How do we define a glenoid component at risk for clinical failure?

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Conflict of Interest

- DePuy – Synthes Royalties
- Wright - Tornier – Royalties
- DJO – Consulting and Royalties
- Custom Orthopaedic Solutions – Equity
- Lippincott WW – Royalties

- None related to this talk

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  - State of Ohio Technology Development Fund
  - Department of Orthopaedic Surgery

Literature: TSA Failure

- Glenoid component is the most common cause for clinical failure TSA
- Component failure results from wear and loosening
- Uncertain definition of a loose glenoid
- Early glenoid loosening is often asymptomatic

Literature: Measuring Component Loosening

- Defining glenoid movement by x-ray is imprecise
- RSA is a very accurate method for measurement of implant loosening in many joints
- RSA is not able to evaluate the implant bone interface
- Need x-rays or CT scans

The early migration of a partially cemented fluted pegged glenoid component using radiostereometric analysis

David Nuttall, PhD*, John F. Haines, FRCS, Ian A. Trail, MD, FRCS

JSES 2012

- 11 patients with RSA measurements
- 6/11 (55%) patients migrated by RSA
- Post op CT Scan at last follow up demonstrated central peg osteolysis on all cases
- Suggesting 55% of cases had a loose glenoid
- No correlation with clinical scores at follow up

Our Goals

- Develop and validate 3D MAR CT scanning to
- Define
  - implant migration
  - Bone implant interface
- Correlation of implant failure
  - Patient pathology
  - Surgical factors and
  - Implant factors

Study Criteria

- 170 patients prospectively enrolled
- Two shoulder surgeons
- Anatomic TSA DePuy Global AP with APG or Step Tech APG
- Intact rotator cuff OA
- 3D CT planning and use of PSI
- MAR 3D CT wilthin 2 months of surgery
- MAR 3D CT 2-3 years after surgery
- Routine x-rays performed at same time of CT

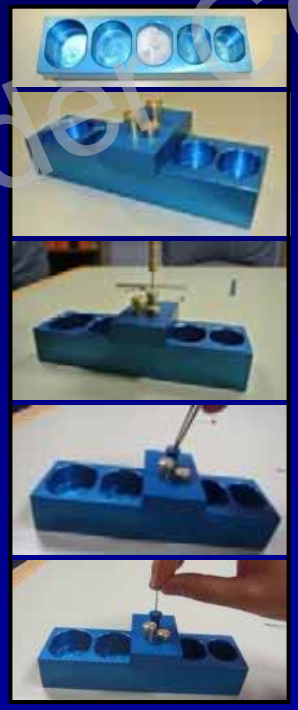
The Question

- Early results of the first 64 patients completing the protocol
- Development and validation of 3D CT imaging
- What are the patterns of glenoid component shift and osteolysis around the center peg

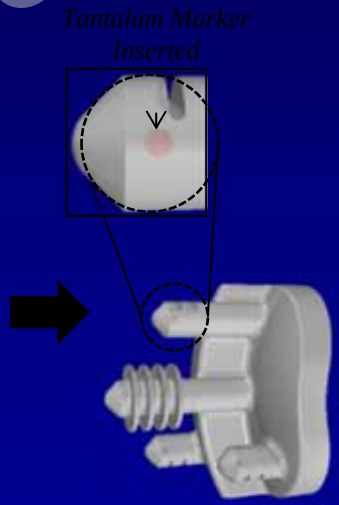
Radiopaque Tantalum Markers

- Intra-operative insertion
  - DePuy *Anchor Peg* Glenoid and *Steptech* Glenoid
  - Current standard of care at Cleveland Clinic
  - Performed on >60 patients, ~ 5 minutes additional OR time

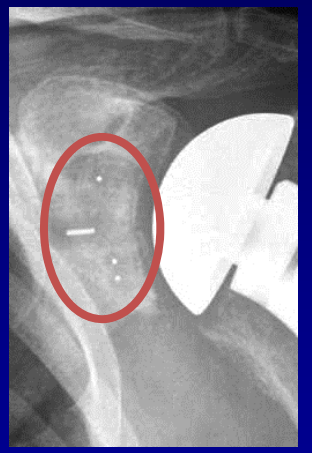
Custom-made Tantalum Marker Insertion Tool



Insertion Steps



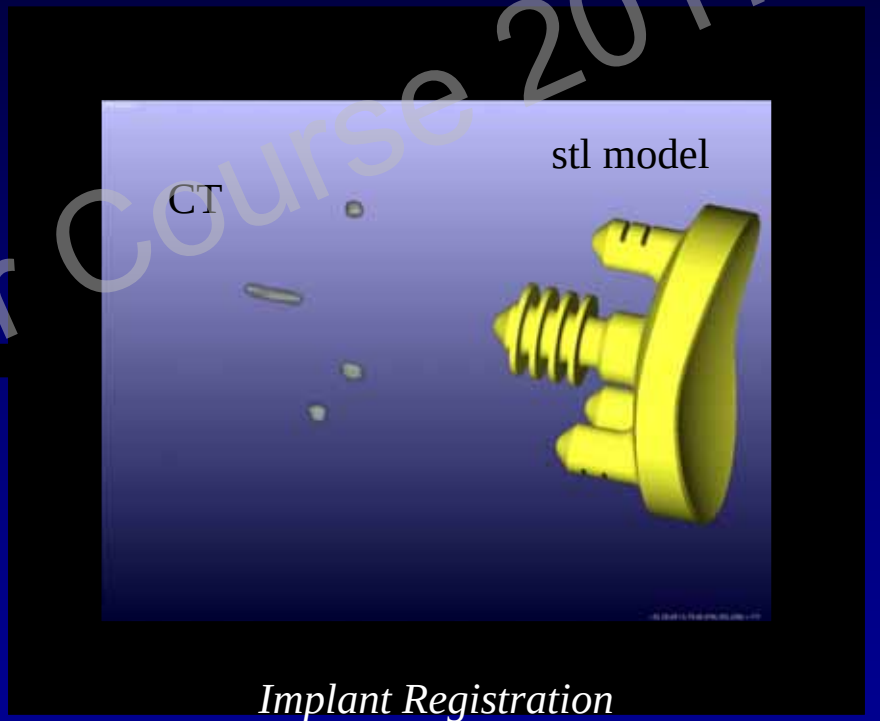
Glenoid Component with Three Tantalum Markers Inserted



Registration Process: Implants

- Glenoid implant registration:

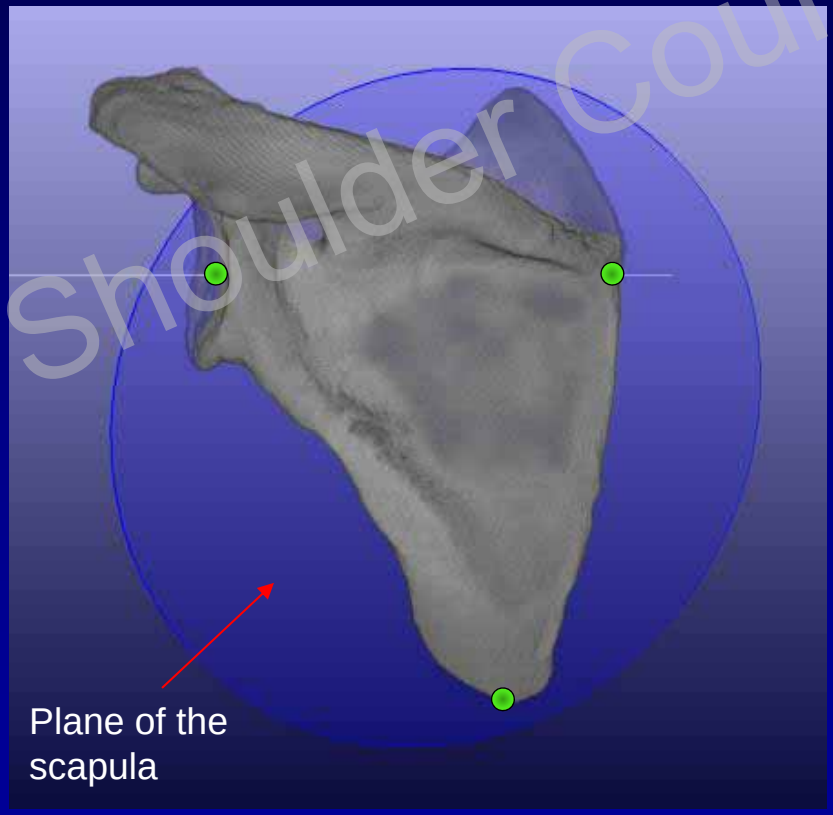
Marker Visualization



Implant Registration

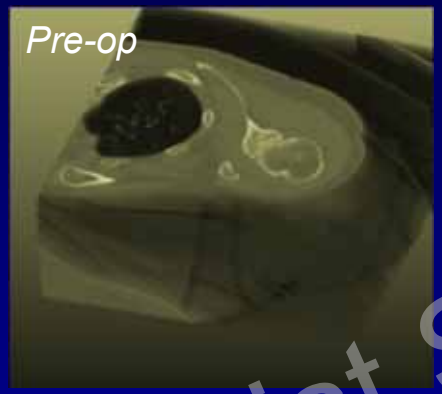
Advanced 3D clinical CT imaging allows defining an anatomic coordinate system

- An anatomic, scapular coordinate system defined based on bony landmarks from the pre-operative CT scan



Advanced 3D clinical CT imaging allows super-imposition of multiple 3-D CT volumes

- Multiple 3D CT volumes (immediate post-operative and follow-up) with respect to a pre-operative scapula bone



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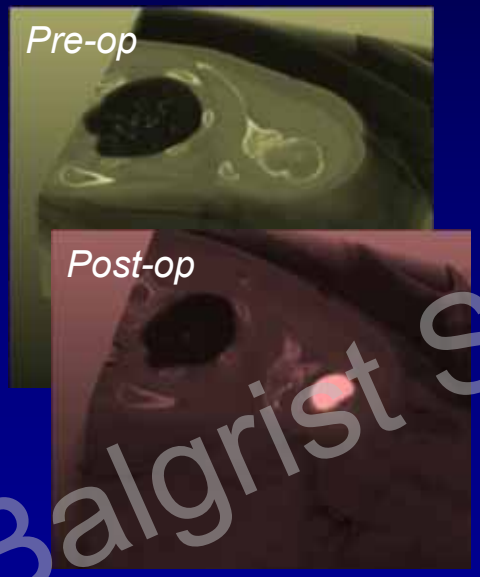

