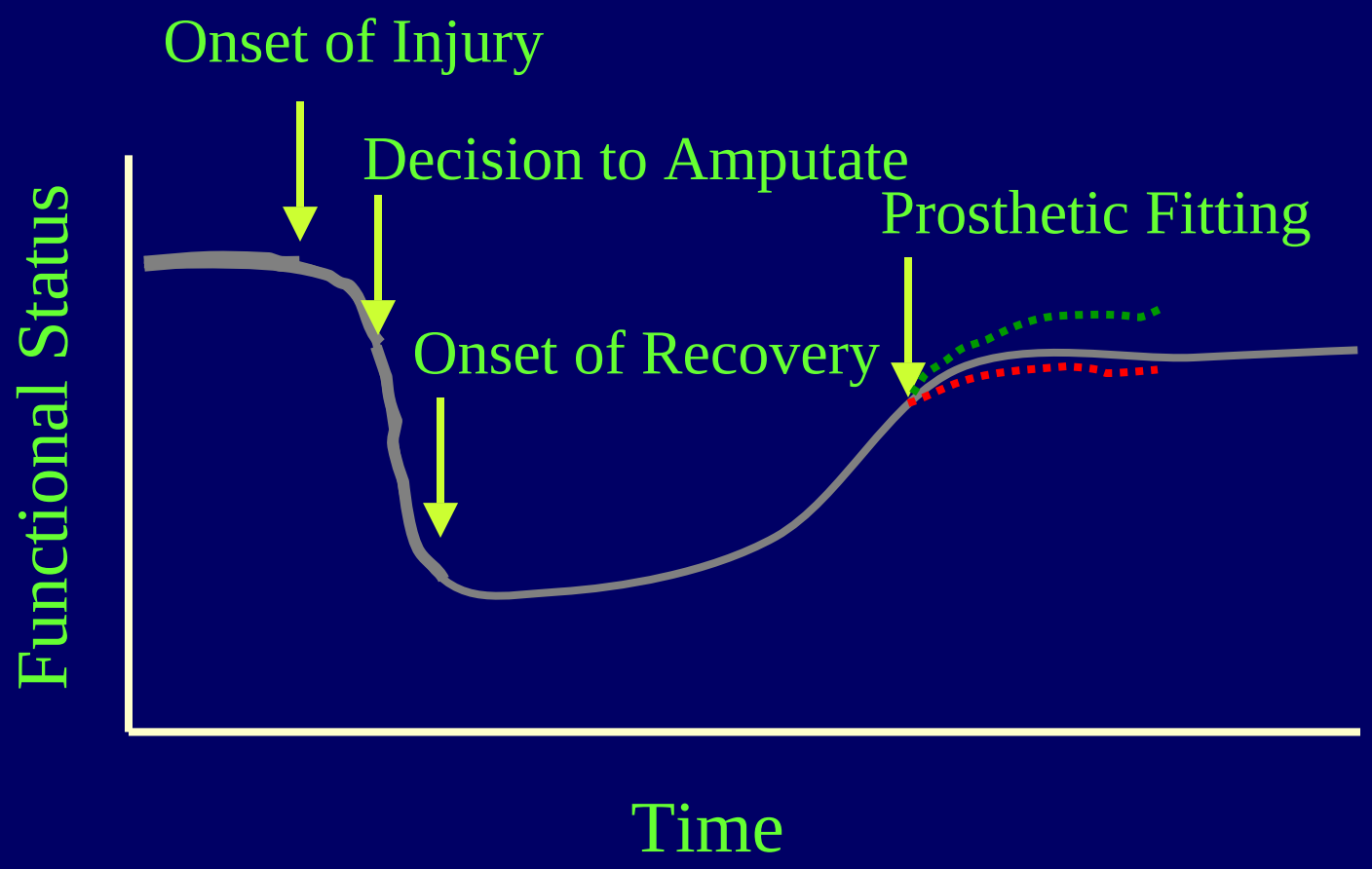
Early Post Amputation Rehabilitation



Early Post Amputation Rehabilitation

- Prevent Complications
  - Joint Contracture
  - Disuse atrophy
  - CV deconditioning
  - DVT
- Wound Management
- Pain management -Phantom Limb Pain
- Psychological adaptation
- Discharge destination
  - Rehab Inpatient stay
  - Home with OP Rehab

