



Reducing Risk in Pellet HRT

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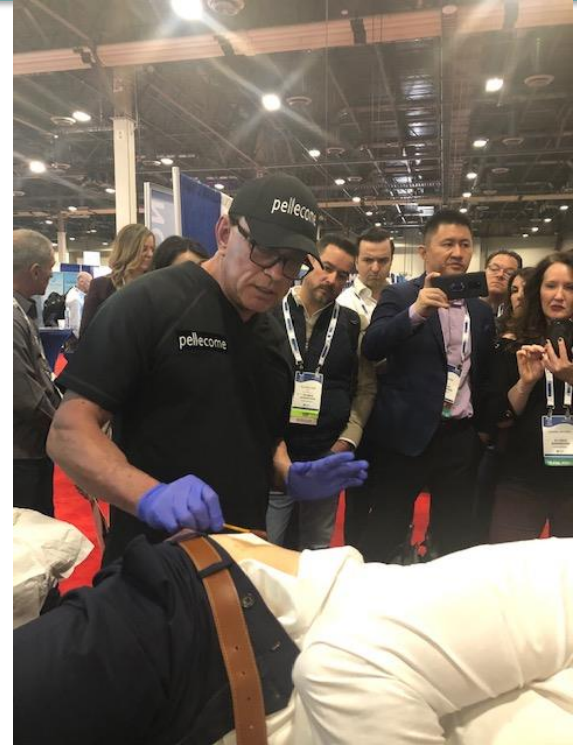
Patient

- Age
- BMI
- Any Absolute Contraindication
- Risk Factors
- Social-Smoking . Drug abuse . HIV status
- CV – Hx of MI- Stroke- TIA – DVT Hx of prosthetic heart Valve replacement
- Immunodeficient conditions SLE –RA
- Hx of Cancer breast-prostate-melanoma-uterus
- Meds Blood Thinners-aspirin –NSAIDs
- Allergies PNC- latex-NSAIDs- epinephrine-anesthetics
- Hx of prior pellet infection- extrusion- rash



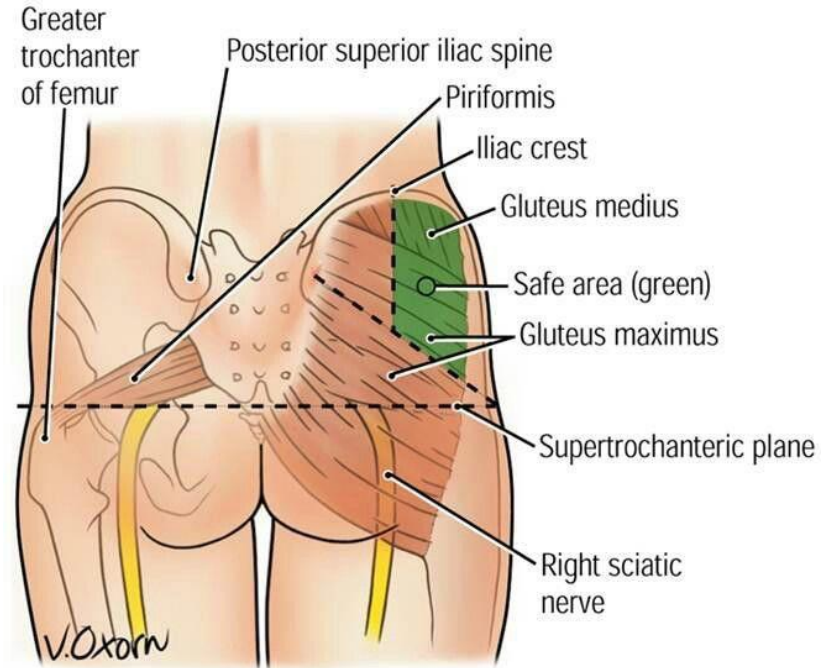
Health Care Provider

- Basic Surgical skills required but more experience is better
- Is Prior Experience on Pellet Insertion required ? No, but is useful
- How many cases are needed to feel comfortable? Unknown but about 5-10
- How many cases are needed to become an expert? Unknown but about 20-50
- Minimum volume to maintain skills ? Unknown but about 1-2 a week
- When is retraining indicated? Unknown but about 12 months