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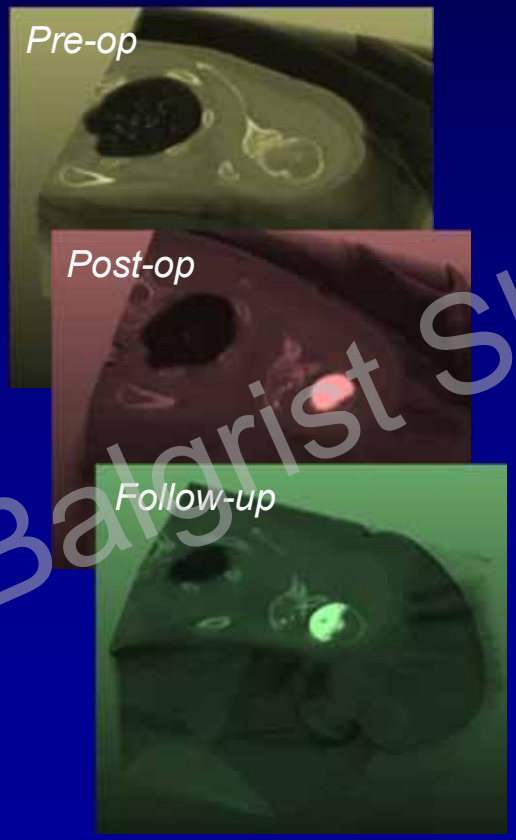

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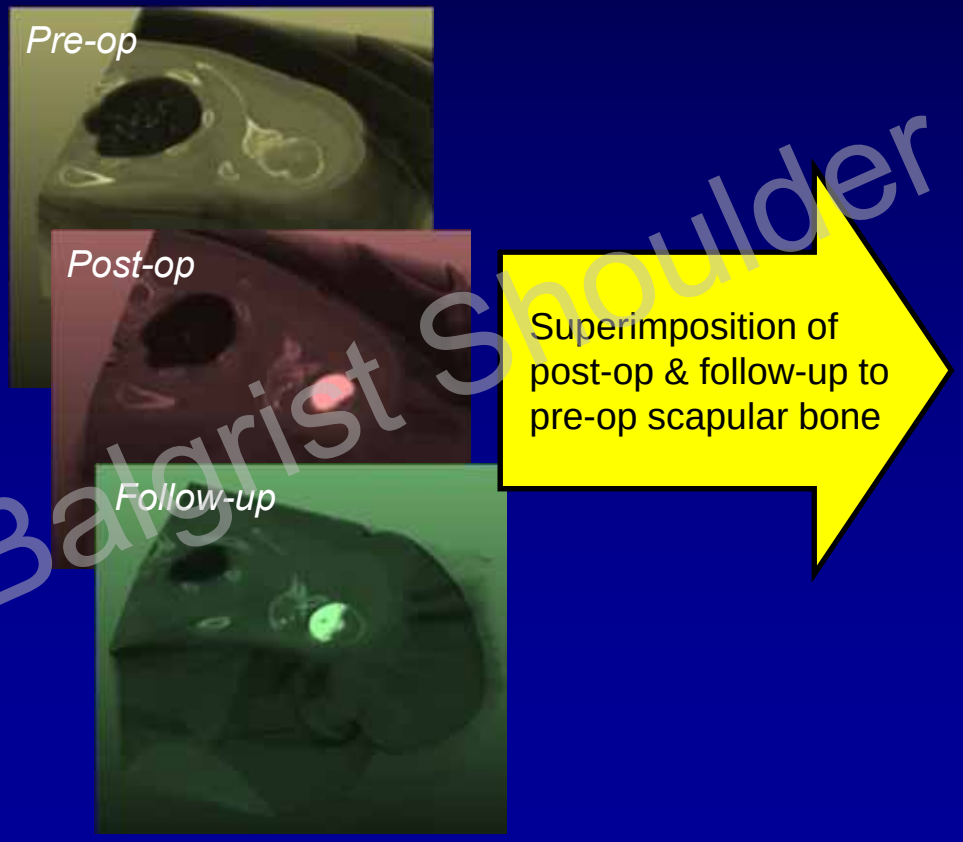

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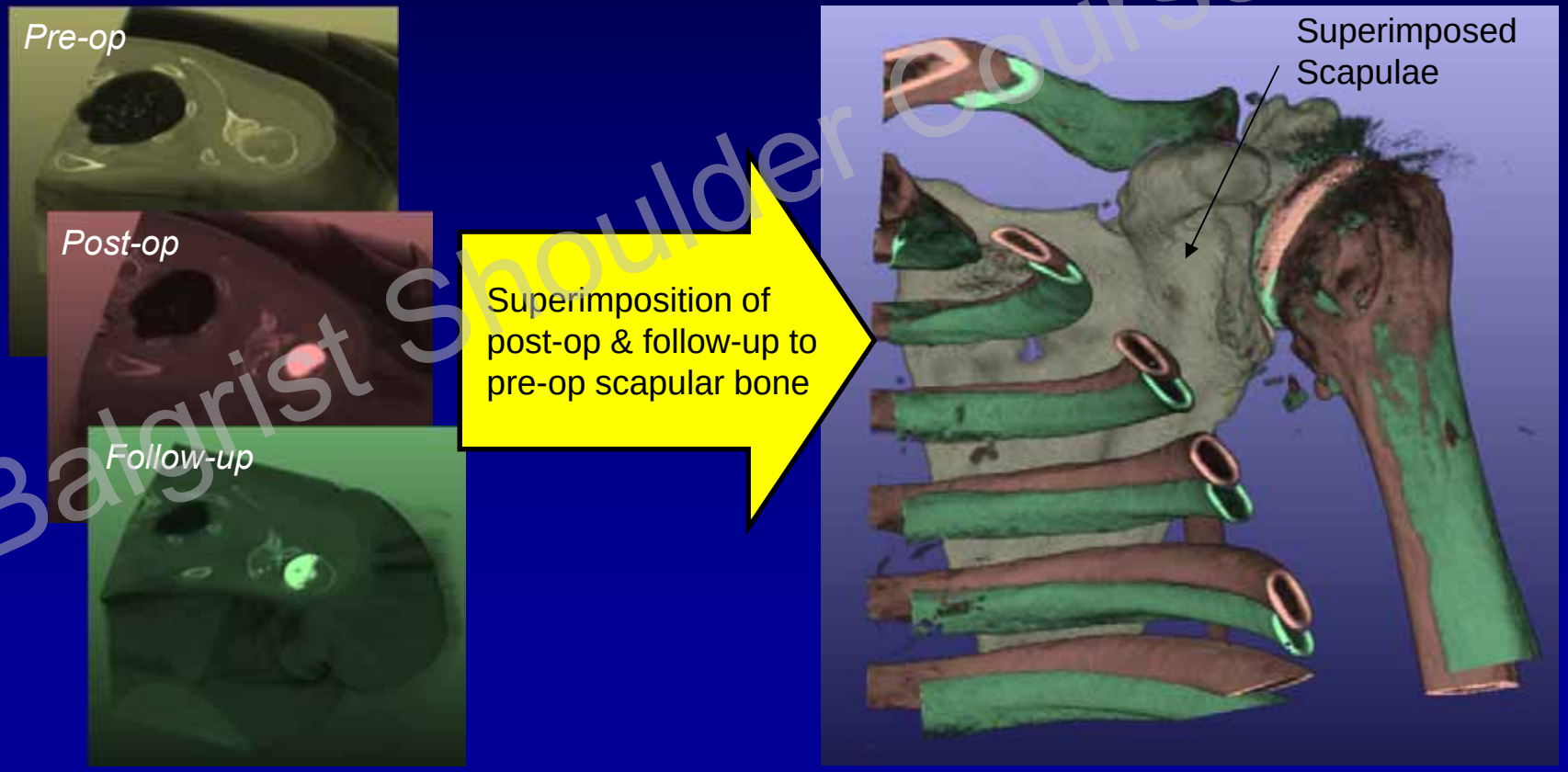
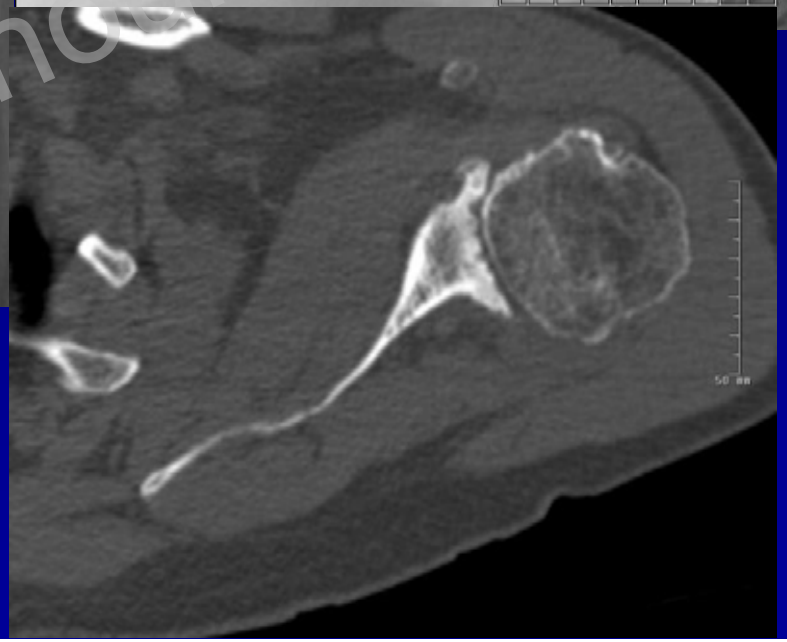


Advanced 3D clinical CT imaging allows quantification of glenoid component migration

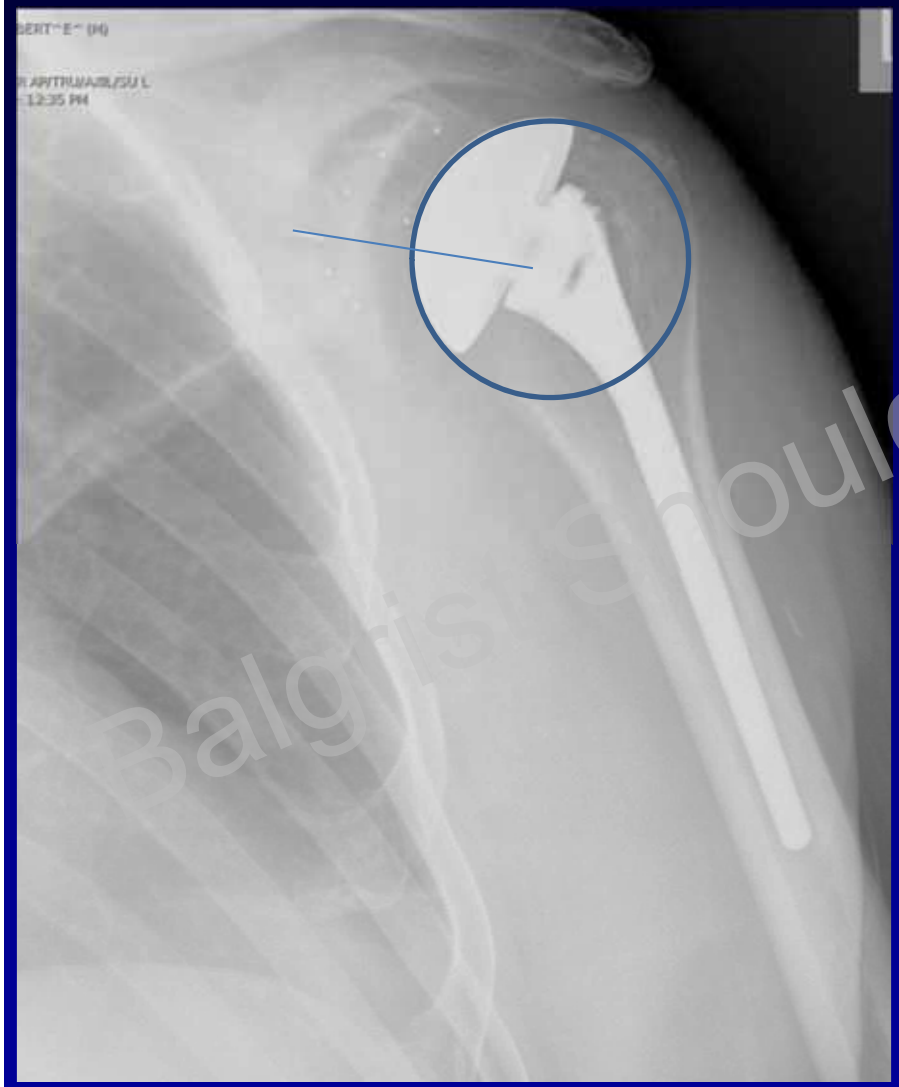
- Intra-operative insertion of three-tantalum bead markers allows automatic detection of glenoid and head component position based on 3-D spatial relationships of the markers and humeral head size

