Caries management by risk assessment: The CaMBRA randomized clinical trial

Principal Investigator:

John D. B. Featherstone

Co-investigators:

Stuart A. Gansky, Chuck Hoover, Marcia Rapozo-Hilo, Kim Tran, Jane A. Weintraub, Joel White, Robert Wilson, Ling Zhan

Mentored students:

Lawrence Li, Gloria Khoo, Maureen Khoo, Dan Walton

Support: US DHHS/NIH/NIDCR R01 DE 12455

In-kind: OMNII Pharmaceuticals, Oral B, Proctor & Gamble

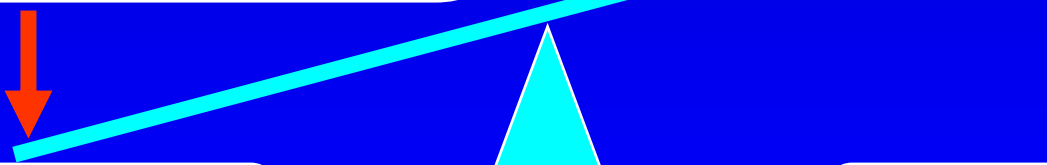
Background: The Caries Balance

Protective Factors

- Saliva flow & components
- Fluoride - remineralization
- Antibacterials: chlorhexidine, xylitol, new?

Pathological Factors

- Acid-producing bacteria
- Frequent eating/drinking fermentable carbohydrates
- Sub-normal saliva flow & function



Caries

No Caries

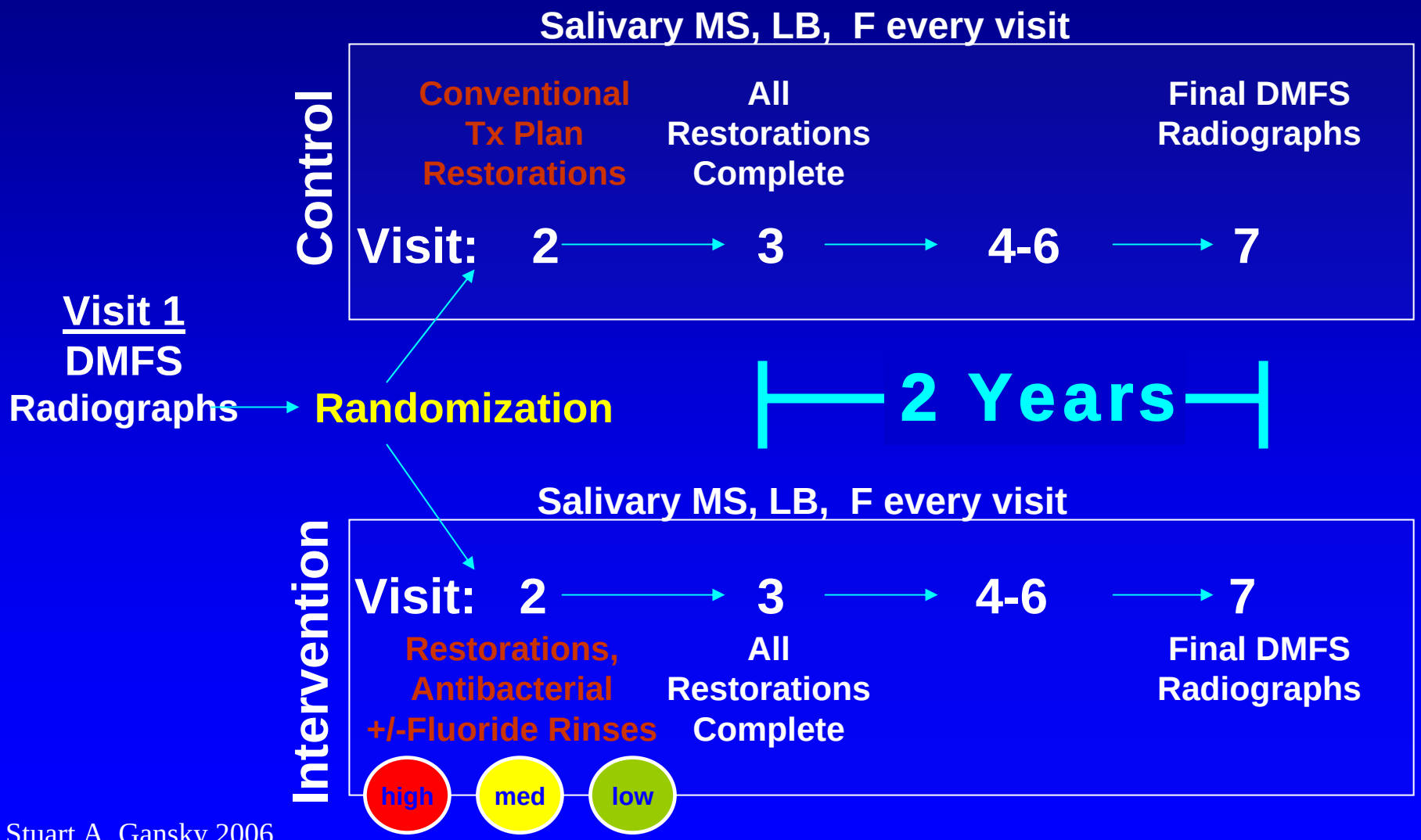
chinowa
Kyoto, Japan
June 2001

Overall Aim of the Study

The overall objective of the study was:

