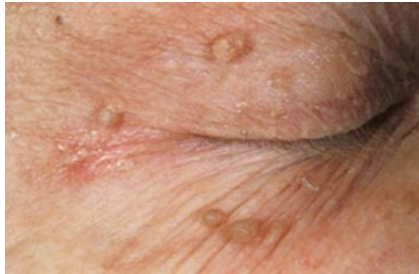




**BL-5010P**  
**A NOVEL PRE-FILLED**  
**APPLICATOR**  
**FOR THE NON-SURGICAL**  
**REMOVAL OF SKIN LESIONS**

**BIOLINERX**

# Skin lesions



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# Skin lesions

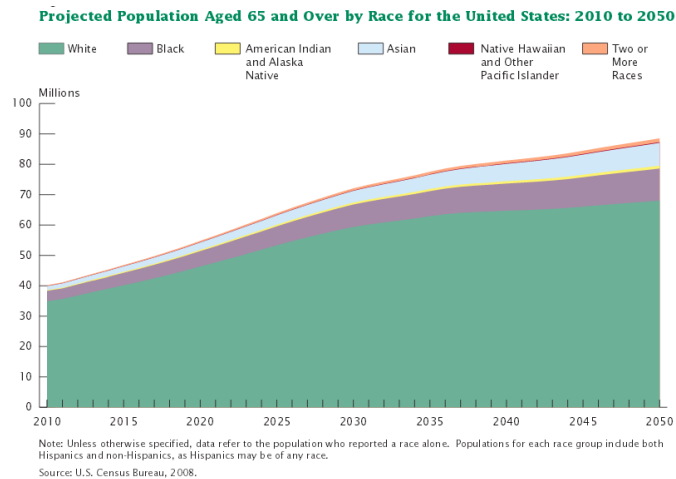
- A part of the skin that has an abnormal growth or appearance compared to the skin around it
- Most lesions are non cancerous or precancerous
- Causes: UV exposure (most lesions), skin aging, infection (e.g. warts)
- Risk factors: genetics (e.g. pale skin), age
- Not all lesions are preventable
- Huge patient awareness
  - Visible, embarrassing, scary, itching...



# Most people have skin lesions

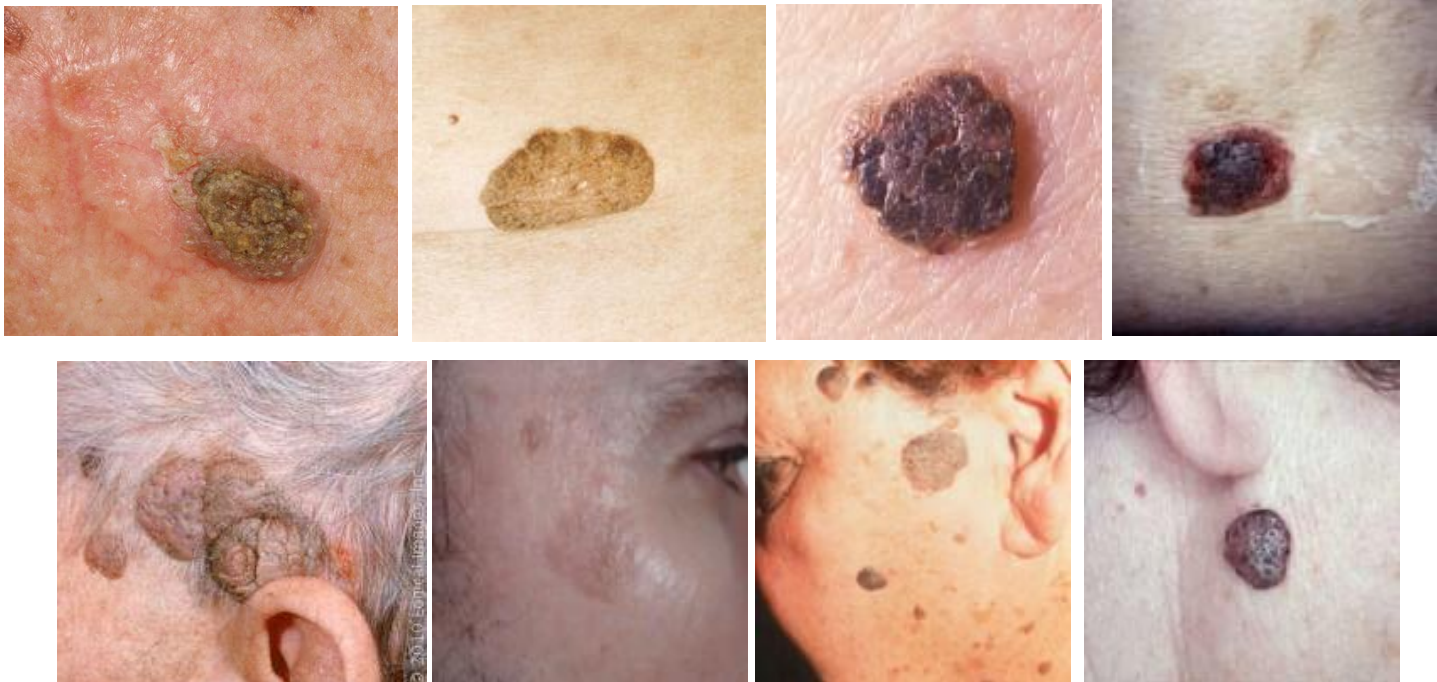
- A significant part of general dermatology
  - SK- the most common lesion dermatologists see
  - AK – estimated 58 million Americans, each with multiple lesions
  - Warts- ~5% of US dermatologist visits
- Many precancerous lesions per individual
  - Having a precancerous lesion predicts more lesions in the future
- Increase with aging, fair skin
  - Socioeconomic burden of skin lesions is expected to rise significantly
- Non-reportable condition