Case Example: What you are missing on x-rays

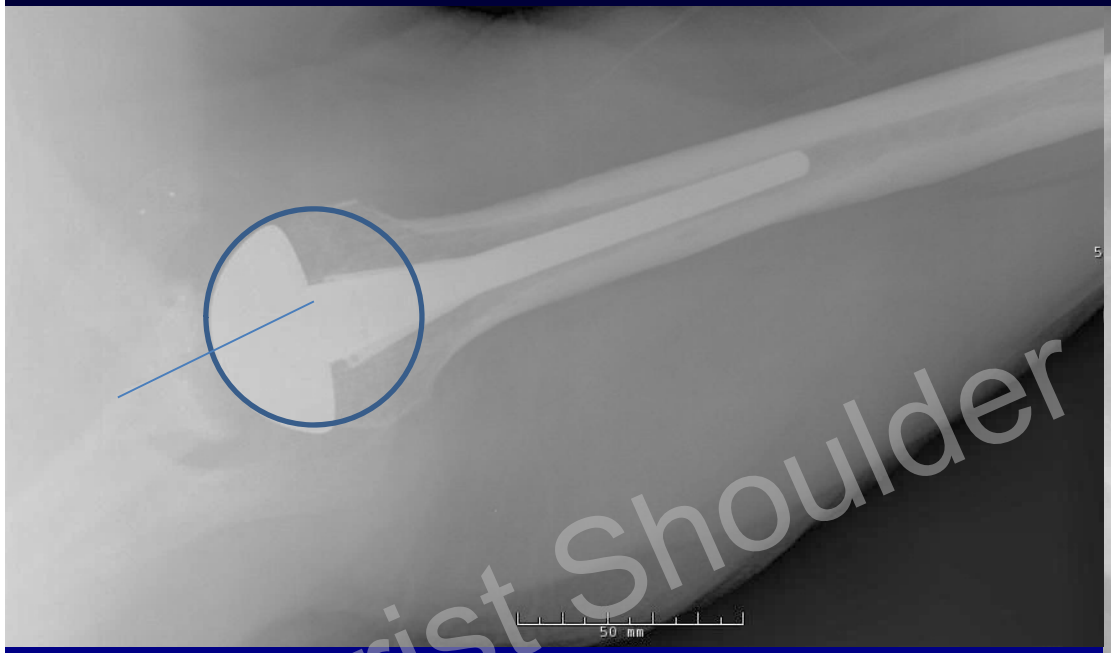
Pre op 1/13



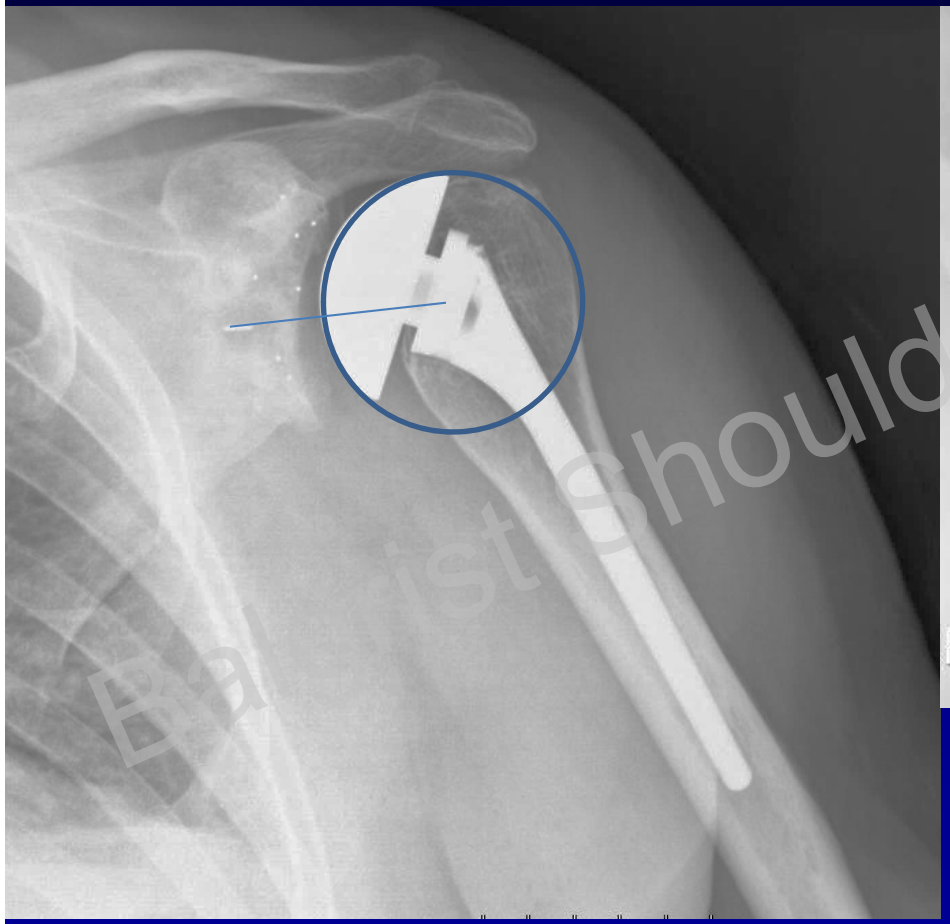
1 month post op

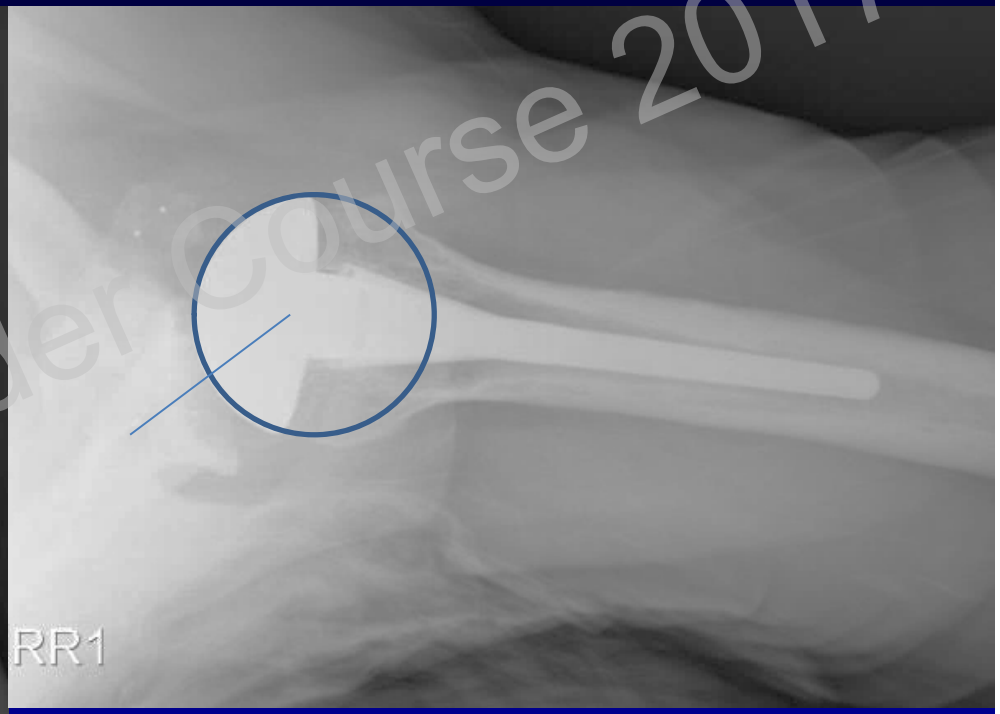


1 year post op



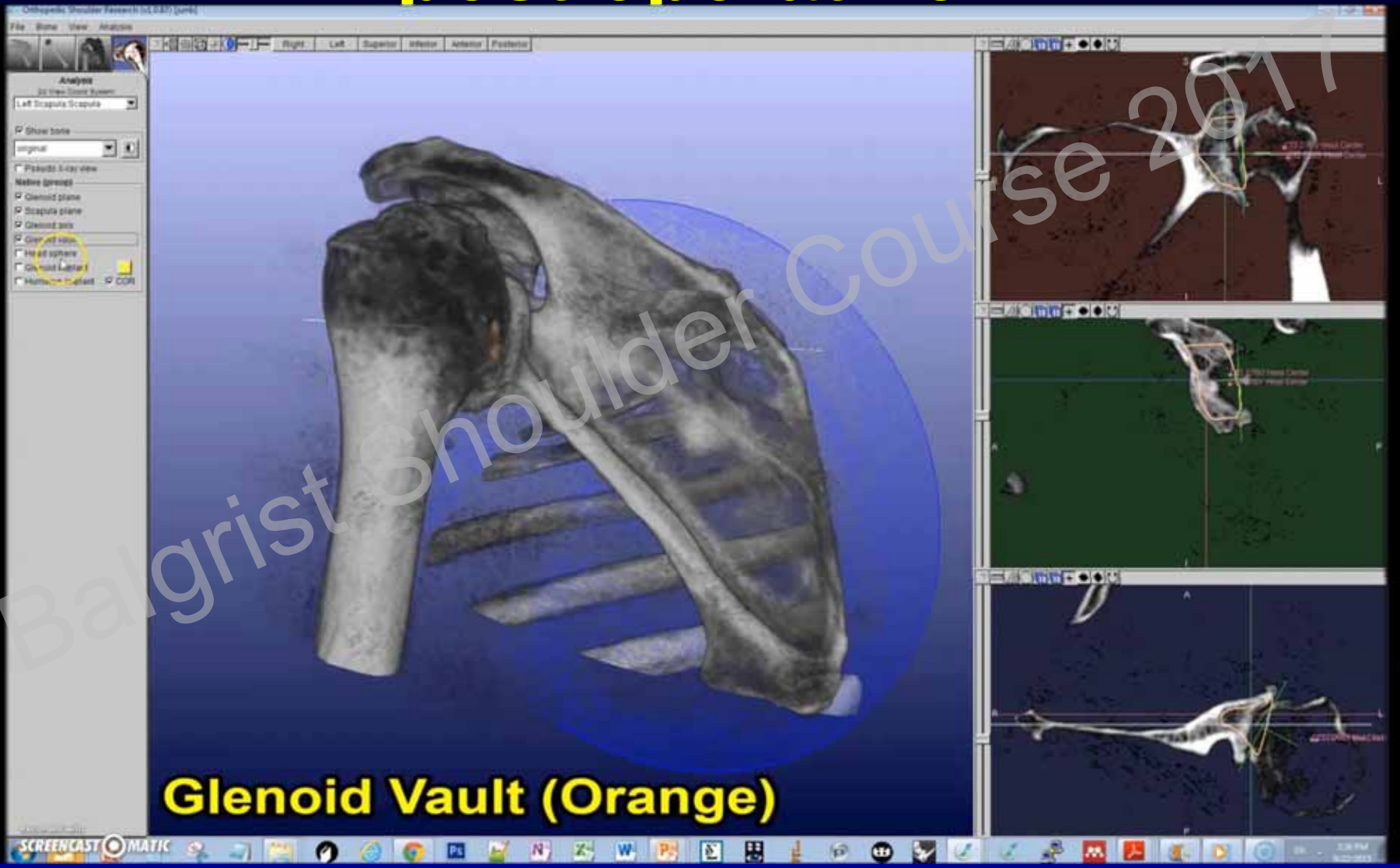
2 year post op



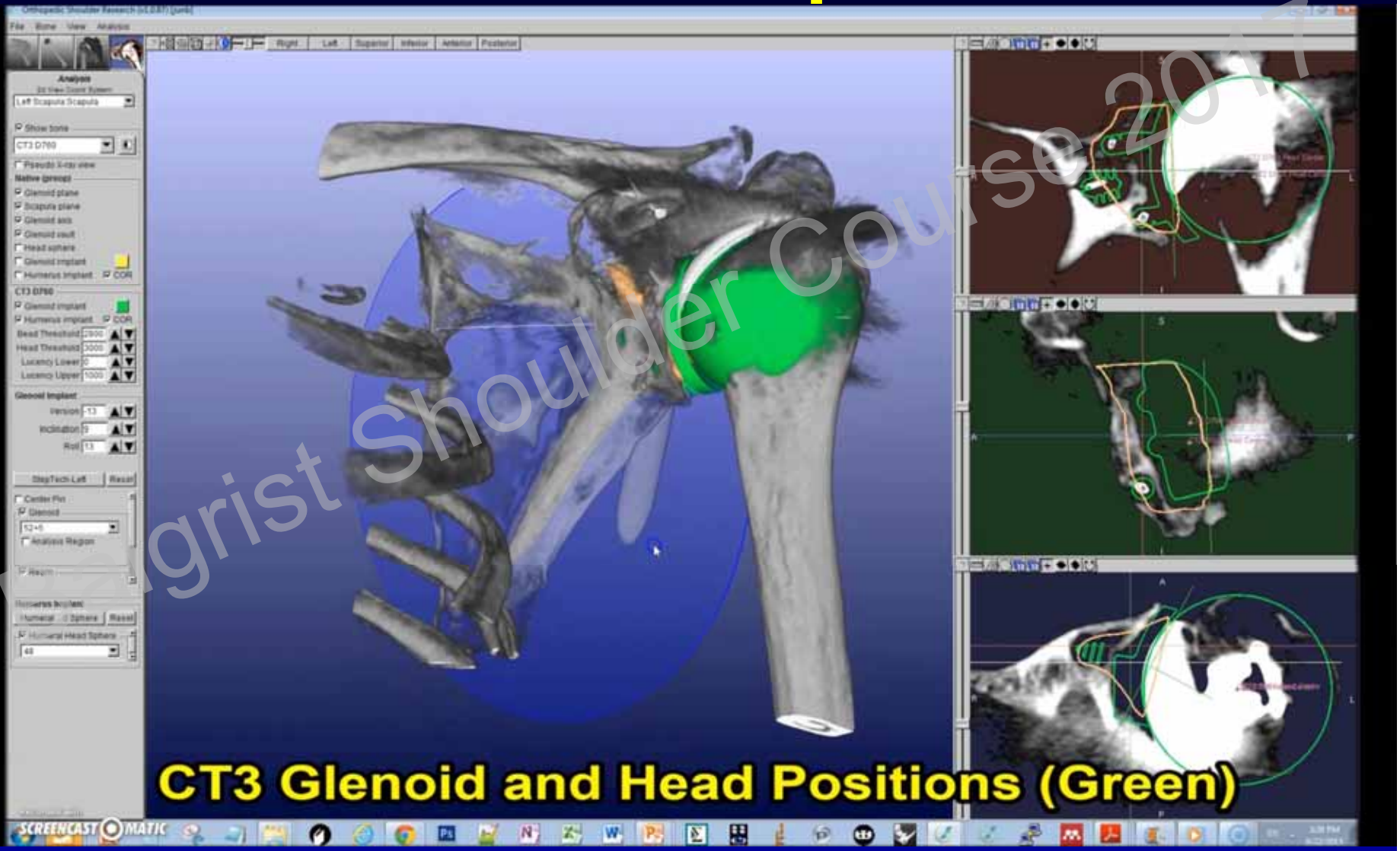


- Shoulder score = 100/100 points

Implant position at 3 months post operative



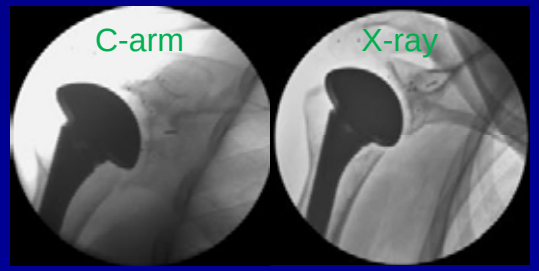
Implant Migration at Two Year Follow up



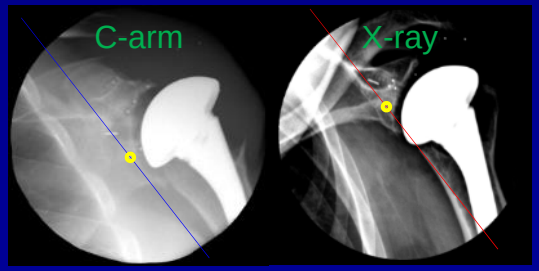
Advanced 3D clinical CT imaging allows quantification of glenoid component migration

- Phantom study
  - Measurement accuracy of quantifying component migration of glenoid and head component was 0.10 mm in translation and 0.19 º in rotation

- In vivo patient study (n = 6 patients)
  - In vivo measurement errors in measuring glenoid component positional shift using advanced CT imaging analysis were 0.3mm, 0.4mm, 0.2mm for translations and 0.4^0, 0.5^0, 0.6^0 for rotations, compared to radiostereometric analysis (RSA) method