Prosthetic Fitting

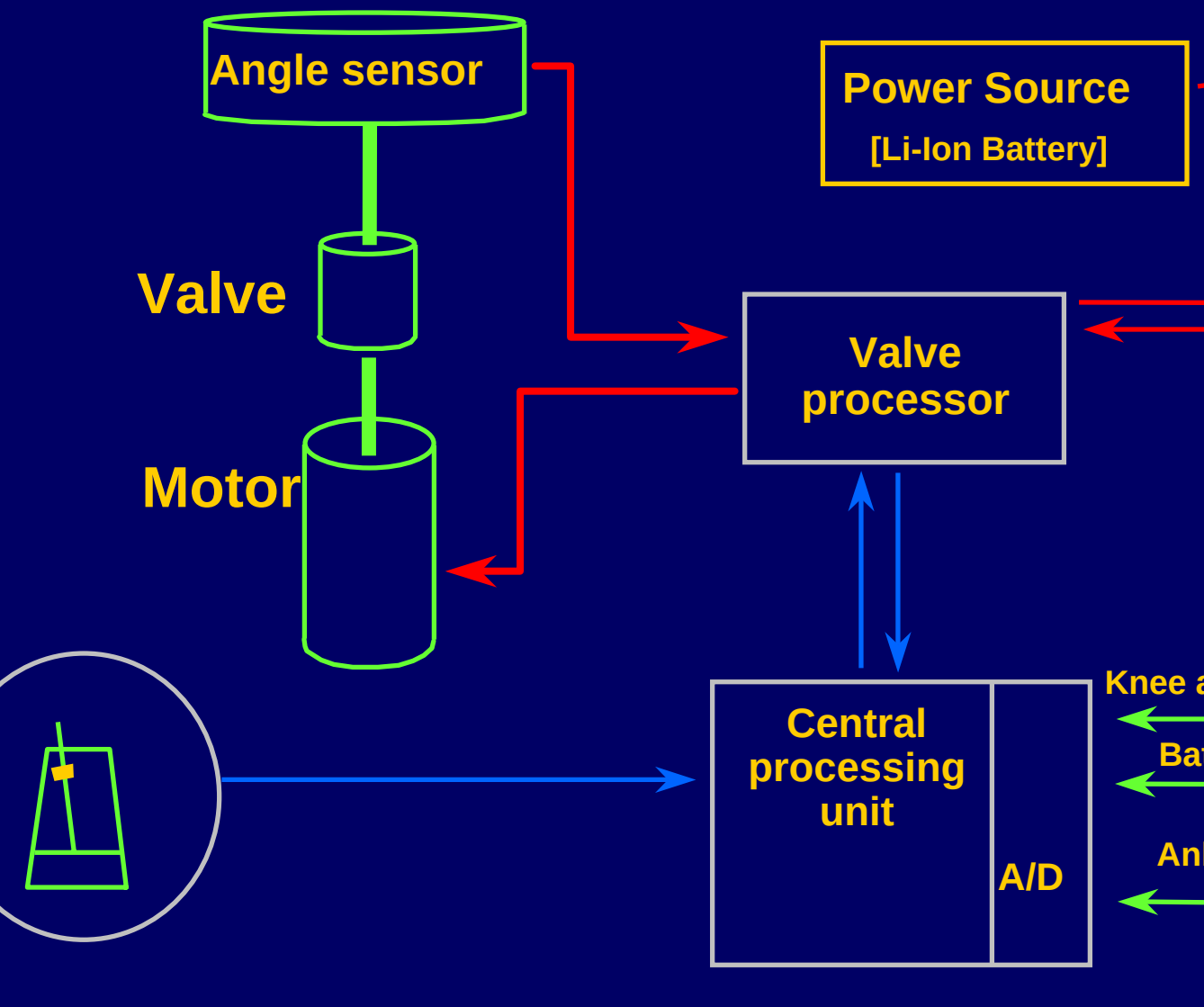


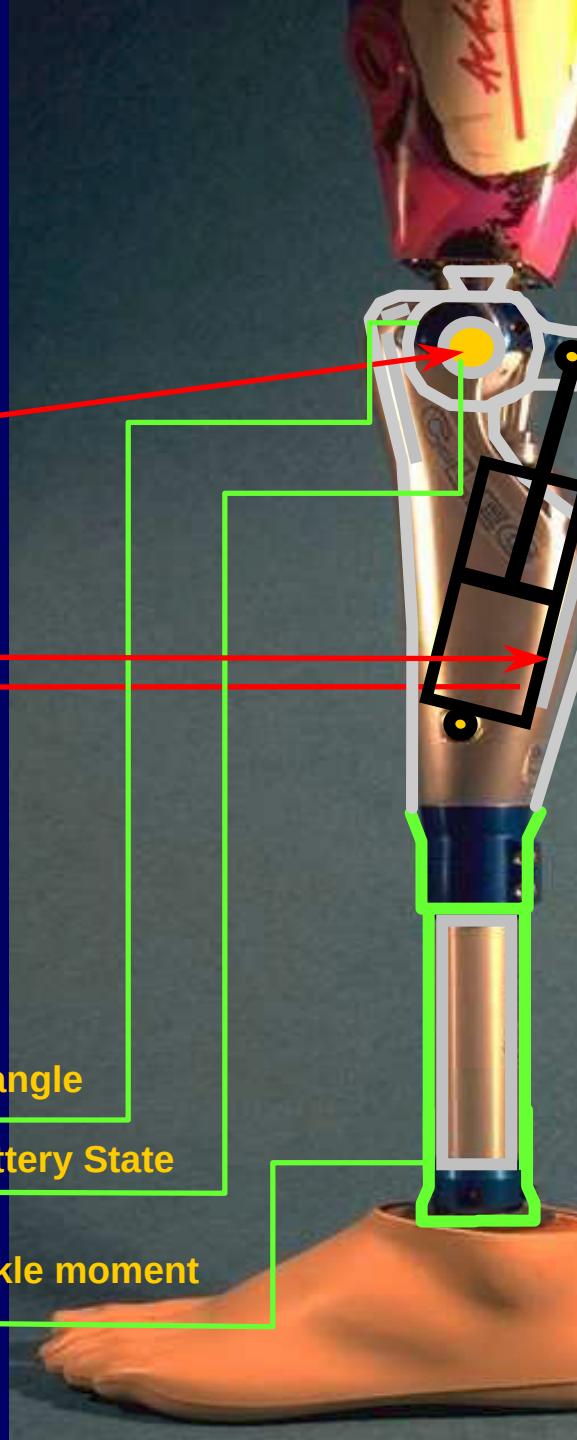
Prosthetic Innovations and Developments to Reduce Primary Disability