To provide clinical evidence that caries risk assessment with aggressive preventive and therapeutic measures can restore the balance between caries pathological and protective factors, thereby reducing new caries formation over 2 years

Caries Management Study



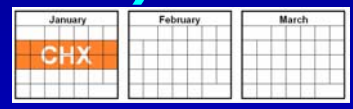
Methods – Study Enrollment

- **3 yr randomized clinical trial: 231 adults (18+ yrs)**
- **Eligibility: 16+ teeth, 1-7 cavities, no root caries**

- **Restorations completed (RC) in average of 12 mo**
- **Saliva samples (paraffin stimulated) every 6 mo:**
  - **selective microbiology (MS & LB, CFU/ml saliva)**
  - **fluoride (F, ppm)**

Methods – Tx Grps

Preventive Intervention (PI) Group (n=116)



- Chlorhexidine gluconate (0.12%) rinse, 1/day for 2 weeks every 3 months (or 1 week / month) based on salivary MS and LB levels
- Fluoride mouthrinse daily (0.05% NaF) based on salivary F level

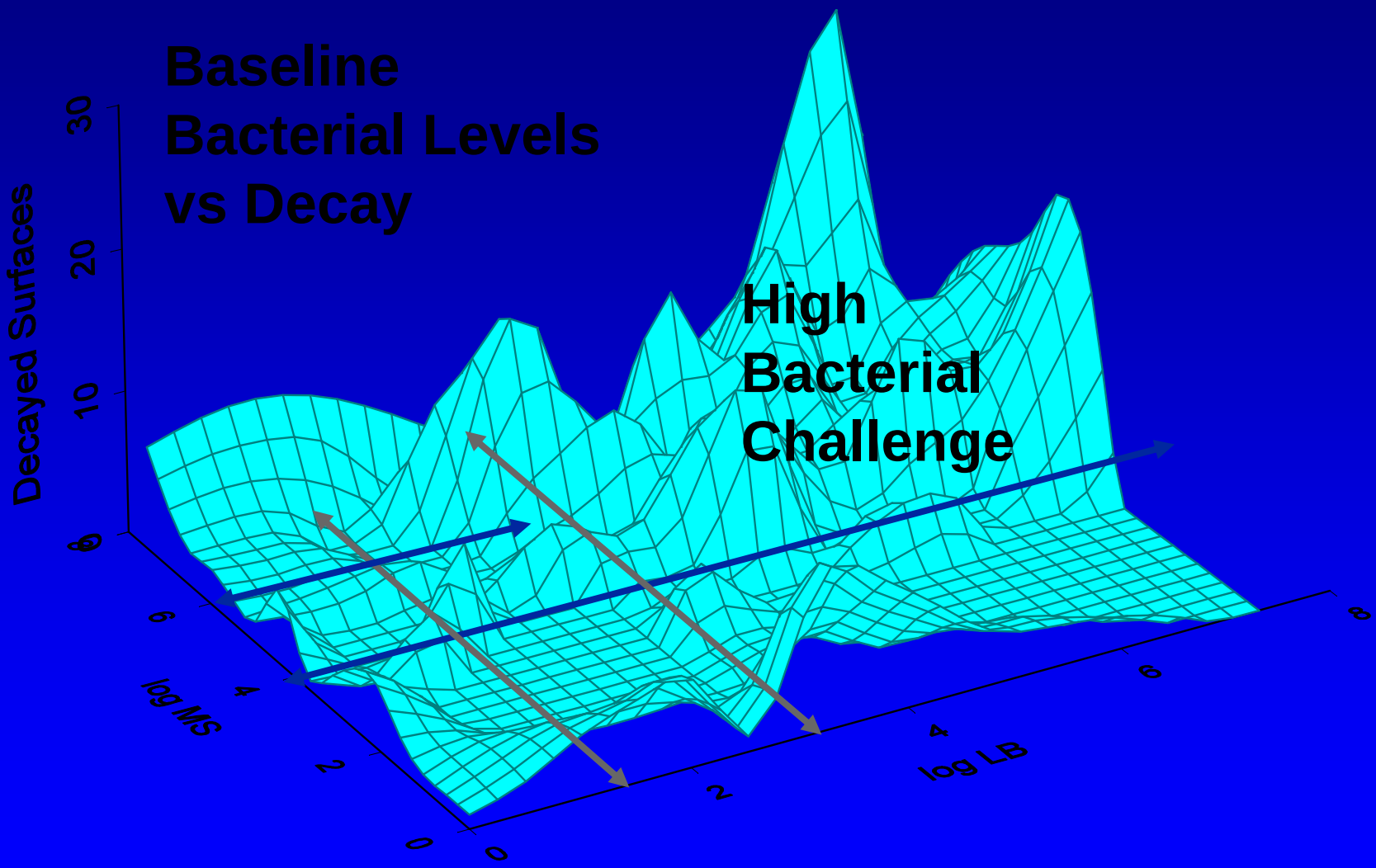
Control (C) Group - conventional care (n=115)