Code	Description	% use
1700 0	Destruction of premalignant lesion - <b>first</b> lesion	10-20
1700 3	Destruction of premalignant lesion - <b>2-14</b> lesions	50-70
1700 4	Destruction of premalignant lesion - <b>15 lesions or more</b>	10-20
1711 0	Destruction of benign lesion up to 15	



# Seborrheic Keratosis (SK)

- Most common, noncancerous skin growths in older adults
- The most common lesion dermatologists see
- Increase with age; **~25% of 15-30 Years old, 30-60% of >60 years old**
- Can look like skin cancer (~1% melanoma resemble SK)
- May itch, get irritated or bleed, cause discomfort and embarrassment



Lesion images in this presentation are from the American Association of Dermatology (AAD), the Mayo Clinic, NIH, and the Centers for Disease Control and Prevention (CDC) Websites

# SK treatment

- Most insurance companies and Medicare pay for SK treatment for intense itching, pain, inflammation, bleeding and infection
- Treatments
  - No topical cream / lotion for therapy or prevention
  - **Freezing with liquid nitrogen (cryosurgery, cryotherapy) - most cases**
  - Scraping the skin's surface with a special instrument (curettage).
  - Burning with an electric current (electrocautery).
  - Vaporizing the growth with a laser (ablation).
- All may leave scars, tight skin, hypopigmentary lesions, permanent hair loss
- ~75% success (LN2)

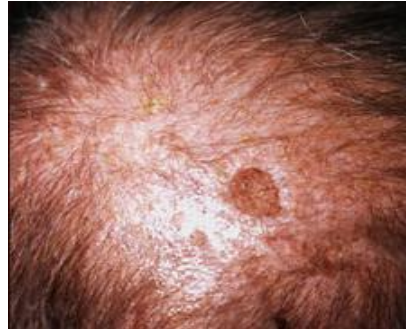


# Actinic Keratosis (AK) – a precancerous lesion

**>58 million (US)**

**The best current estimate of the number of Americans with AKs**

- AKs are among the most common reasons for a US Derm visit
- Between 1990-99, 14% of US Derm visits were related to AKs
- Location: sun-exposed areas
- Most common  $\geq$  age 50 (can appear as early as 30)
- A marker for cumulative UV damage and NMSC risk