Impact Absorbing Pylons

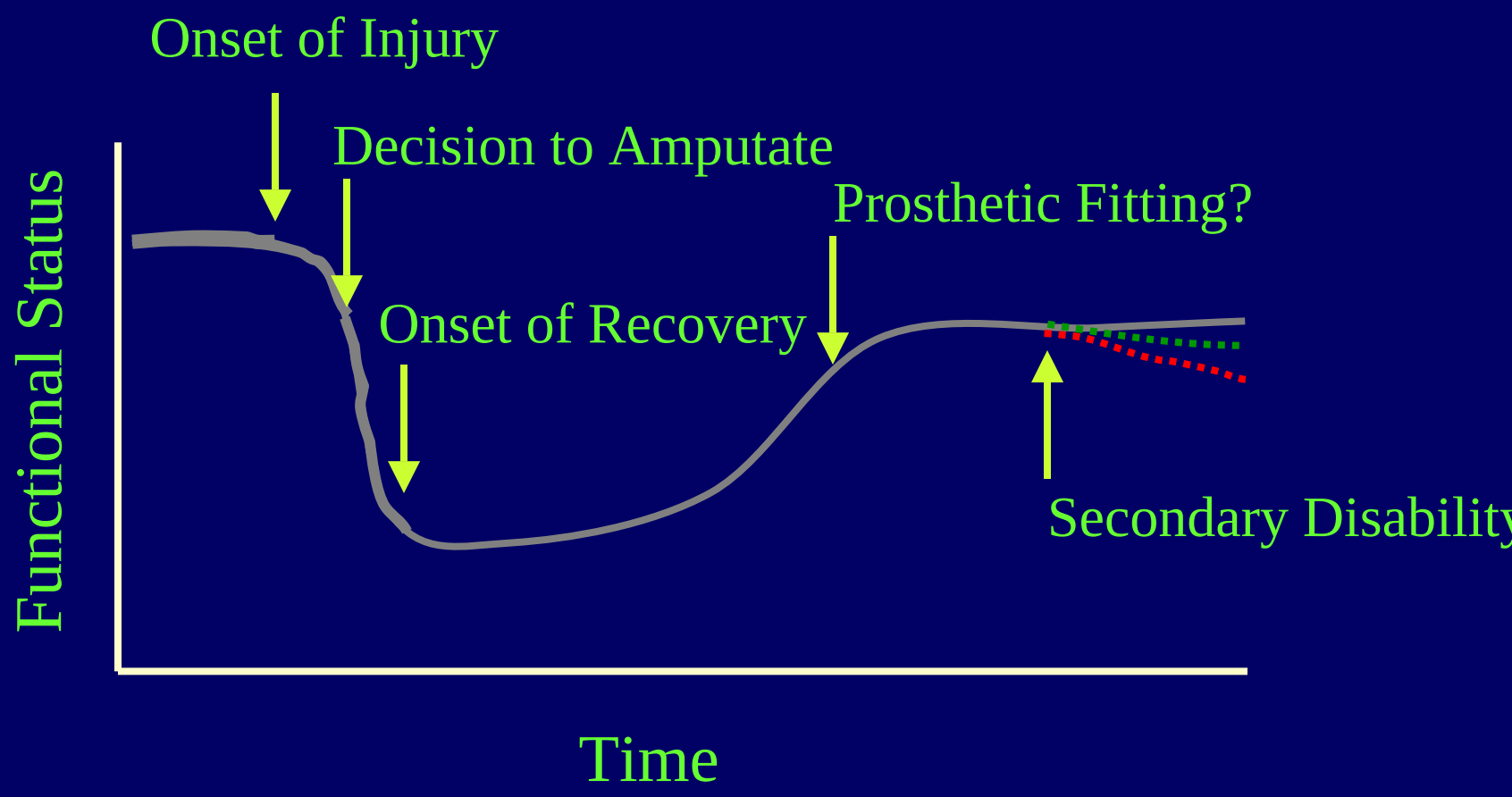
Prosthetic Feet

Adaptive “Intelligent” Knees





Prevention of Secondary Disability



Secondary Disability

- Low Back Pain
  - Incidence 52% (Ehde et al. 1999), 76% (Smith et al. 1999).