Relevant Anatomy

- What location are pellets placed- UOQ gluteal area
- Where are the pellets placed- In the subcutaneous space above the gluteus maximus
- Structures under the gluteus maximus include
 - Gluteus medius and minimis
 - Below and more medial - Sciatic nerve



B. Posterior View, Intragluteal Injection

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Vascular supply of Gluteal area

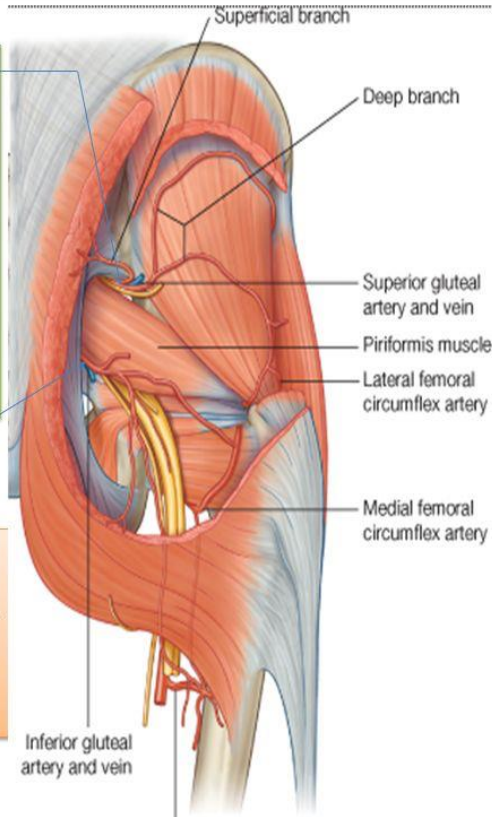
Arteries of the Gluteal Region

1-Superior Gluteal Artery

- is a branch from the internal iliac artery
- enters the gluteal region through the greater sciatic foramen above the piriformis
- It divides into superficial and deep branches.
- The **superficial branch** supplies the gluteus maximus muscle
- The deep branch supplies the glutei medius and minimus.

2-Inferior Gluteal Artery

- is a branch of the internal iliac artery
- enters the gluteal region through the greater sciatic foramen, below the piriformis
- It divides into numerous branches that are distributed throughout the gluteal region.