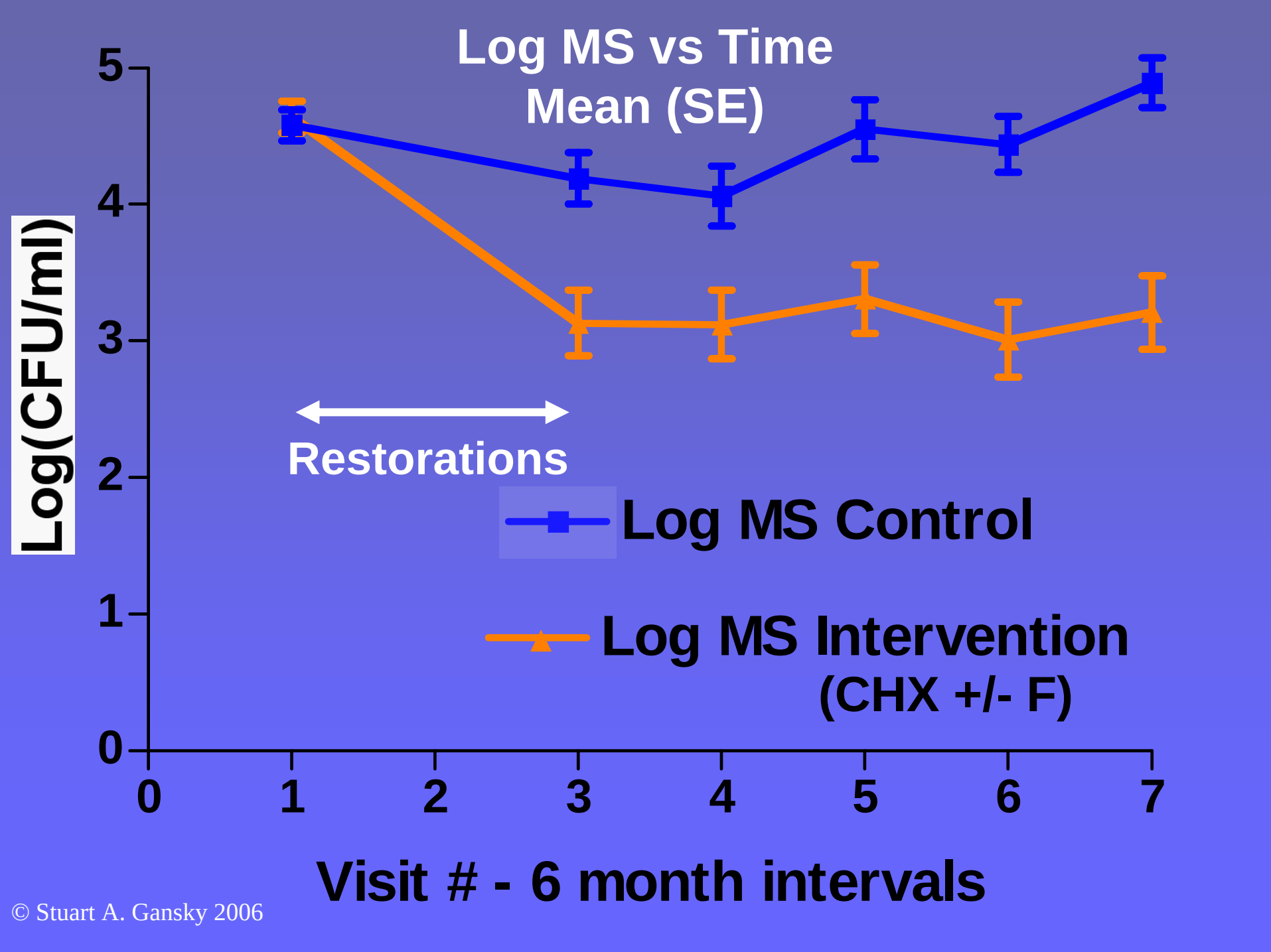
- No fluoride or chlorhexidine rinse supplied
- Providers unaware of salivary assay results