    - 50% mod to severely bothersome (Ehde et al. 1999)
- Knee Degenerative Arthritis
  - 63% TF, 41% TT, 21% Control (Hungerford and Cockin 1975)
- Knee Pain

  3 times increased risk in TF,

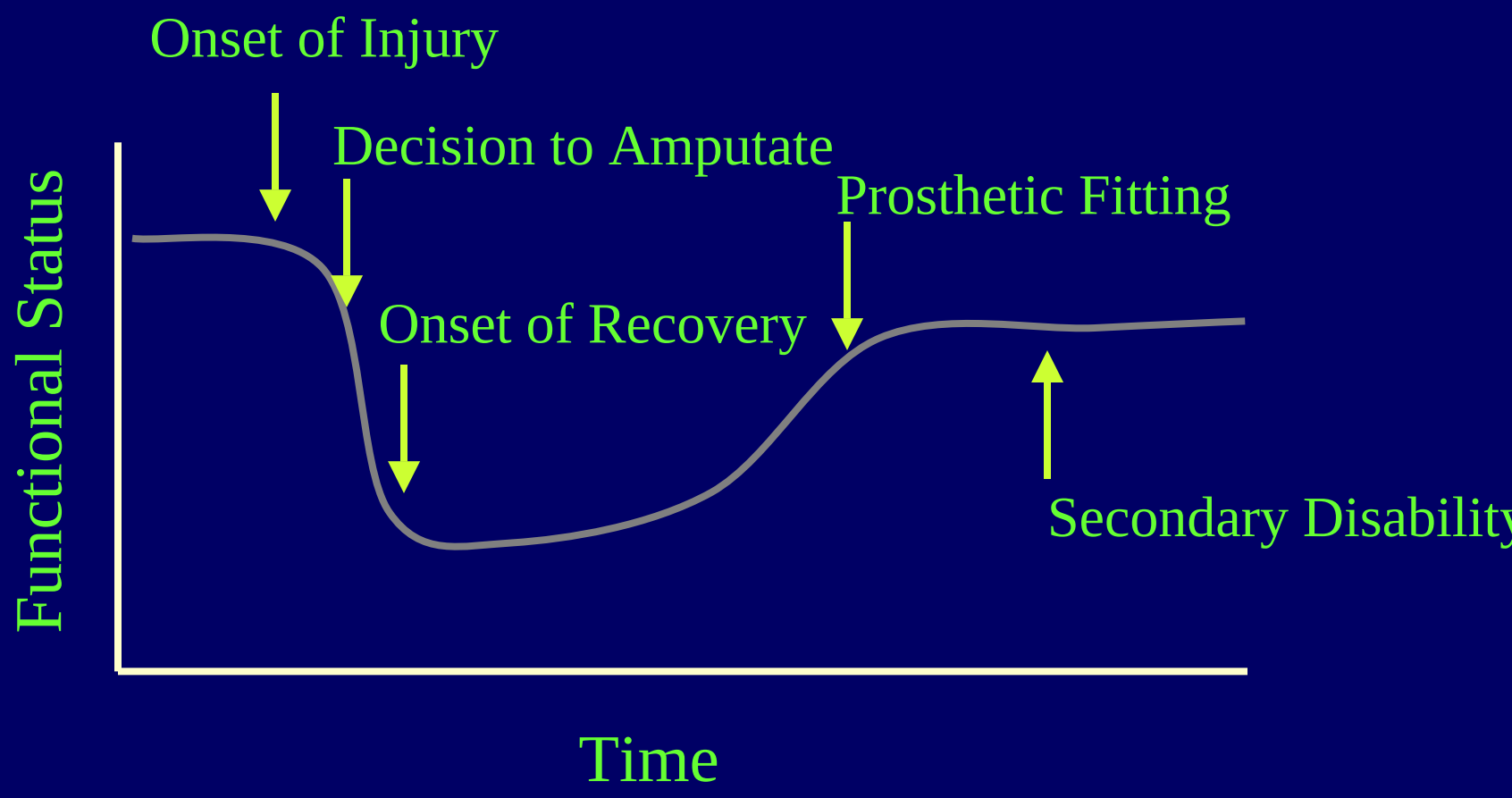
  2 times increased risk in intact limb TT amputees,