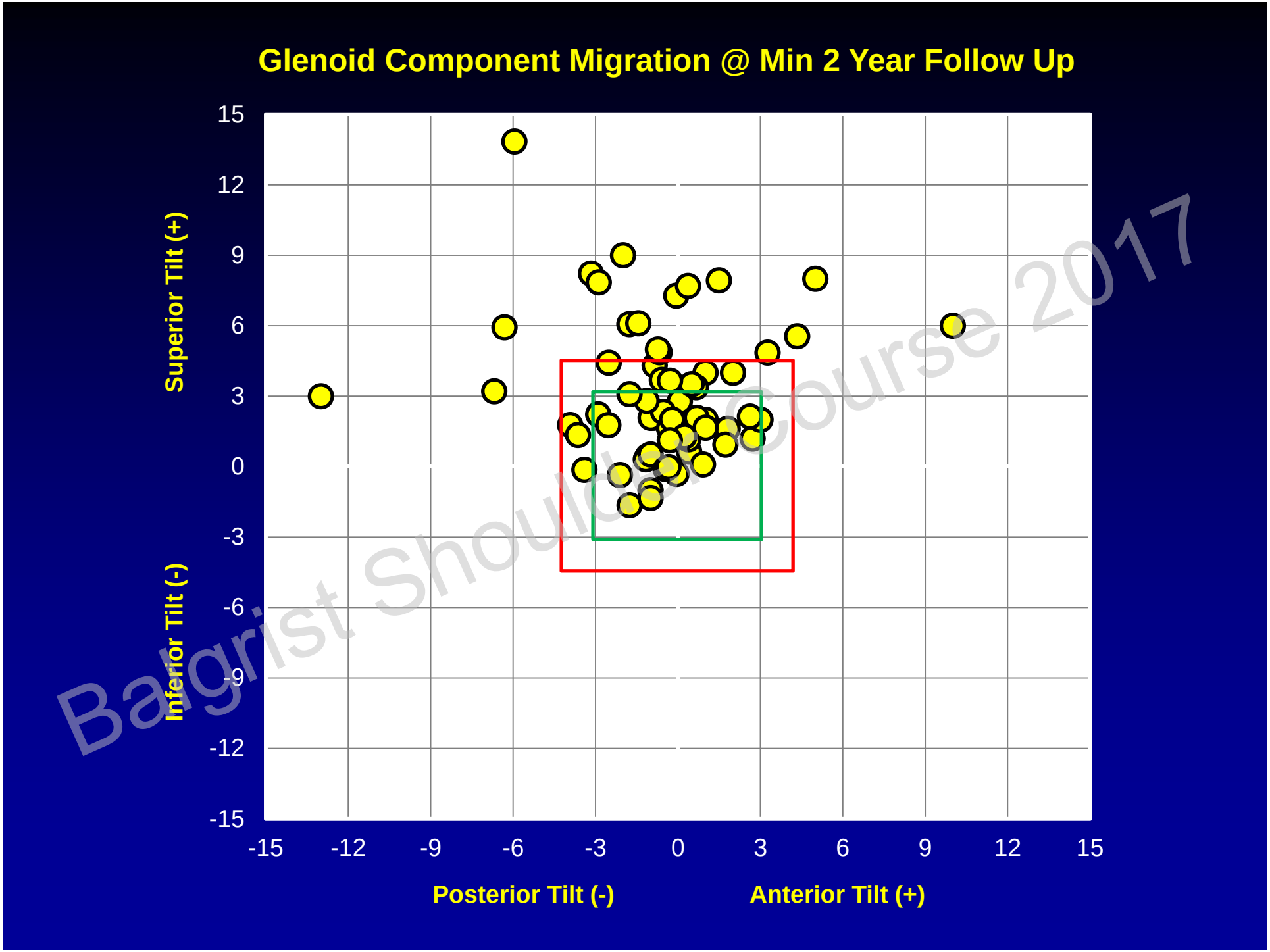
Before Post-image Processing

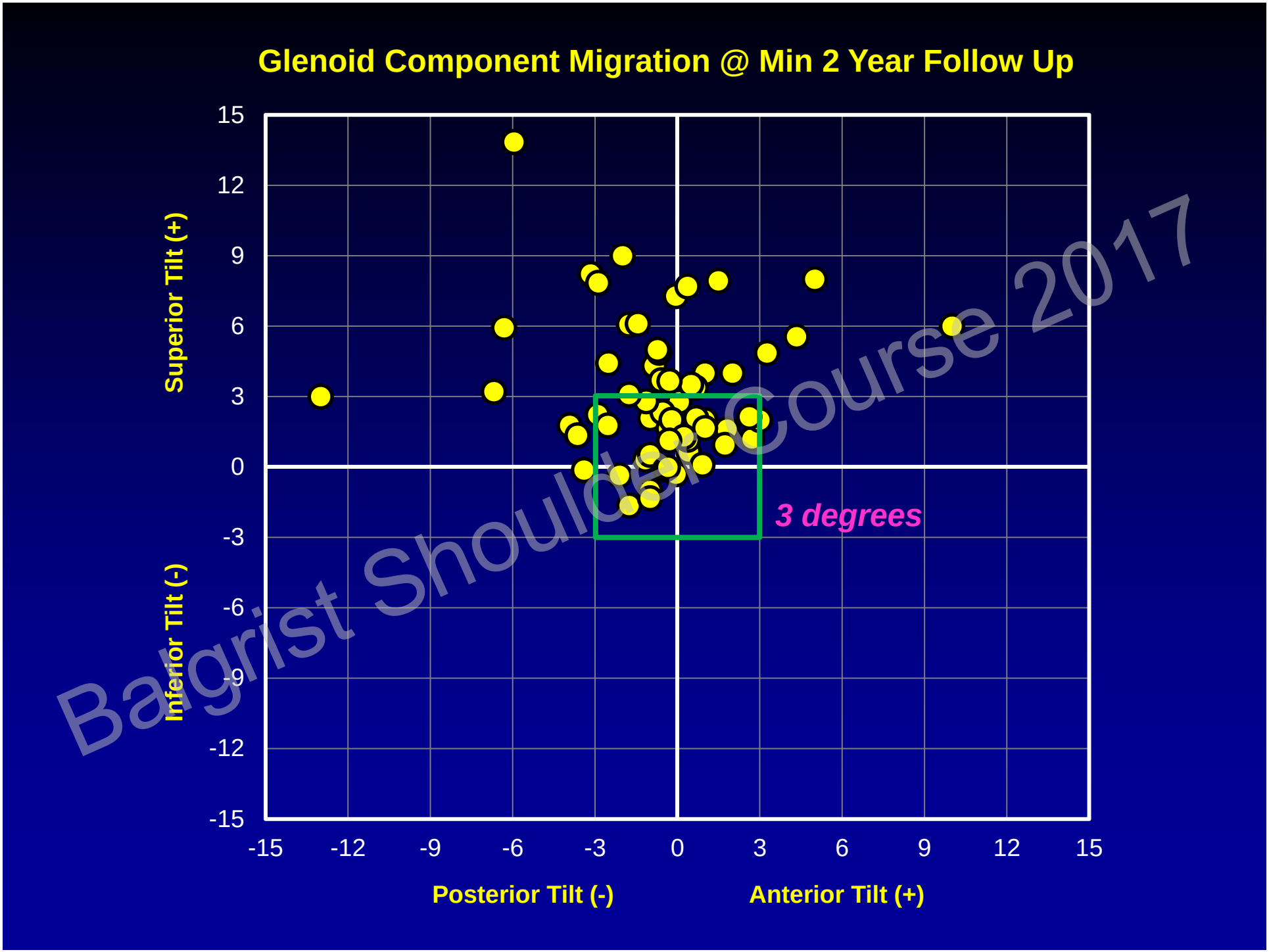


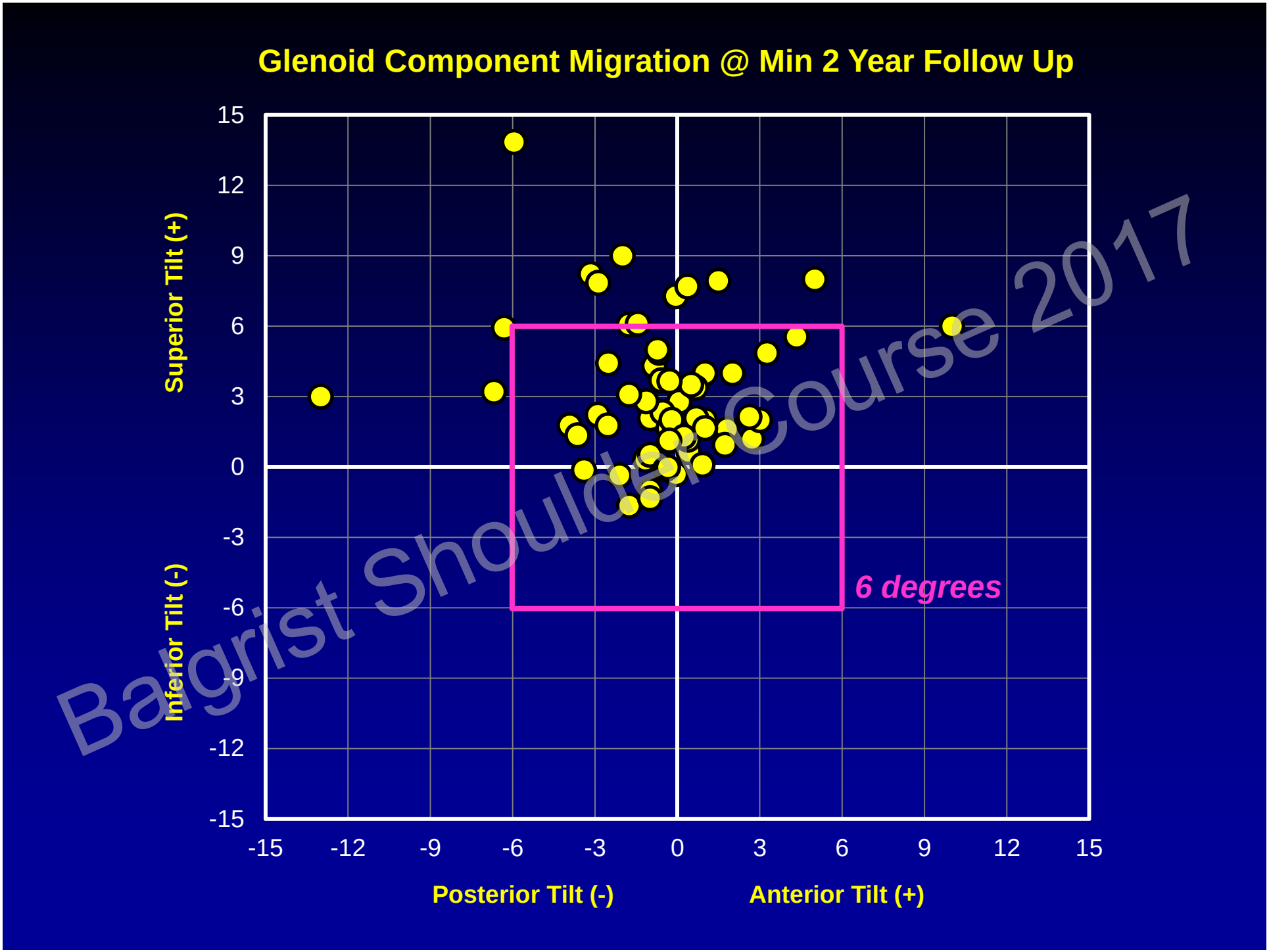
After Post-image Processing

A Preliminary Study of Advanced 3D CT Imaging Analysis in a Cohort of Patients

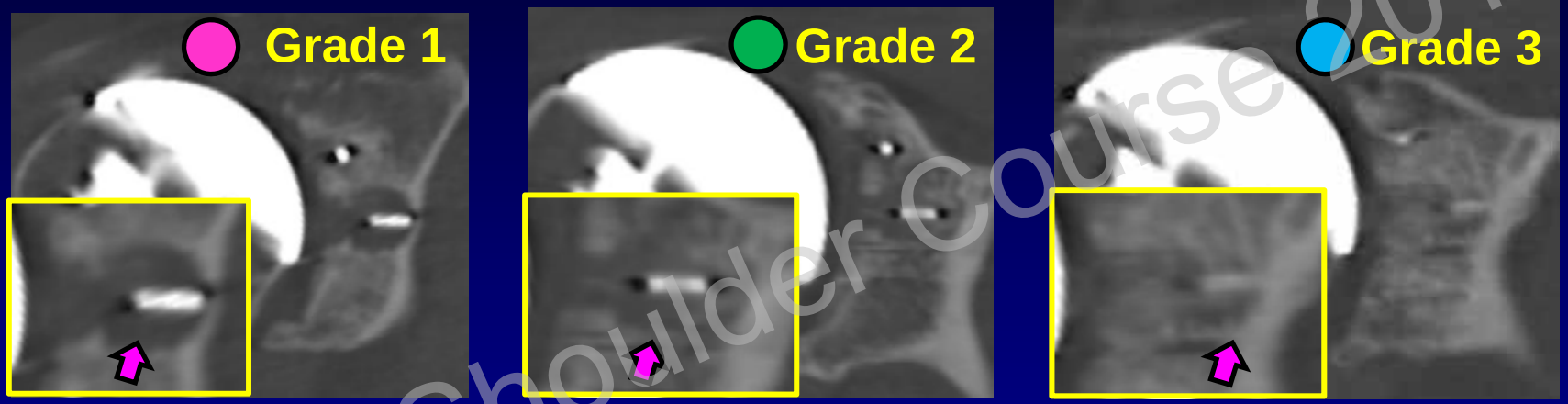
- A total of 64 patients who underwent an anatomic total shoulder arthroplasty between 2013 and 2015
  - Gender
    - Male: 44
    - Female: 20
  - Age
    - 64 ± 8 years old
- Advanced 3-D CT imaging analysis was performed using sequential clinical CT scans @ pre-, post-op, & min 2yr
  - Implant migration was analyzed for rotations in superior/inferior and anterior/posterior directions
  - Central peg osteolysis grade (1, 2, and 3) was assessed using the minimum 2 year follow up CT scan


Glenoid Component Migration @ Min 2 Year Follow Up
Superior Tilt (+)
Inferior Tilt (-)
15
12
9
6
3
0
-3
-6
-9
-12
-15
-15
-12
-9
-6
-3
0
3
6
9
12
15
Posterior Tilt (-)
Anterior Tilt (+)
Bangrist Shoulder Course 2017


Glenoid Component Migration @ Min 2 Year Follow Up
Superior Tilt (+)
Inferior Tilt (-)
15
12
9
6
3
0
-3
-6
-9
-12
-15
-15
-12
-9
-6
-3
0
3
6
9
12
15
Posterior Tilt (-)
Anterior Tilt (+)
3 degrees
Bagnist Shoulder Course 2017