Nerves of Gluteal area

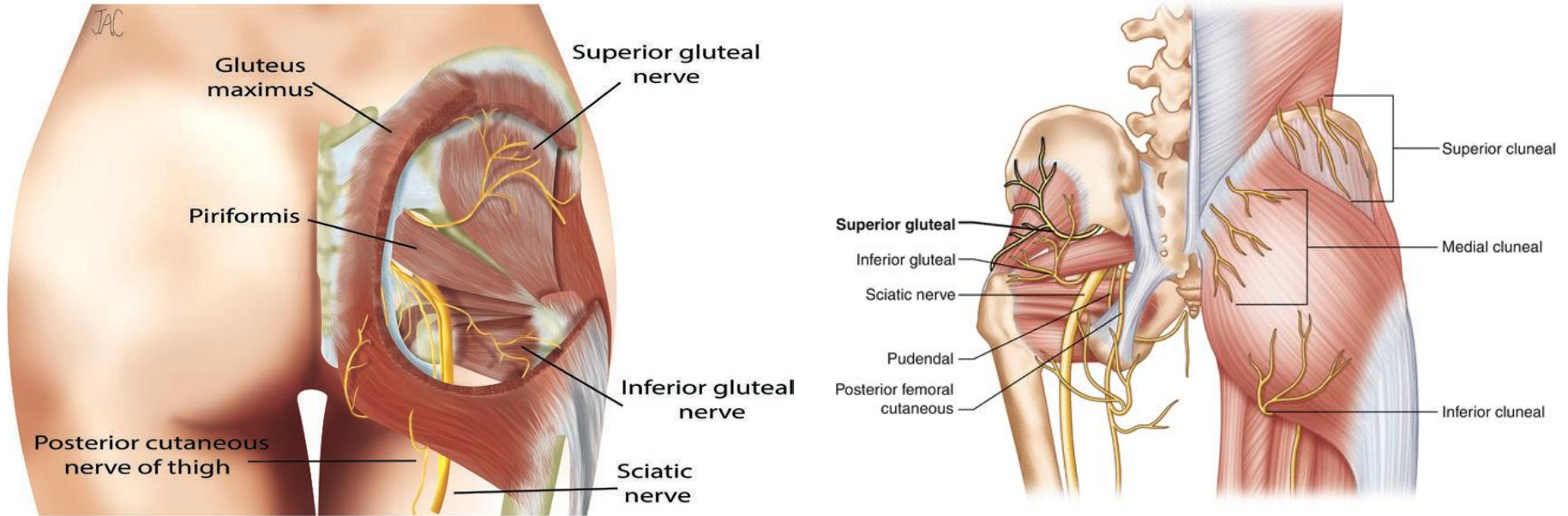
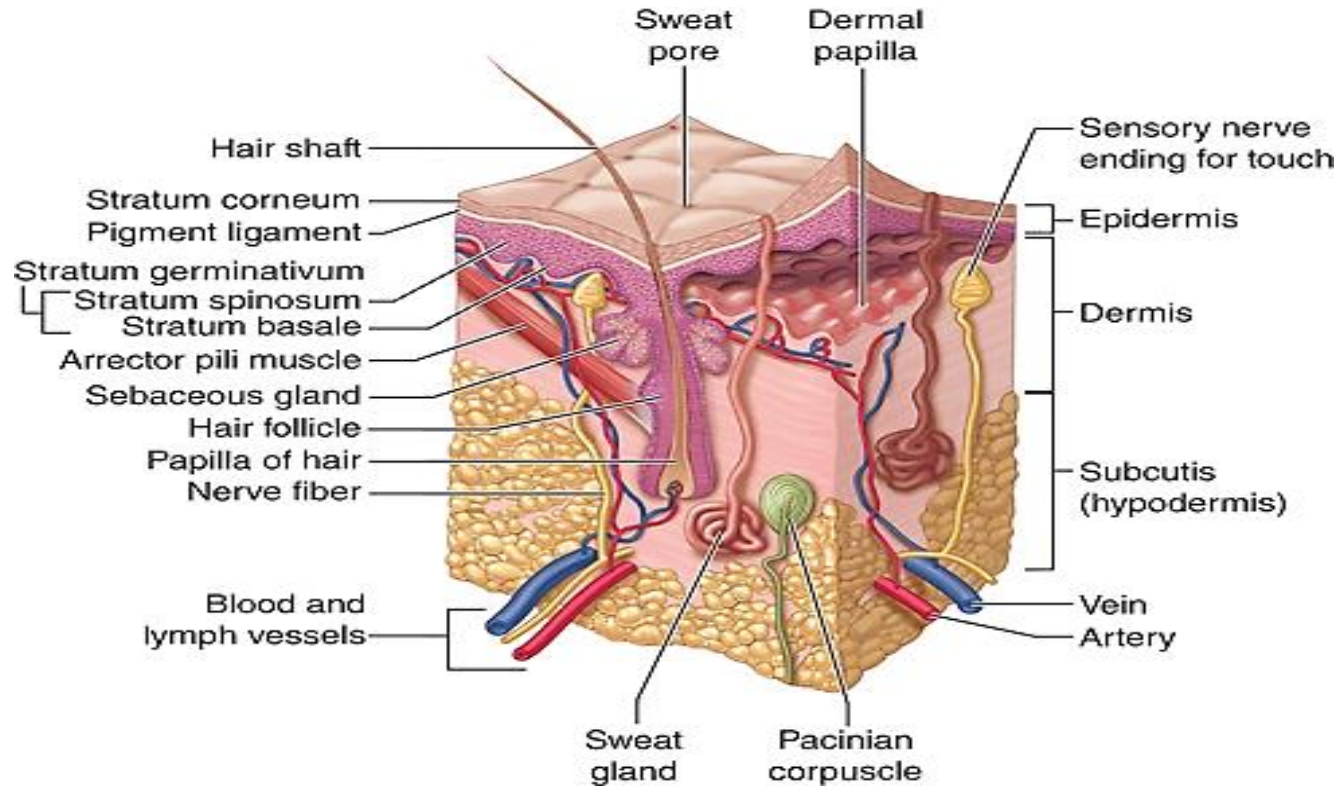