  5 times less relative risk in prosthetic limbs of TT amputees (Norvell et al 2003)

Prevention of Secondary Disability

- Very early stage in understanding what the contributing factors are.
- Recent information suggests that choices of prosthetic components and optimizing prosthetic alignment may influence loading of the intact extremity.

Maximizing Functional Outcomes



Osseointegration

Tissue Loading in Amputation

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

- Loads to Residual limb
  - Body weight
  - Moments of force to stabilize and produce movement
- Decreased Length Increased Tissue loads

Current Prosthetic Technology

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

- Soft Tissue / prosthetic socket interface
- Socket designs
- Interface materials

Interface/Suspension Systems

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

ources of Functional Limitation

Patient Perceptions - a Qualitative Approach

- Legro et al. 1999 amputee rating of importance
  - Comfort
  - Avoidance of mechanical skin injury
  - Enhancement of ability to ambulate

- Kegel 1980 factors that limit sports participation
  - Discomfort and mechanical skin injury
  - Fatigue and reduced endurance
  - Inability to walk distances and to run

esidual Limb Pain and Functional Limitation

Traumatic amputees/ mixed levels of amputation.

- 78 consecutive amputee patients admitted to a US urban trauma center, 85% motor vehicle related.
- 43% satisfied with prostheses comfort.
- 25% very/extremely bothered with mechanical skin injury.
- 25% very/extremely bothered by perspiration and heat
    - Dillingham et al. 2000 Am J Phys Med Rehabil

esidual Limb Pain and Functional Limitation

Mixed amputation levels and etiologies.

- 35% rated residual limb pain as severe.
  - Smith et al. Clin Orthop 1999

- 38% rated residual limb pain 7/10 or greater.
- 33% rated residual limb pain as severely bothersome.
  - Ehde et al. Arch Phys Med Rehabil 2000

Residual Limb Pain and Functional Limitation

- 62% report being somewhat or completely satisfied with their health.
- And only 6% reported being dissatisfied with their lives.
- The Mental component summary of the SF-36 is the same as age and sex matched controls.
  - in spite of significant reductions in physical role functioning and pain on the SF-36.
  - Dillingham et al 2000 and Pezzin et al 2000

Osseointegration

- History
  - Acknowledge Douglas Smith, MD
  - VA funded animal research since early 1960's
    - Vitallium, ceramic, carbon implants
    - Other materials to bridge the soft tissue gap.