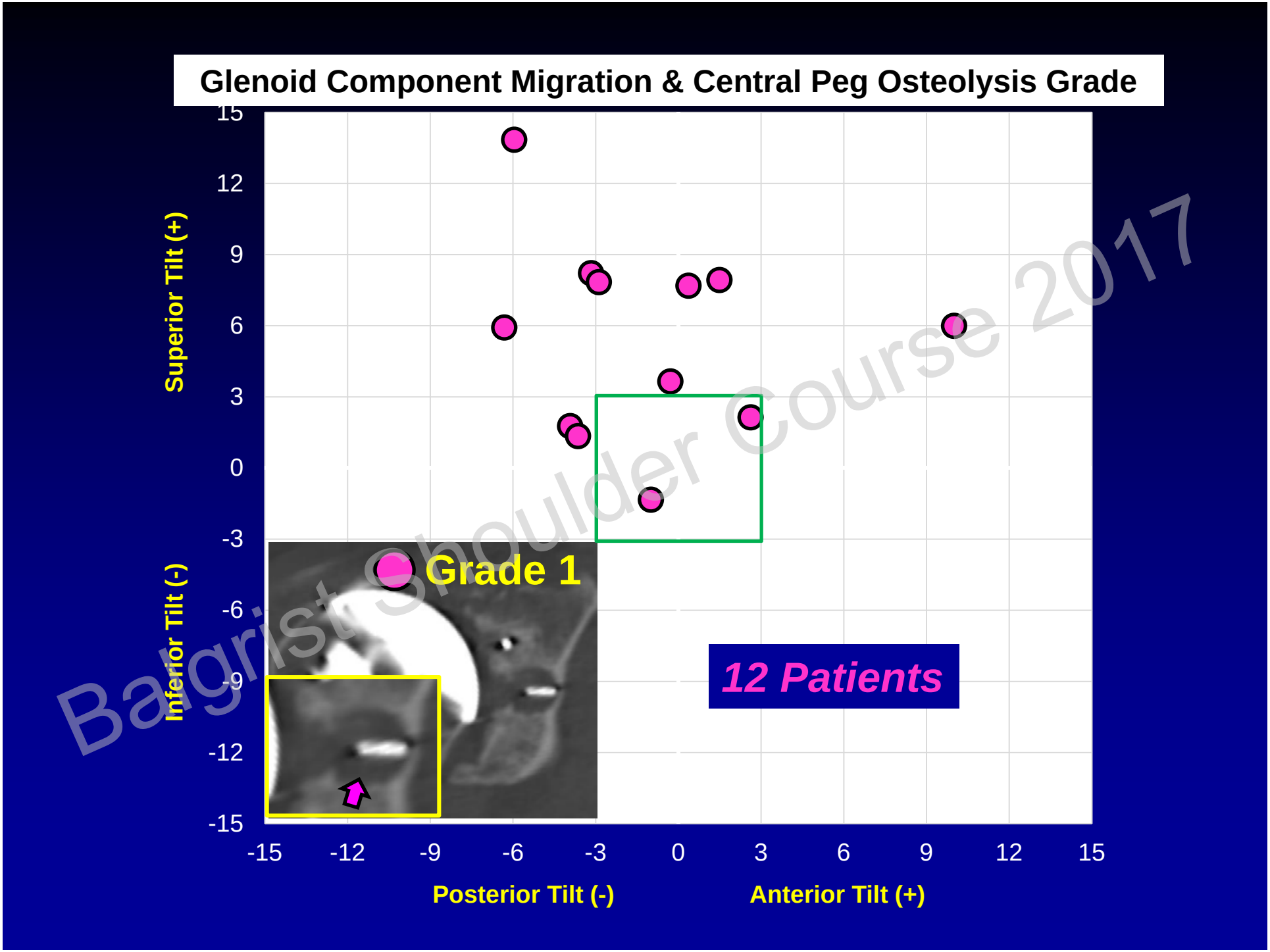

Glenoid Component Migration @ Min 2 Year Follow Up
Superior Tilt (+)
Inferior Tilt (-)
15
12
9
6
3
0
-3
-6
-9
-12
-15
-15
-12
-9
-6
-3
0
3
6
9
12
15
Posterior Tilt (-)
Anterior Tilt (+)
6 degrees
Bagnist Shoulder Course 2017

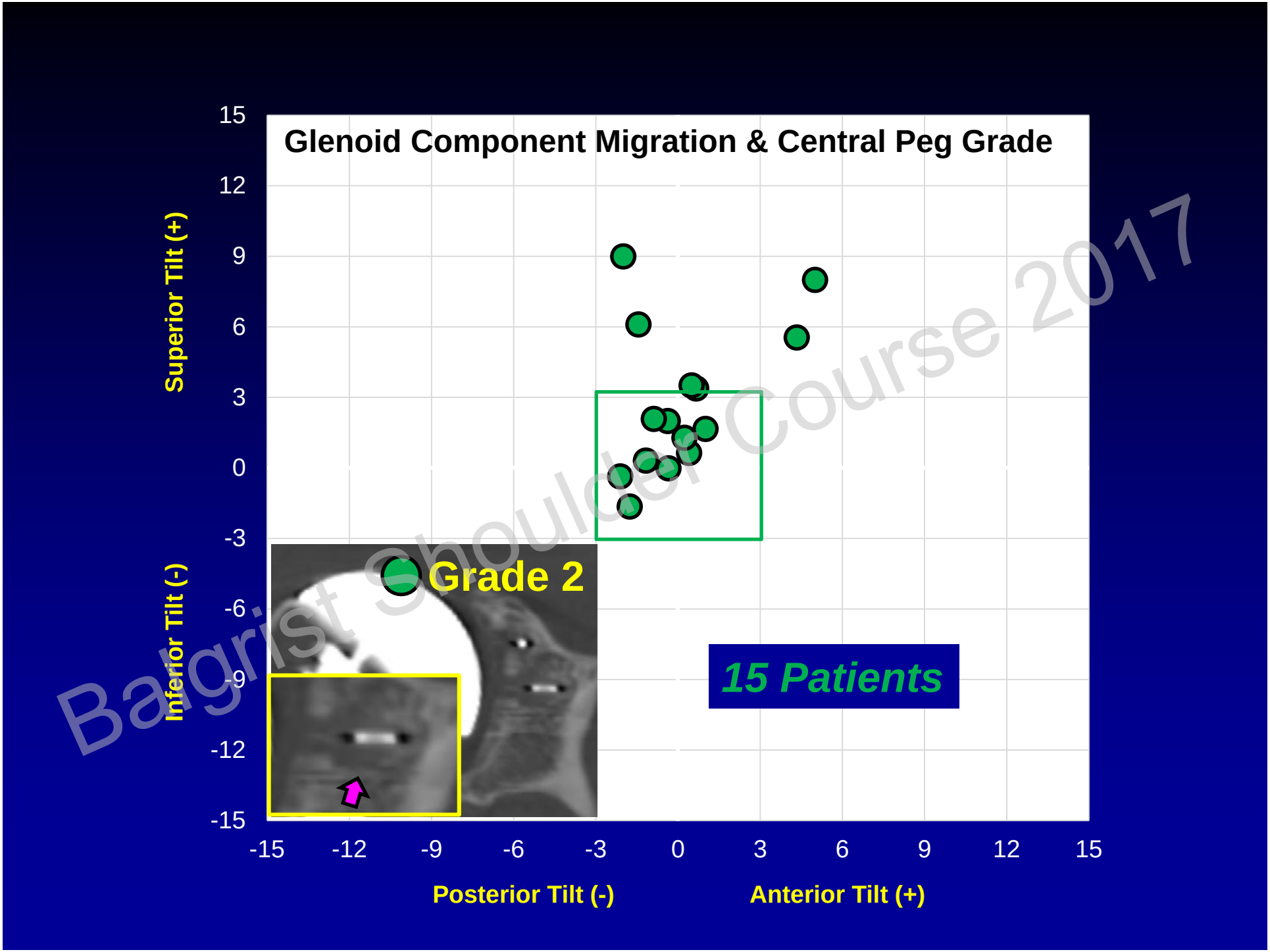
Central Peg Osteolysis Grade



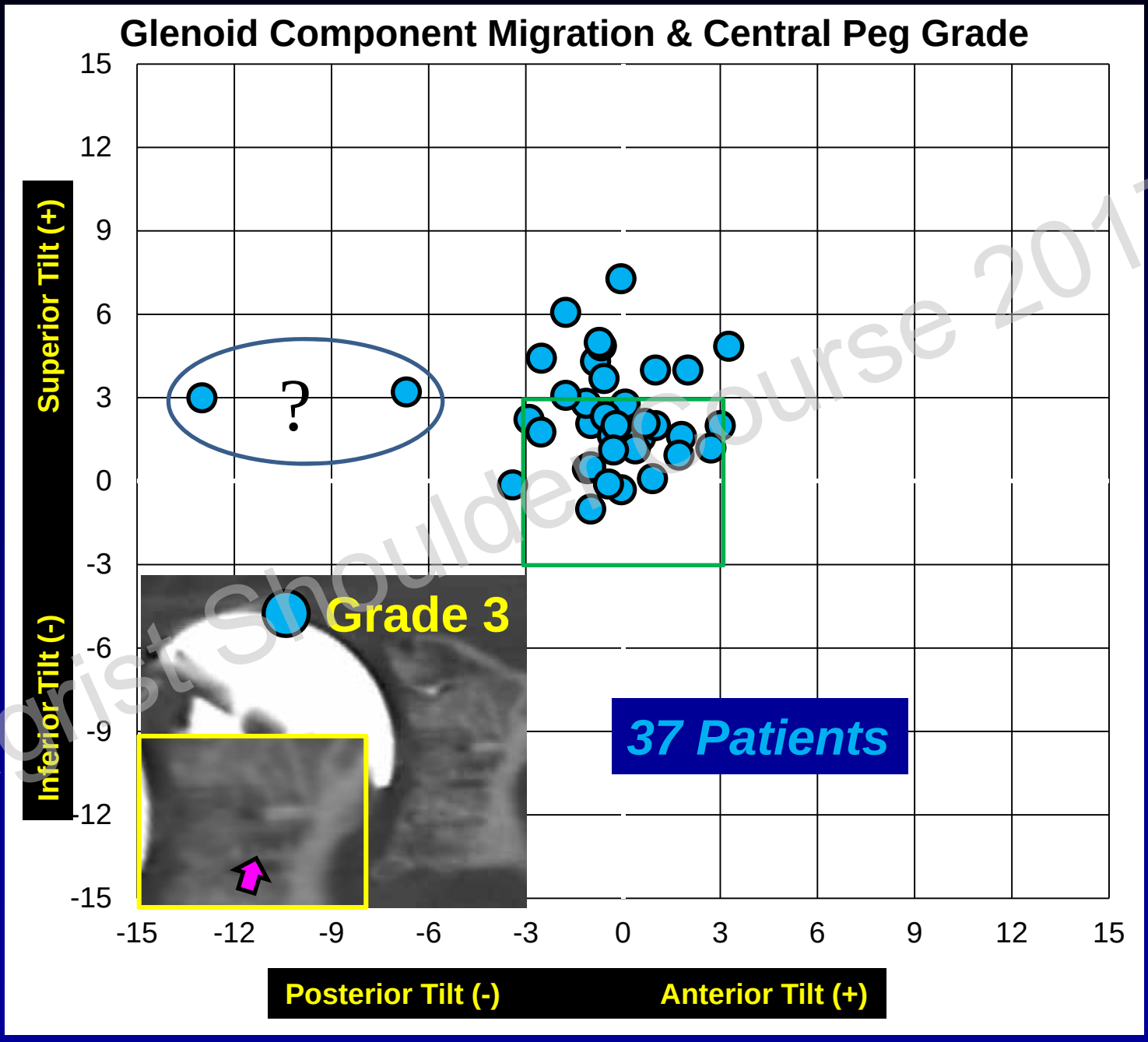
Central peg osteolysis grade was assessed three-dimensionally through anterior-posterior and superior-inferior view