Fig. 3. Gluteal nerves

Anatomic Subcutaneous Structures

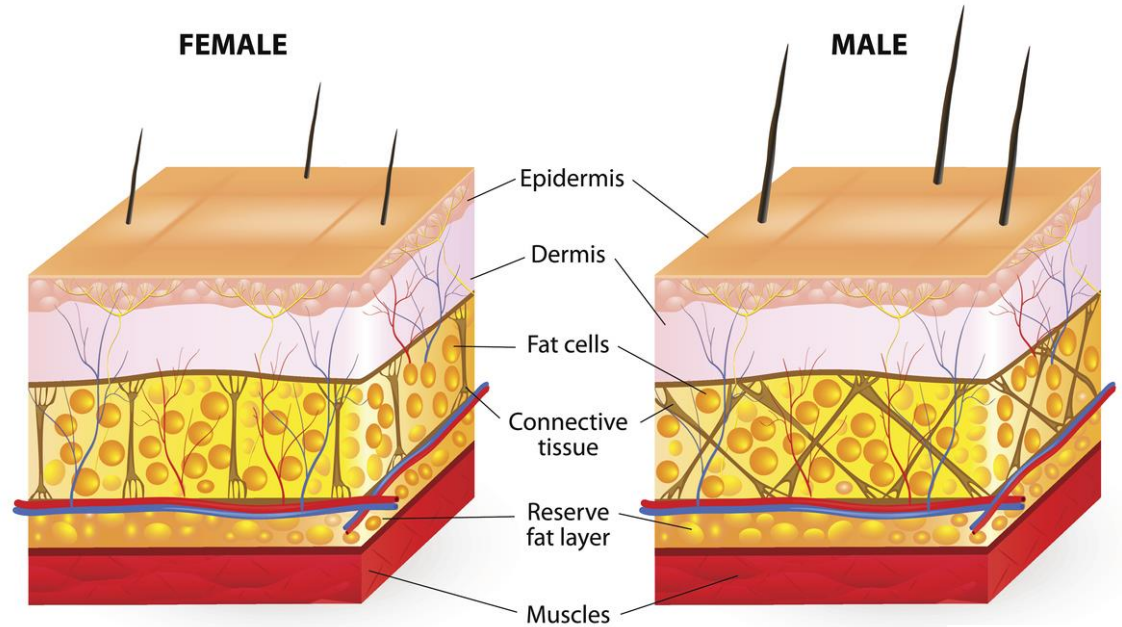


Subcutaneous structures

Compartmentalization

- Vertical
- Oblique partitioning

MALE AND FEMALE SKIN



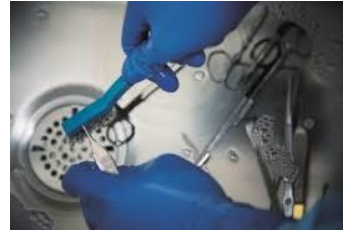
Procedure: Complications

Infection-

Rate .3% to 6.8%

- **Device Reusable**

In Office Sterilization Protocol
Autoclave, disinfectants, Brushes



- **Disposables**

Cumbersome
Awkward Pellet loading
Unpredictable pellet deployment



Local Nerve Irritation: Temporary irritation of small superficial nerves

Lumping, Scarring and fibrosis

Analysis of testosterone implants for androgen replacement therapy

Objective: To review 13 years of experience using fused crystalline testosterone implants for androgen replacement therapy in order to identify pattern of usage (including continuation rates) and adverse events emerging during therapy and factors associated with adverse events including implant extrusions

- Over 13 years 973 implant procedures in 221 men
- Continuation rates and adverse events such as extrusions, bleeding, infection or others were recorded
- The most common adverse effect was extrusion (83/973, 8.5%)
 - related to occupational classification ($P = 0.033$)
 - increasing work activity ($P = 0.044$)
- Bleeding (22/973, 2.3%) associated with an increased number of implants
- Infection was rare (6/973, 0.6%) but occurred more among thinner men
- The overall continuation rate was 92.7% increasing from 86% after the first implantation to > 99% after the tenth implant
- An improved method of implant delivery would enhance this old but durable technology.



Handelsman, Mackey Clin Endocrinol 1997 Sep;47(3):311-6

Extrusion of testosterone Pellets A Randomized controlled Clinical Study

Objective: To determine whether the washing of testosterone pellets to remove potentially surface-adherent particles decreased the rate of extrusion of pellet implants.