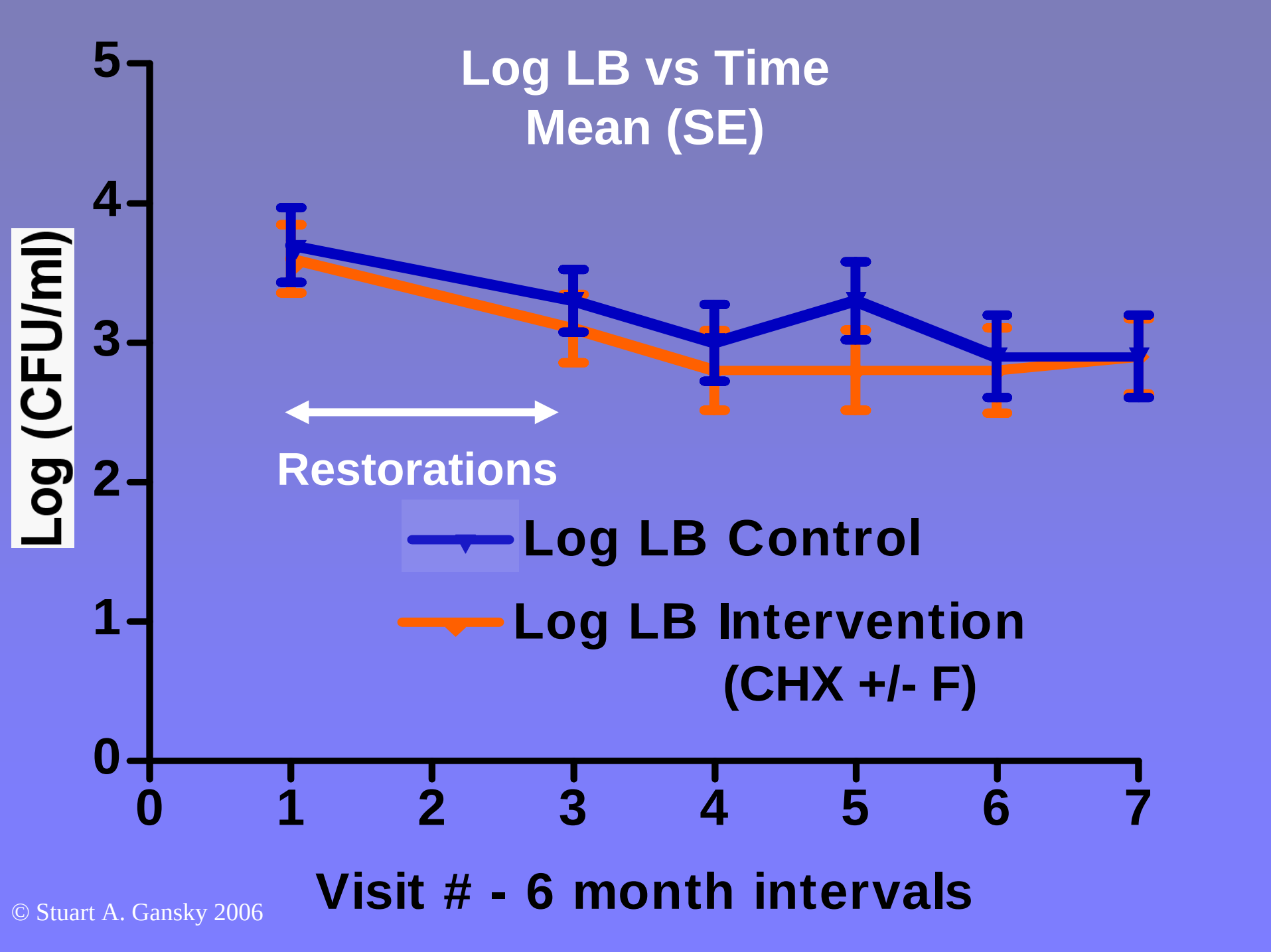
- 2 year follow-up after RC to final examination
- Final examination (1 calibrated examiner - JAW)

Overall Caries Risk F > 0.08 ppm		Log_{10} (Mutans Strep + 1) (CFU/ml) Low ≤ 4.0	Medium 4.0 – <6.0	High ≥ 6.0
Log_{10} (LB +1) (CFU/ml)	Low < 1.3	Low	Medium	High
	Medium 1.3 – <3.0	Medium	Medium	High
	High ≥ 3.0	Medium	High	High