Glenoid Component Migration & Central Peg Osteolysis Grade

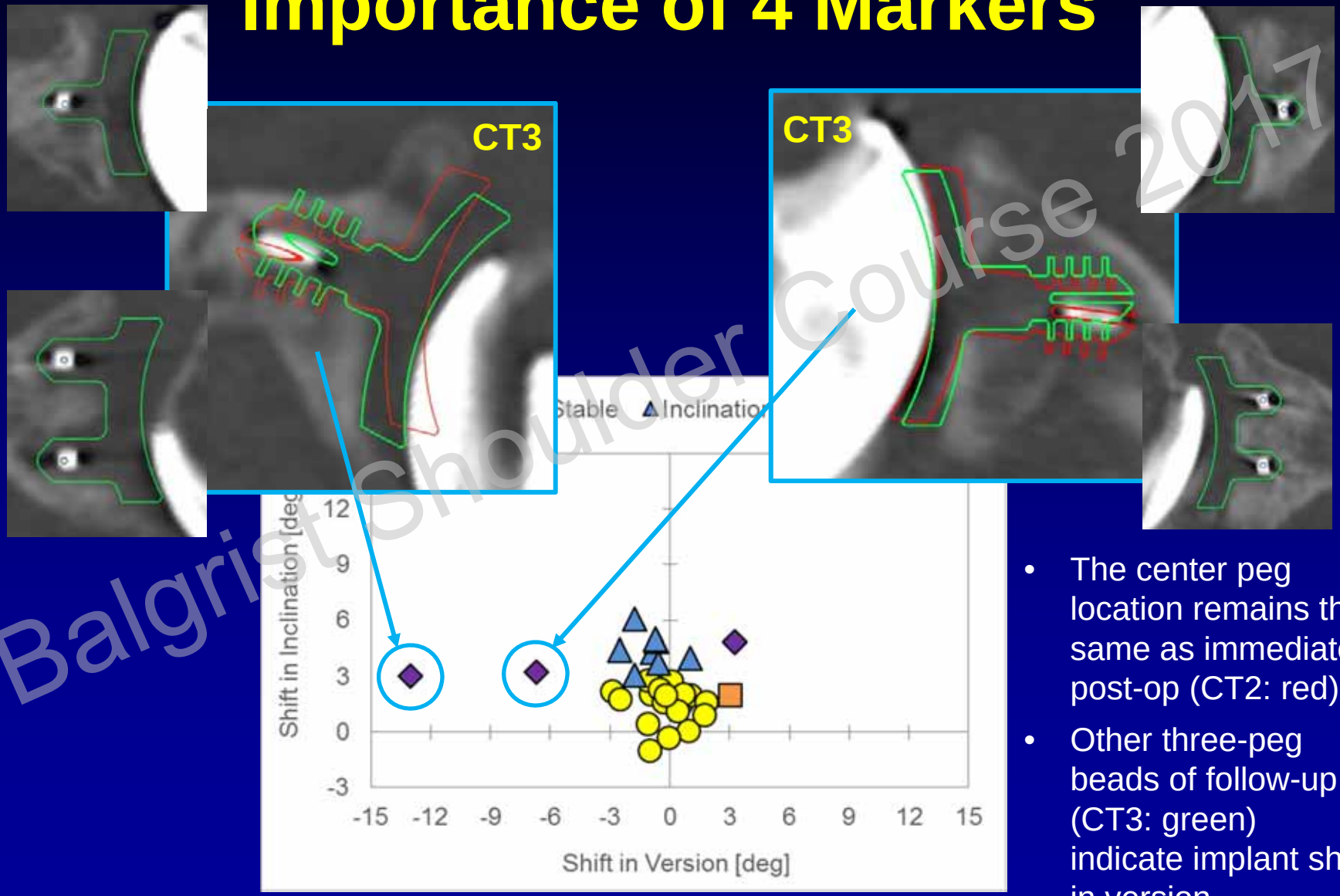



Glenoid Component Migration & Central Peg Grade
Superior Tilt (+)
Inferior Tilt (-)
15
12
9
6
3
0
-3
-6
-9
-12
-15
-15 -12 -9 -6 -3 0 3 6 9 12 15
Posterior Tilt (-)
Anterior Tilt (+)
Grade 2
15 Patients
Baugrist Shoulder Course 2017

Glenoid Component Migration & Central Peg Grade

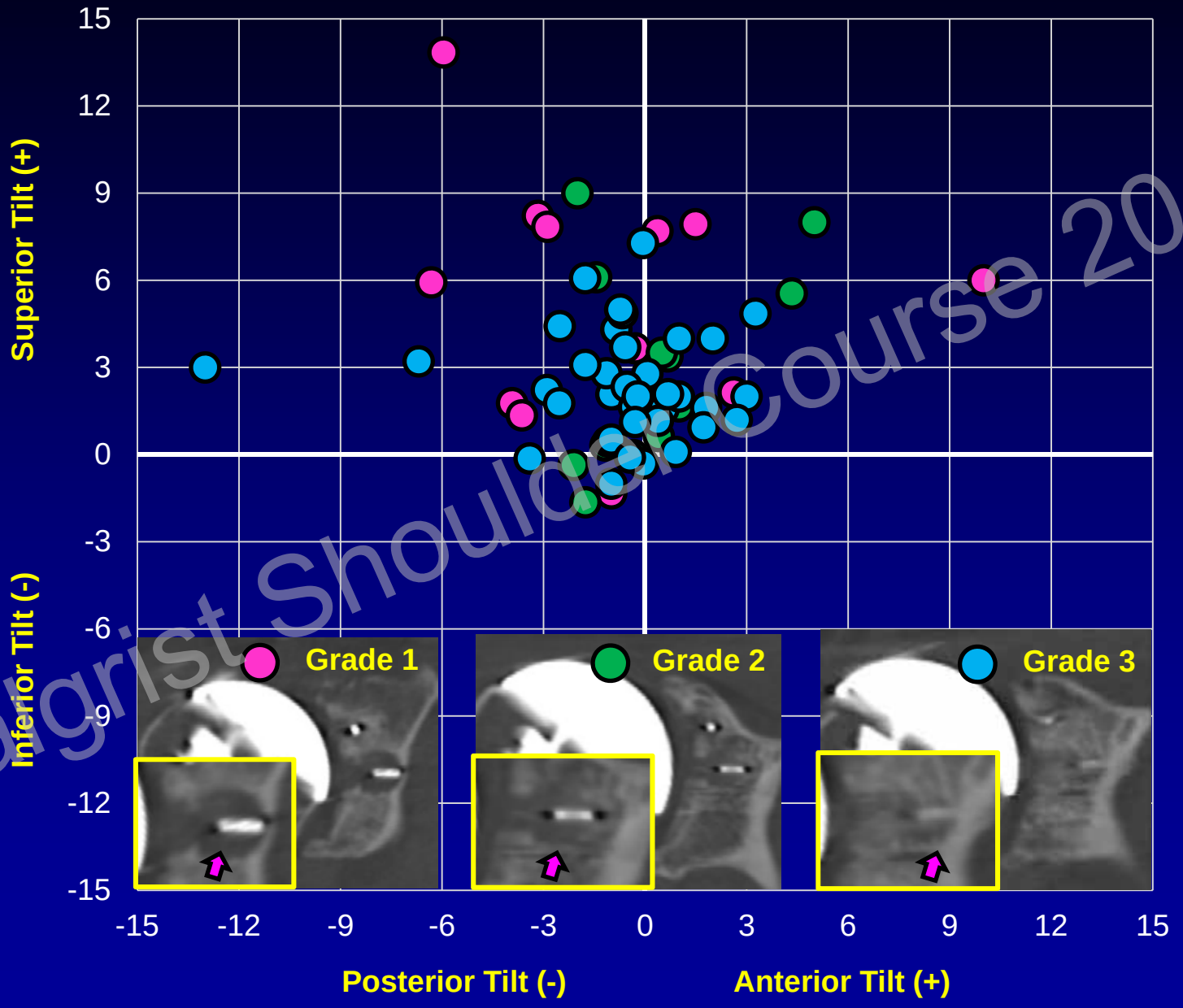


Center Peg Bent Overtime: Importance of 4 Markers

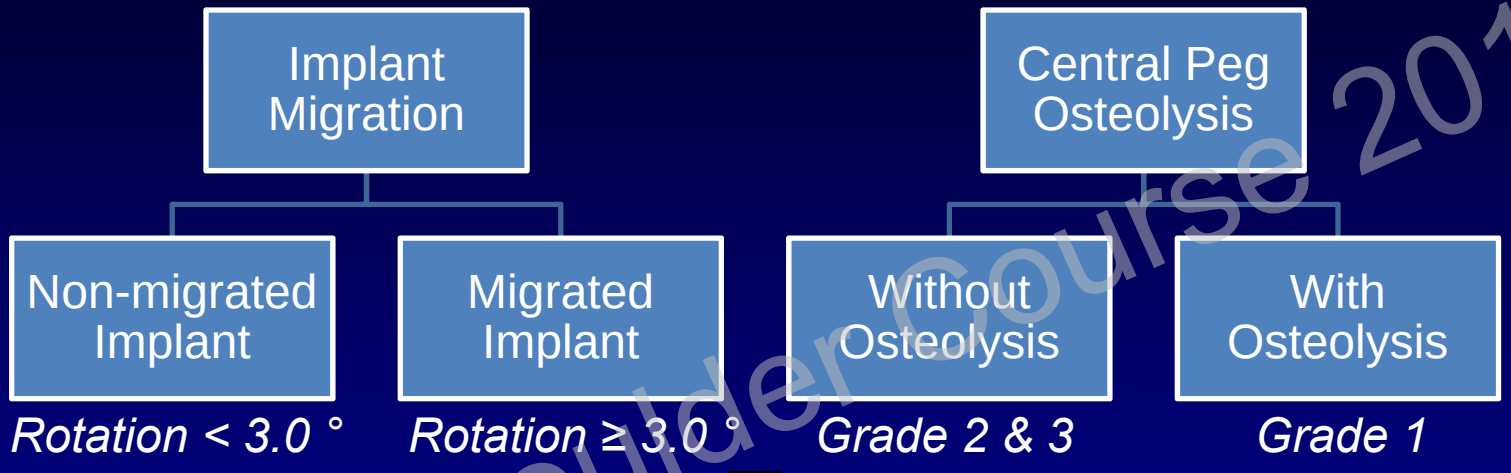


- The center peg location remains the same as immediate post-op (CT2: red)
- Other three-peg beads of follow-up (CT3: green) indicate implant shift in version

Glenoid Component Migration & Central Peg Osteolysis Grade



Patterns of Glenoid Component Loosening Assessed by Advanced 3D Clinical CT Imaging



Non-migrated implant without central peg osteolysis STABLE IMPANT 28/64 (44%)

Migrated implant without central peg osteolysis 24/64 (37.5%)