- n-251 testosterone implantation procedures prospective to be Randomized into Wash or Control Group
- Wash group extrusion rate was 12% per procedure
- Control group extrusion rate was 11.1% per procedure
- No evidence of any benefit of the wash procedure
- Among men reporting an infection requiring antibiotic treatment, six/ten (60%) subsequently experienced an extrusion.
- Bleeding/bruising (8.8%) and infection (4.0%)



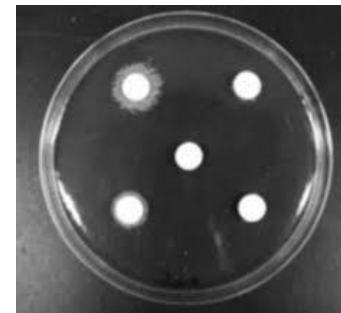
Kelleher S Turner Clin Endocrinol 1999 Oct;51(4):469-71



A randomized controlled clinical trial of antibiotic impregnation of Testosterone pellet implants to reduce extrusion rate

Objective: to determine whether extrusion rate could be reduced by antibiotic impregnation of pellets immediately prior to implantation

- Design: Prospective, randomized, parallel-group, open-label study design in a single center, with 400 procedures in 186 men
- One group with pellets soaked for 2 min in gentamicin solution prior to implantation and a control group who had the standard pellet implant procedure.
- The extrusion rate was not statistically different between the two groups
- There was a 4.6-fold excess of multiple over single extrusions
- Extrusions were not related to
 - Batch number
 - Location
 - Shaving site
 - Old or new site
 - Presence of suppuration
 - Povidone-iodine skin disinfectant had statistically fewer extrusions than mixed alcohol solution.
- The overall extrusion rate for this study was 10.25%.



S Kelleher and others EUROPEAN JOURNAL OF ENDOCRINOLOGY (2002)

Pain Control

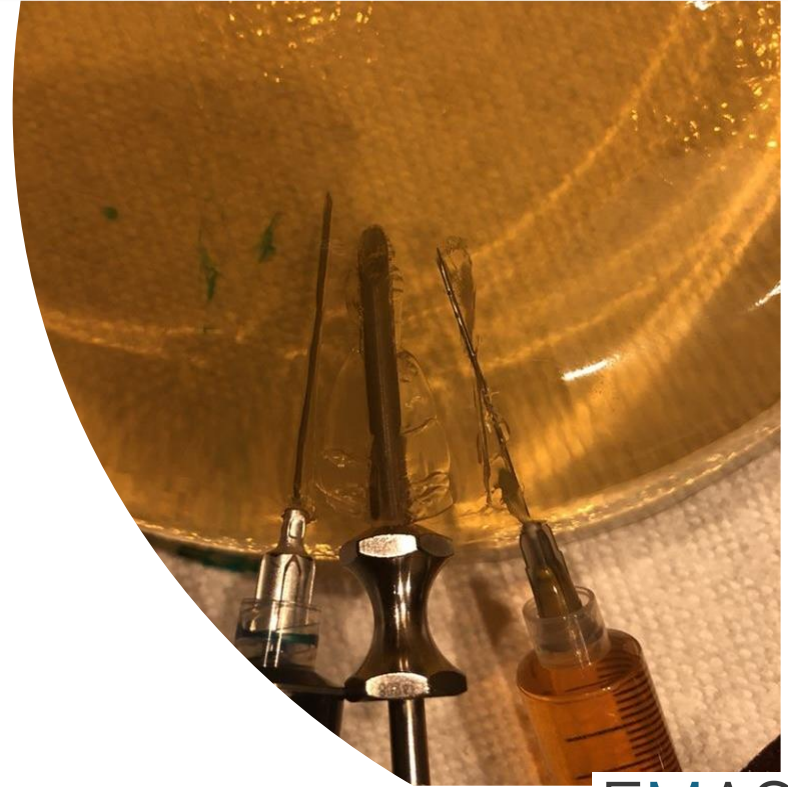
Maximum Lidocaine Dose (local anesthetic)