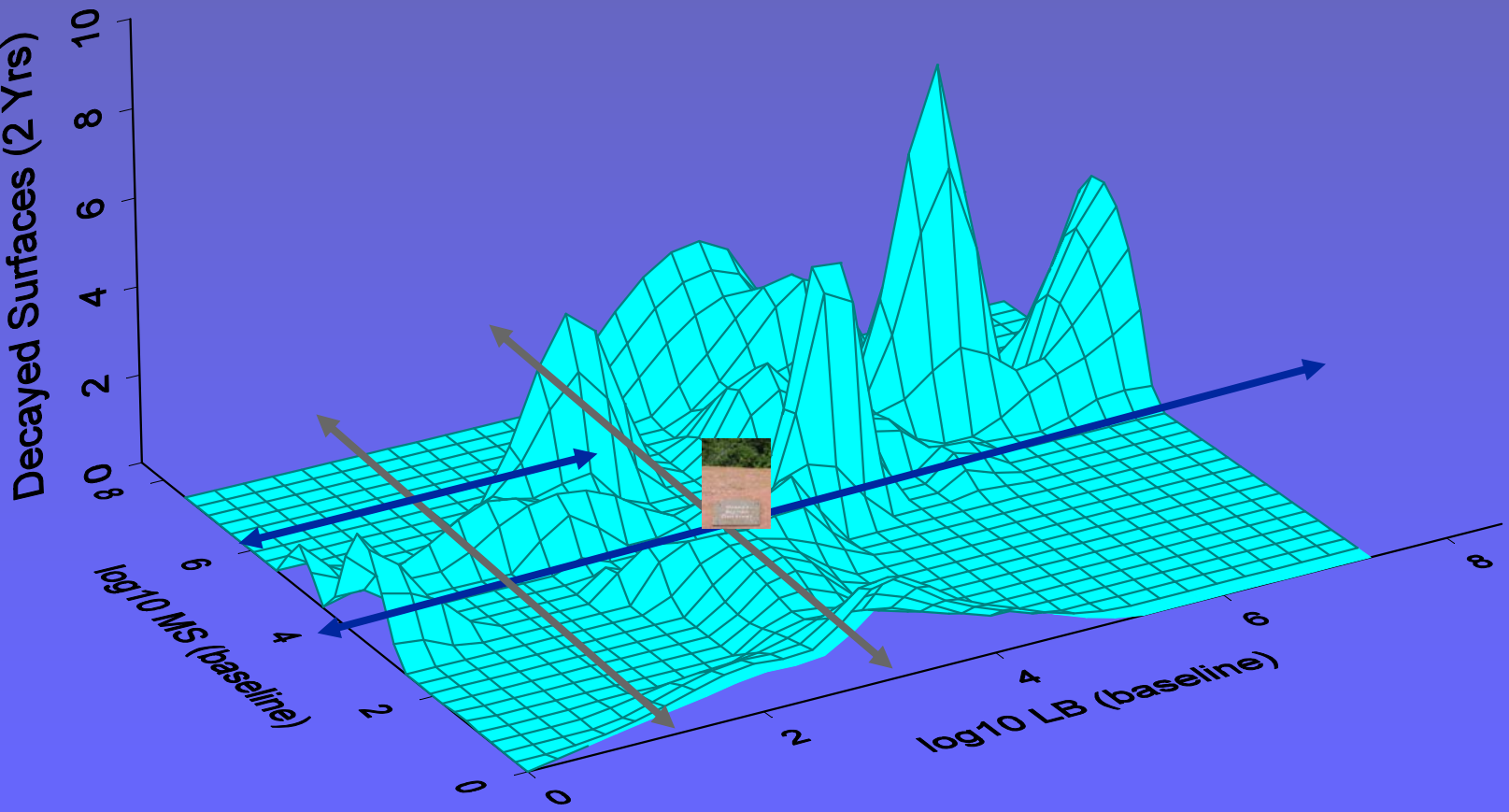
Decayed Surfaces vs. log MS and log LB





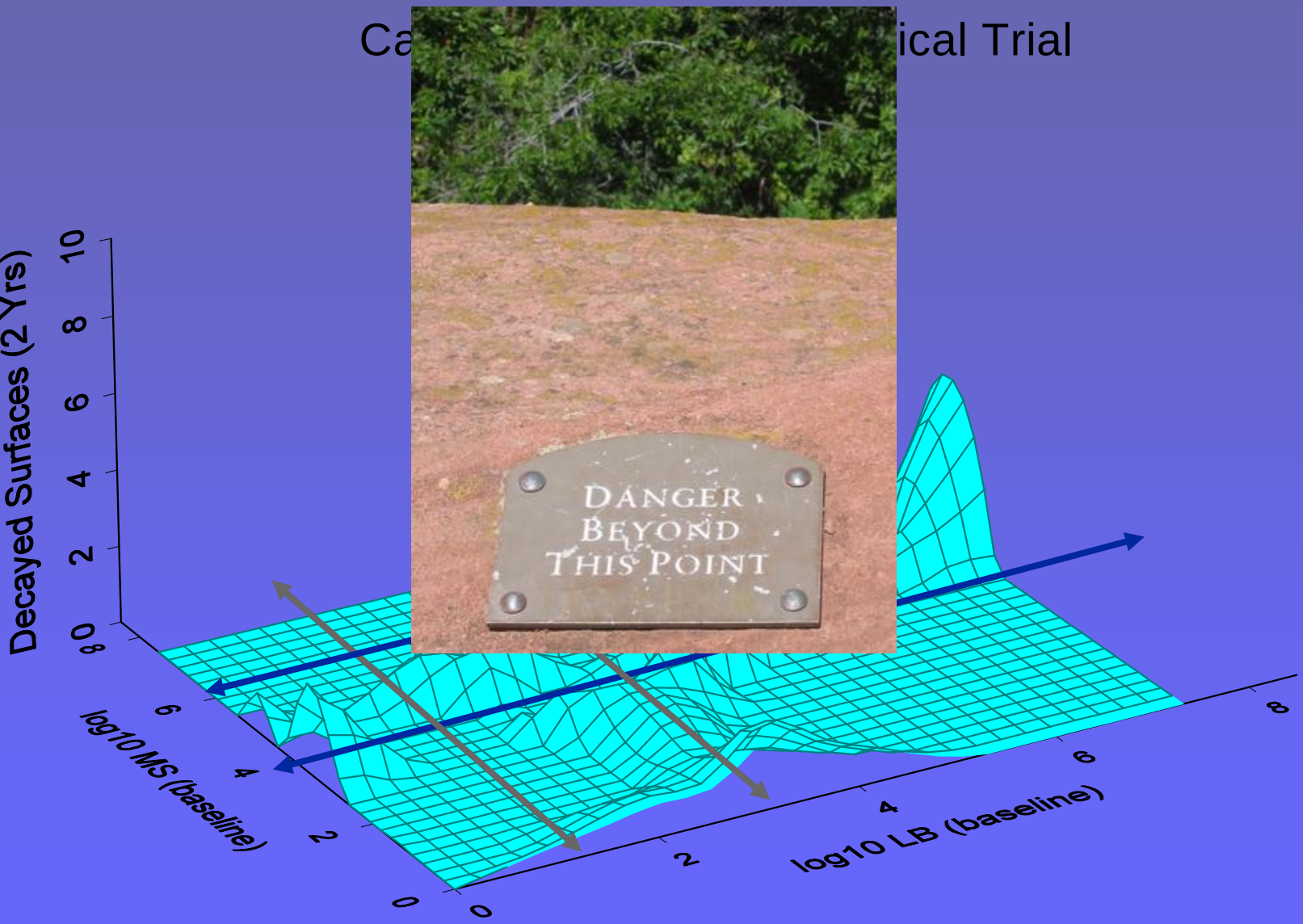


Final Caries Status Related to Baseline Bacterial Levels
CaMRA Randomized Clinical Trial