    - "the animal managed exceedingly well. A freak accident broke the Vitallium rod when the animal jumped a drainage ditch. He was, at the time, being pursued by the principal investigator who was attempting to rope the goat in order to inspect the leg. During this rodeo performance, the animal was leading the herd by several lengths, which proves the function of the artificial limb. Hall WC, Bulletin of Prosthetics Research 1973

Osseointegration; Phase I Surgery Insertion of Titanium Implant

- Phase I
- Surgical revision of muscular attachments
- Insertion of implant
- Most do not wear a prosthesis during this time.

Osseointegration; Stage II surgery Revision with Insertion of Abutment

- 6 months after Phase I
- Surgical revision of residual limb with insertion of abutment.

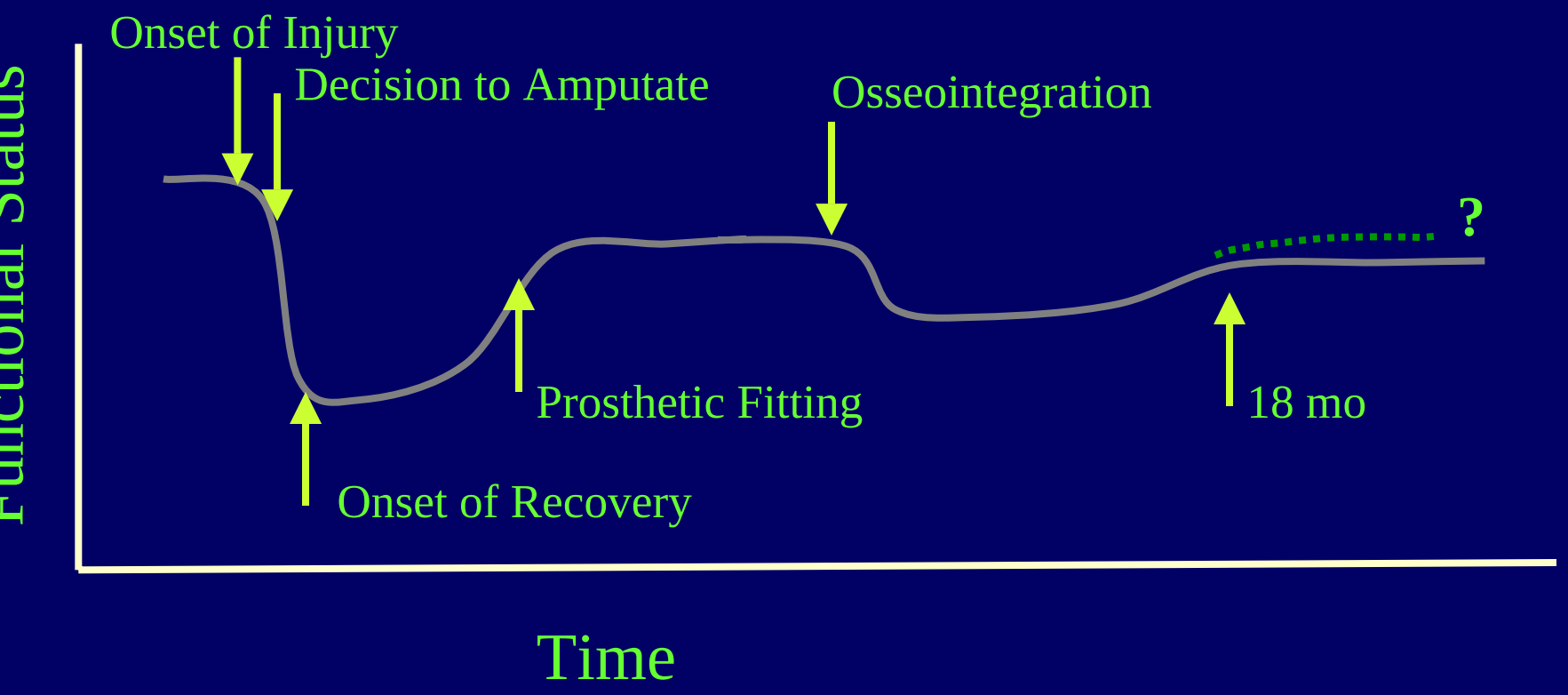
Osseointegration; Progressive Limb Loading