- Choice
 - Lidocaine 1-2% - Onset 2-5 min, duration 30-60 min
 - Bupivacaine 0.25%- Onset 5-10 min duration 4-8 hs
- WHAT'S THE MAX DOSE OF LIDOCAINE I CAN GIVE MY PATIENT
 - lidocaine alone: max dose 4.5 mg/kg
 - lidocaine WITH epinephrine: max dose 7 mg/kg
- QUICK MATH:
 - Lidocaine 1% (10mg/ml) – max dose 4.5mg/kg
 - for the average 70kg patient: $70\text{kg} \times 4.5\text{mg/kg} = 315\text{mg}$
 - $315\text{mg} / 10\text{mg/ml} = 31.5 \text{ ml max}$
- BOTTOM LINE: max dose 1% lidocaine is ~30 ml for average 70kg person
- Practice
 - One 10 cc syringe with Lidocaine with epinephrine
 - Second 10 cc syringe 7cc plain Lidocaine Plus 3 cc 8.4% Sodium Bicarbonate



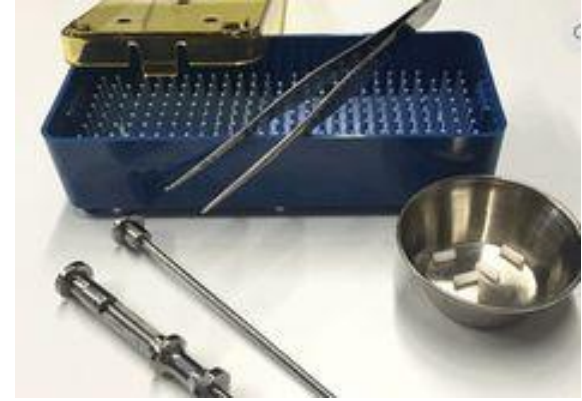
Procedure: Pain Prevention

- Be sure to anesthetize entire length of trocar tract
- Consider length discrepancy
 - Trocar 2 inch
 - 1 ½ inch needle standard
 - 2 inch needle required



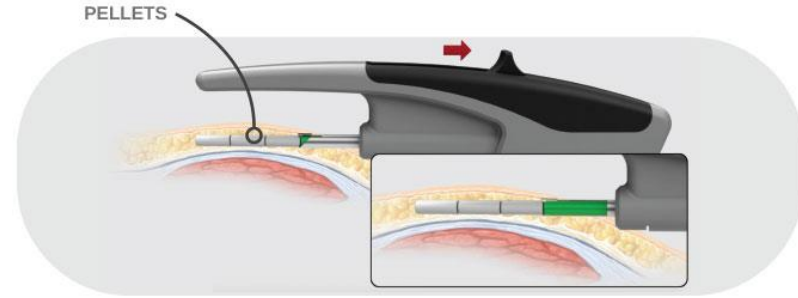
Standard Device Drawbacks

- Cumbersome surgical technique
- Awkward Pellet Loading
- Inconsistent Depth of Insertion
- Unpredictable Pellet Deployment
- Increased learning curve



Advanced Pellet Delivery System

- Simpler
- Easier to learn
- Integrated Safety Features
- Precise and consistent depth of insertion
- “No Force” linear pellet deployment may reduce risk of bruising, lumping, pain, and scarring crushing, fragmenting and overlapping pellets



Female Standard Device



Female New Device



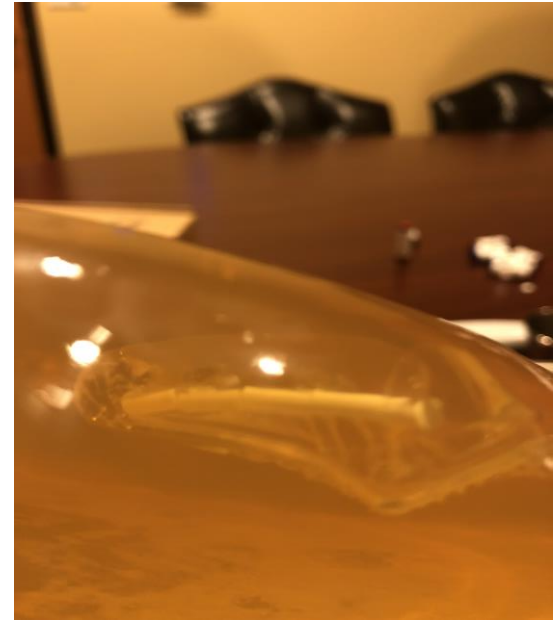
Pellet Deployment

Old Device



Stacking
Overlapping
Crowding
Dispersion
Crushing

New Device



In Conclusion



- Reducing risk is about paying meticulous attention to all factors involved in the procedure



THANK YOU FOR YOUR ATTENTION

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