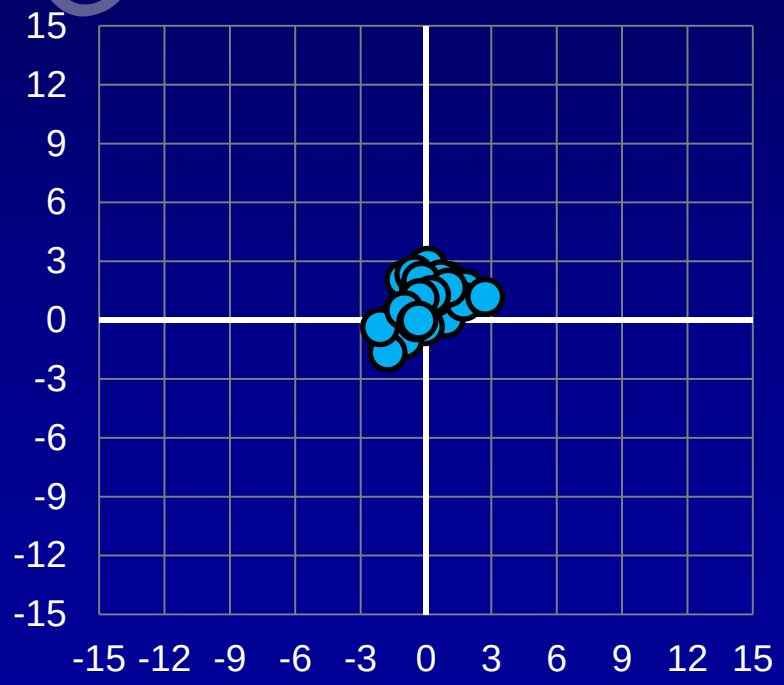
Non-migrated implant with central peg osteolysis 1/64 (1.6)

Migrated implant with central peg osteolysis LOOSE IMPLANT 10/64 (17%)

Preliminary Results of Advanced 3D CT Imaging Analysis in a Cohort of Patients

Non-migrated implant without central peg osteolysis

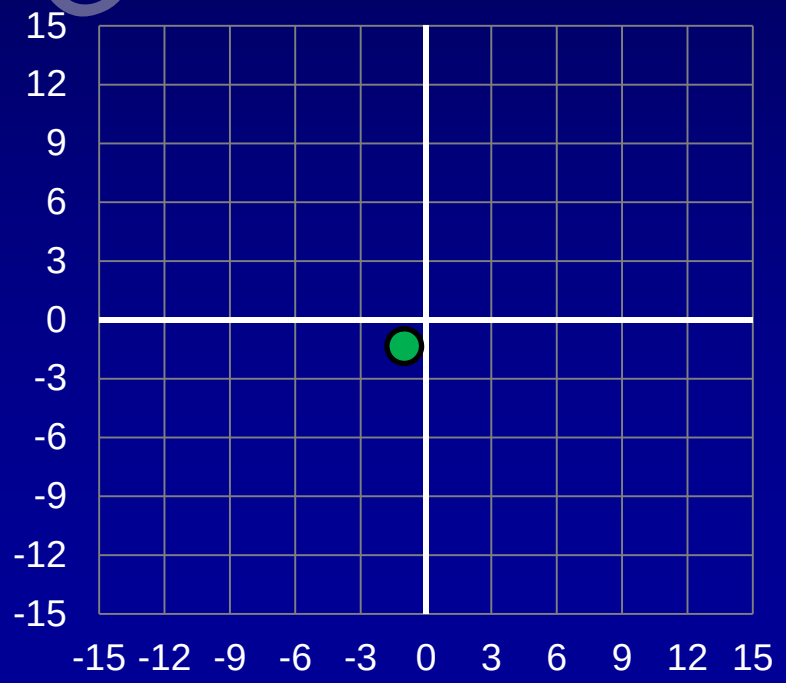
- 28/64 (43.8%) patients
- Implant migration
  - Mean version: 0.9 ± 0.7 °
  - Mean inclination: 1.2 ± 0.8 °
- Central peg osteolysis
  - Grade 1: 0 patient
  - Grade 2: 9 patients
  - Grade 3: 19 patients



Preliminary Results of Advanced 3D CT Imaging Analysis in a Cohort of Patients

Non-migrated implant with central peg osteolysis

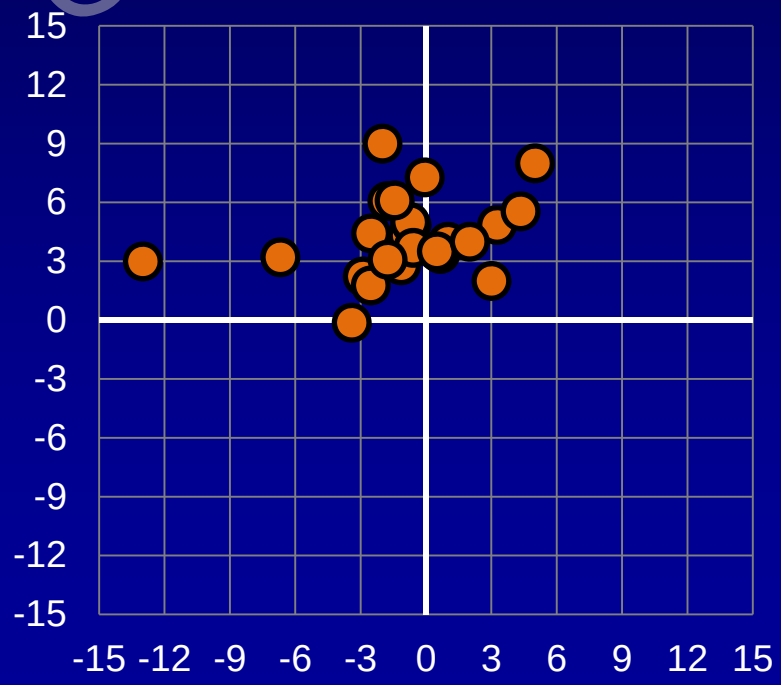
- 1/64 (1.6%) patients
- Implant migration
  - Posterior tilt: -1.0 °
  - Inferior tilt: -1.3 °
- Central peg osteolysis
  - Grade 1: 1 patient



Preliminary Results of Advanced 3D CT Imaging Analysis in a Cohort of Patients

Migrated implant without central peg osteolysis

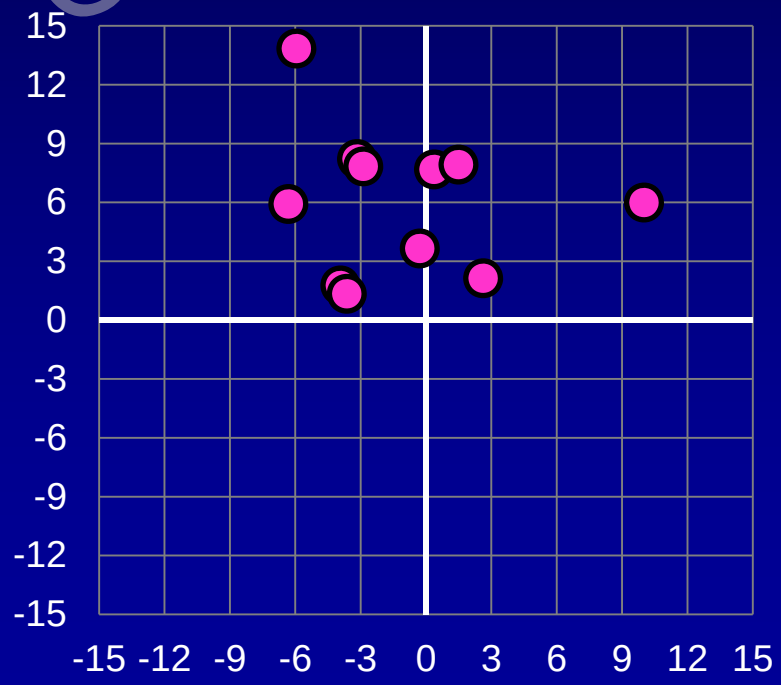
- 24/64 (37.5%) patients
- Implant migration
  - Mean version: 2.6 ± 2.7 °
  - Mean inclination: 4.3 ± 2.0 °
- Central peg osteolysis
  - Grade 1: 0 patient
  - Grade 2: 6 patients
  - Grade 3: 18 patients



Preliminary Results of Advanced 3D CT Imaging Analysis in a Cohort of Patients

Migrated implant
with central peg osteolysis

- 11/64 (17.1%) patients
- Implant migration
  - Mean version: 2.5 ± 4.7 °
  - Mean inclination: 1.8 ± 2.4 °
- Central peg osteolysis
  - Grade 1: 11 patient



Summary of Advanced 3D CT Imaging Analysis in a Cohort of Patients

- Patterns of implant migration more than 3°
  - Superior tilt (27 pts) was the major direction of the implant migration, followed by posterior (8 pts) and anterior tilt (5pts)
  - No inferior tilt was found
- Patterns of central peg osteolysis
  - Grade 1 found in 12/64 patients (19%)
  - Grade 2 found in 15/64 patients
  - Grade 3 found in 37/64 patients
- Relations between implant migration and osteolysis
  - 11/12 patients with central peg osteolysis grade 1 had shown implant migration more than 3°
  - 24/64 Implants with migration (34%) more than 3° was not always associated with central peg osteolysis

Summary of Advanced 3D CT Imaging Analysis in a Cohort of Patients

- Implant migration may occur prior to development of central peg osteolysis
- Implant migration may causes later onset of central peg osteolysis
- Development of central peg osteolysis may promote implant migration

Conclusions

- We have developed a 3D CT based imaging method that has a detection accuracy for glenoid implant shift, validated in vivo patients, to be < 1 degree of translational or < 1 degree of rotational movement when compared to RSA measurements.

Conculsions

- In a series of 64 patients using this CT based method, at two years follow up, we demonstrated that 34/64 (53%) patients have at least 3 degrees of shift

- In patients with shift there are patients with and without radiolucency around the pegs. 70% with shift have no radiolucency

- Shift ǂ Loosening

Conclusions

- At this time we have not defined the progression of these imaging findings over time. At this length of follow these finding are not correlated with a significant decrease in PRO or revision surgery.

- It is our current working hypothesis that those implants with greater than 3 degrees of shift AND radiolucency are at risk for progression and earlier clinical failure defined by a decrease in PRO and the need for revision surgery.

Conclusions

- Our study demonstrates the novel finding of glenoid implant shift without radiolucency which we currently interpret to be a stable implant. The fate of these implants are not know but we anticipate that progression of implant shift may not be as likely or will result in earlier clinical failure.

Conclusions

- When assessing shift of a glenoid implant it is important to assess the implant bone interface to assess if the shift is associated with resorbtion of bone around the implant as an additional feature of an implant at risk for clinically relevant loosening.

Future Studies

- Additional 110 patients due for 2 year 3D CT scans by June 2018.
- Correlation with:
  - Pre op Walch type and humeral head subluxation
  - Correction of retroversion and inclination, joint line medialization
  - Back side contact and
  - Humeral head position
  - Trabecular bone patterns and bone quality
- Correlation with x-rays findings
- Longer term follow up 5-10 years

Cleveland Clinic

Every life deserves world class care.