# AK treatments

- AKs could develop into SCCs (a skin cancer which could metastasize)
- Treatments are reimbursed
- **Freezing with liquid nitrogen (cryosurgery)**
  - **~80% of procedures**
  - ~75% success
  - Scraping the skin's surface with a special instrument (curettage)
  - Photodynamic therapy
  - Laser therapy
  - Dermabrasion
- Chemical peeling (TCA, might be considered cosmetic)
- Topical creams or ointments
  - Mainly for large areas, prevention
  - 5FU, ~60% of topicals, 61-92% cure rate  
long/pain/inflammation/redness, inexpensive
  - Imiquimod, 65-100% cure rates, milder, expensive
- All may leave scars, tight skin, hypopigmentary lesions, permanent hair loss



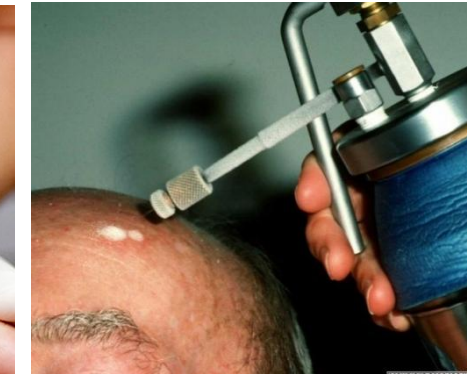
# Viral Warts

- A small, rough, solid growth (“cauliflower “)
- Mostly on hands and feet
- Ten types (non-genital, genital), most are harmless
- Viral infection (HPV)
  
- Lasts months to years, can disappear and reoccur
- Prevalence is increasing, highest in young (20-29) adults
  - 2-20% of teens have plantar warts
  - 2-10% of adults have warts
  - 0.4% (1MM/year US) have genital warts
  - ~5% of US dermatology visits
  
- Treatment
  - Topical salicylic acid (2-3 months)
  - Cryotherapy (LN2)
  - Curettage, electrodesiccation ,laser
  - “Duct tape” (ineffective)



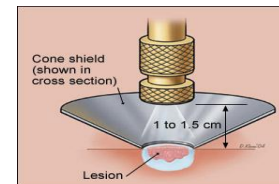
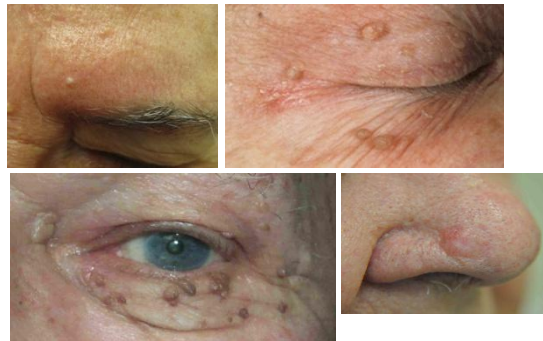
# Liquid Nitrogen (LN2)

- Compressed gas – hazardous material
  - A tremendous amount of force can be generated if liquid nitrogen is rapidly vaporized
- Temperature  $-196^{\circ}\text{C}$ ;  $-321^{\circ}\text{F}$  or lower



# Pros and Cons of LN2

- Most common method used by dermatologists, decades
- Highly effective, many types of lesions
  - 75% success (all skin lesions incl. warts, corn); 90% success (NMSC)
- Quick, low risk, minimal wound care, inexpensive, reimbursed procedure
- Lesions are destroyed – no pathological evaluation
- Accuracy of application
- Cumbersome LN2 logistics
- High sensitivity to pain - fingertips, ears, and temples
  - Alternative might be Mohs surgery (long, costly)
- Bleeding, blister formation, headache, 3-4 days recovery
  - Infection
- Permanent hair loss, hypopigmentation



# Skin lesions - summary

- Most people will have more than one non-cancerous skin lesion
  - Increase with aging, fair skin
  - A significant part of dermatology
  - A huge market
  
- Most lesions are removed with LN2
  - “Simple”, quick, inexpensive
  - ~75% success
  - Not always possible (pain, accuracy)
  - Short and long term side effects