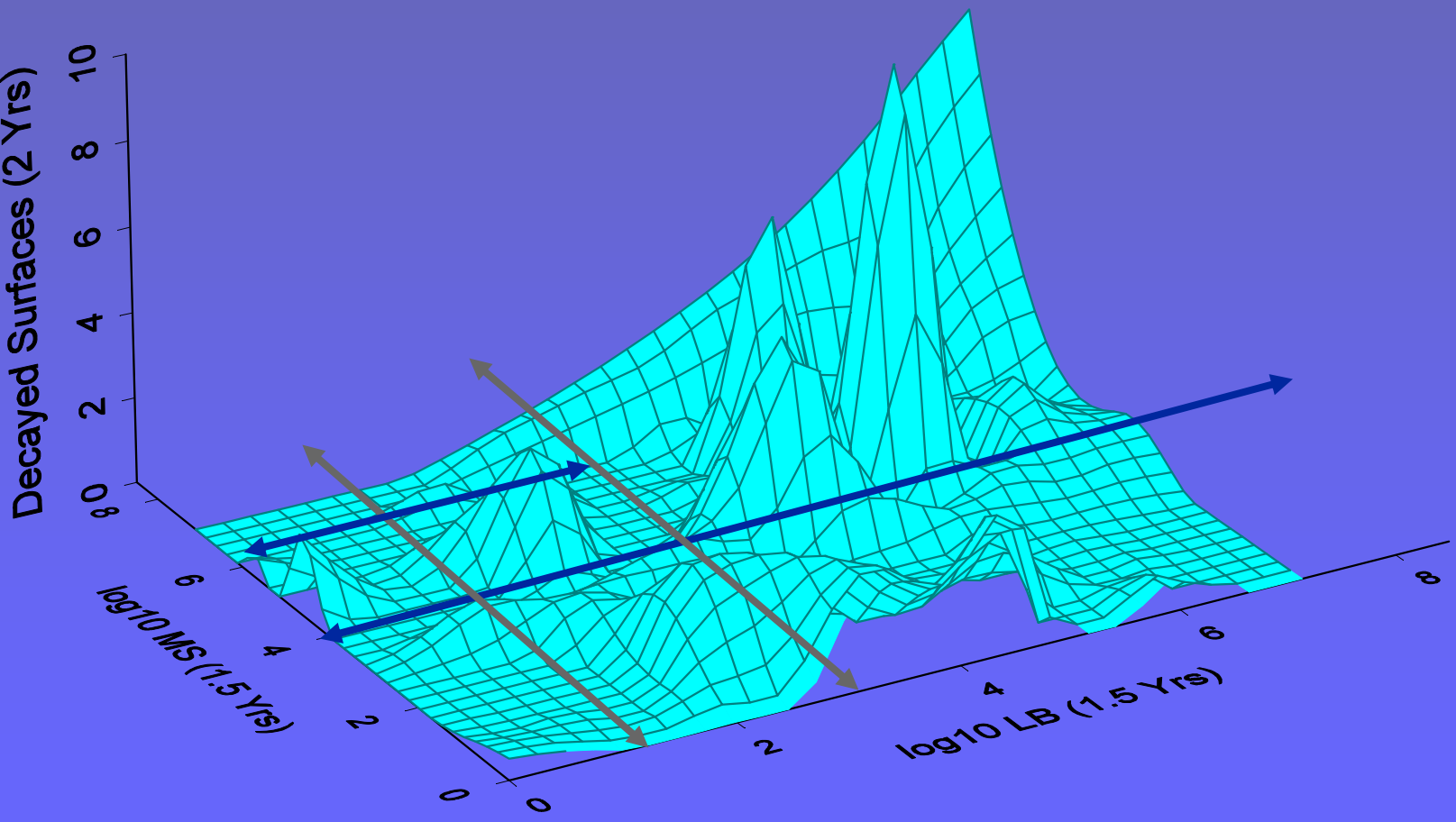


Final Caries Status Related to Baseline Bacterial Levels

Ca ical Trial



Final Caries Status Related to Bacterial Levels 6 Months Prior
CaMRA Randomized Clinical Trial