- Limb loading
- Begins 8wks after Stage II surgery.
- Add 10 kg/wk
- Approx 3 mo. to achieve loading to full body weight.
- Muscle strength,ROM program.
- Pain as an issue in relation to limb loading

Osseointegration; Progressive Prosthetic Weight Bearing

- Progressive weight bearing and ambulation for 3 mo. in parallel bars.
- Followed by progressive ambulation with crutches and canes for additional 3 mo.
- Conventional components
  - Require 140 deg knee flex
  - Torque absorber
  - Fail safe component

sseointegration



Osseointegration; Data

Sullivan et al. Roehampton experience..Prosth Orth Int. 2003

- Program Started in 1997 (Experimental Program)
  - 11 patients selected from 56
  - No patients with Diabetes or Vascular disease or immune deficien
  - Primary indication“Failure of conventional prosthetic fitting”.
    - skin soft tissue problems
  - Adults less than 70 years of age.
  - Medical status will allow two surgical procedures.
- Time
  - 18 mo. time investment from start to full weight bearing
  - On average 46 outpatient visits after stage II surgery.
  - Need for relative geographic proximity (150 miles?) to amputation/rehabilitation care.

Osseointegration; Outcomes

- 3 patients with osteomyelitis (28%)
  - 2 had implant removed,
    - (two additional surgeries), gentamycin impregnated cement insertion and removal.
    - No shortening of residual limb, one returned to prosthetic use.
  - 1 on chronic antibiotics
- Psychosocial consequences
  - 4 divorces in 11 subjects.
- No improvement in gait (descriptive)
- No other measures of function, mobility, quality of life.

Osseointegration; Outcomes

- Activity limitations
  - Swimming; infection risk?
  - Limitations in running, jumping, heavy manual work; risk of mechanical failure.
  - Cosmetic limitations, no cover above the prosthetic knee.

Osseointegration; Outcomes

In successful candidates (no objective measures)

- Enthusiastic expression of appreciation.
  - “like the blind being able to see?”
- Enhanced Comfort
- Perceived improved proprioception.
- Perceived reduced energy cost during ambulation.

Osseointegration: Is it currently a clinical strategy that is ready to be used on Veterans or Combat related amputees?

- In some countries it is an accepted clinical procedure.

- In some countries it is considered an experimental procedure? (Canada, Australia, England)

Osseointegration:
A Clinical procedure vs Experimental procedu

- Who? When do benefits outweigh risks?
- Roehampton
  - Only those that are a failure of conventional prosthetic management. Skin soft tissue problems.
  - No vascular disease, diabetes, or medical conditions that would increase risk of infection, or medical disease that would pose undue surgical risk.
  - Less than 70 years of age, less than 100 kg
- What outcome measures? Control population?
- Multi-center?

Informed Consent

Moving away from the concept of legalistic protection of physician and hospital.

"Reasonable people need to know their treatment options, the general risks, benefits, and probable outcomes of each option, and the reasons that the physician has recommended a specific treatment."

Informed Consent: James Bernat, Muscle and Nerve, 2001

Challenges of Osseointegration

Bone - Implant Interface

Three Piece Implant Modeled after Dental Implant Design

Skin - Implant Interface

Creation of Sub-Dermal Skin/Bone Interface

Challenges of Osseointegration; the Bone-Implant Interface

- Key limitation is time
  - 6 months to begin wt bearing.
  - Additional time for progressive weight bearing.
  - Rehabilitation delay
  - Remove patients from their typical social/physical roles.

Challenges of Osseointegration; the Bone-Implant Interface

- Is it possible to accelerate the loading without adverse effect?
- Is it possible to insert the implant as part of the primary amputation.
  - ? Limit the adverse impact on rehabilitation time
  - Is there a difference to time of osseointegration if there is normal cancellous bone or osteopenic bone?

Challenges of Osseointegration; the Skin Implant Interface

- Infection
  - Serious Adverse Outcome
  - ? Novel biomaterials approach to reduce risk of infection.

Summary

- Dilemma
  - Intervention is not trivial and is costly
  - Published outcomes are limited in quality and number
  - Significant side effects
  - BUT……in those that are successful patient response is very impressive.
- Clinical utility?
- Experimental procedure?
- Basic science research on bone implant and skin implant interface.

Can we do better?

Event	Class	Time
Men's 100 m	A2	12:86
	A4	11:33
Men's 200 m	A2	27:39
	A4	22.85
Men's 1500 m	A 4	5:50.88