Final Caries Status Related to Bacterial Levels 6 Months Prior
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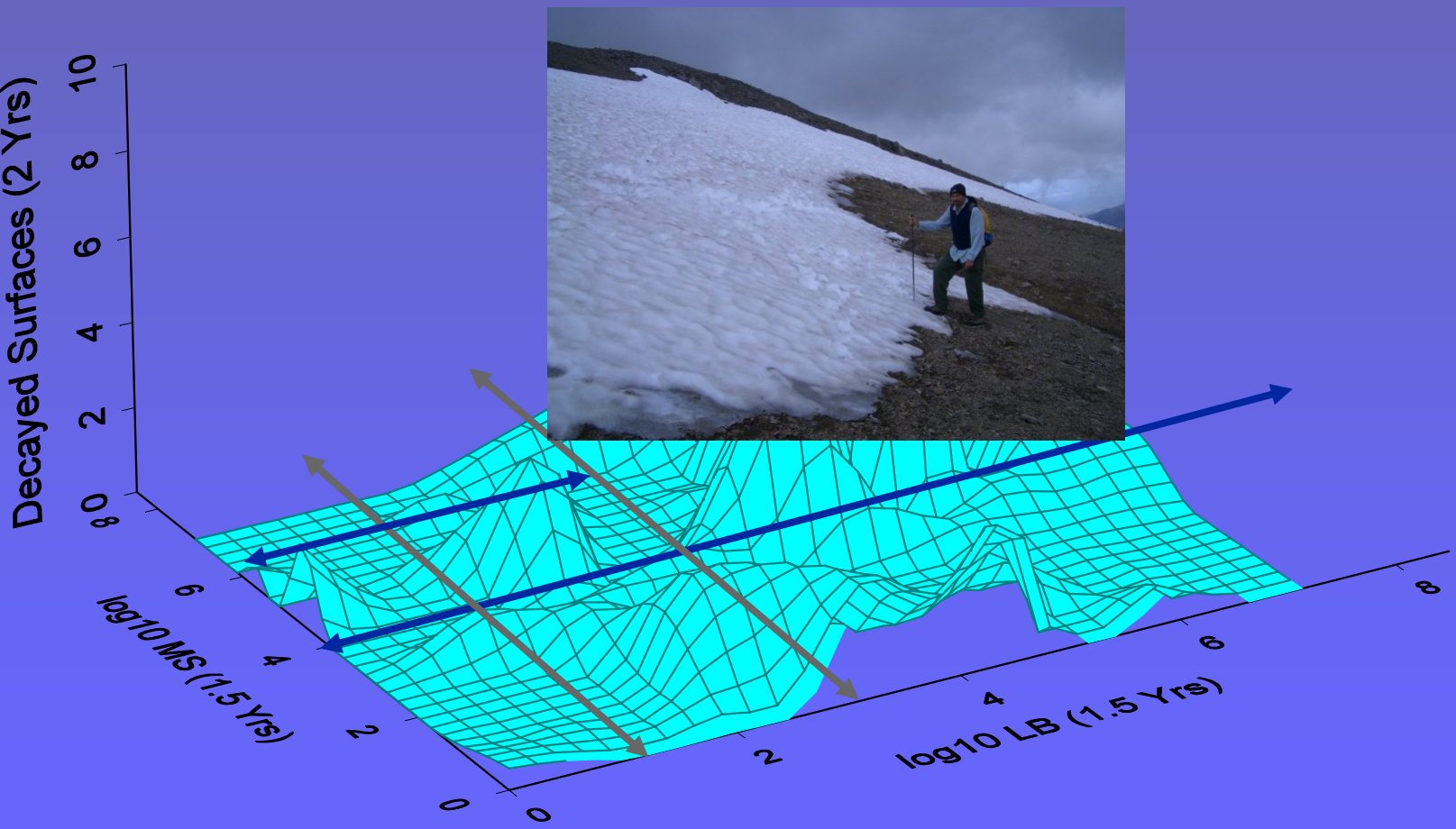
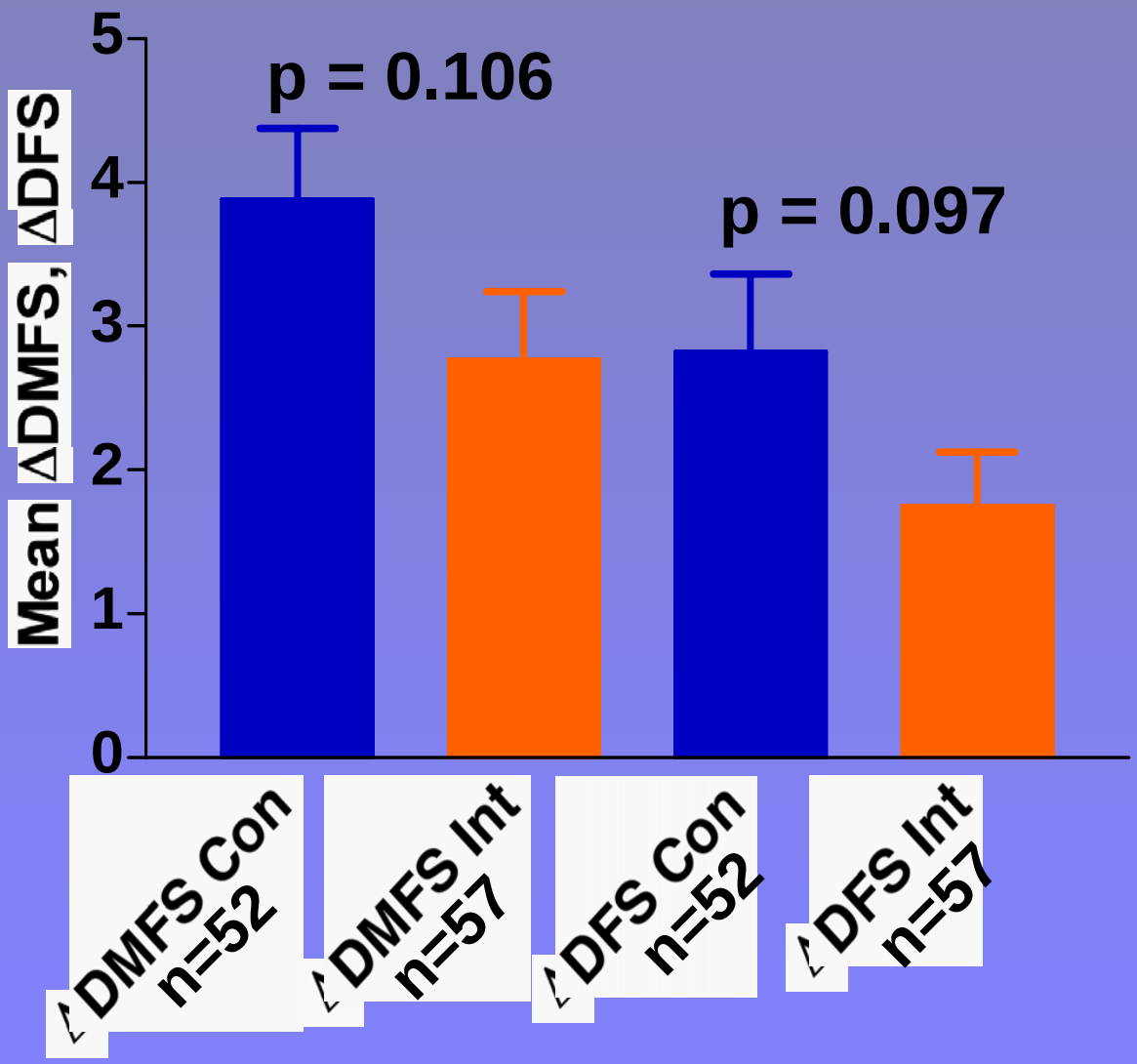


Mean (SE) ΔDMFS, ΔDFS



Limitations

- **Lower enrollment than (231 not 296), but better retention than planned**
  → slightly smaller sample size (109 not 122)

- **Compliance**

Overall Conclusions

- **Oral MS challenge stays essentially the same even after restoring all teeth with cavities**
- **Chlorhexidine gluconate (0.12%) +/- F (0.05% NaF) intervention is valuable during and after treatment to reduce caries risk status**
- **Caries risk status can be determined from MS, LB counts and F concentration in saliva**
- **Favorably altering the Caries Balance somewhat reduces subsequent caries levels**

Did We Prove Our Hypothesis?

This randomized clinical trial:

provided clinical evidence that caries risk assessment with aggressive preventive and therapeutic measures can beneficially alter the balance between caries pathological and protective factors somewhat reducing new caries formation over 2 years