Post-op Accountability: Innovasis registry: HA PEEK and Why

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Intermountain Spine Institute, Salt Lake City, UT

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Overview

- Case
- Intro to HA PEEK
- Why registries?
- Registry details


Whistler
@jerrybftheday


L
CJS

The problem: Nonunions

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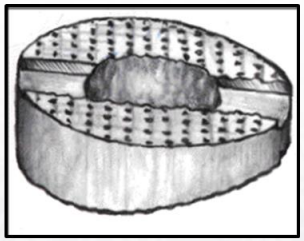
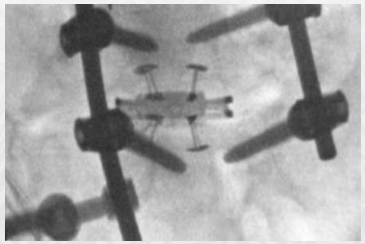
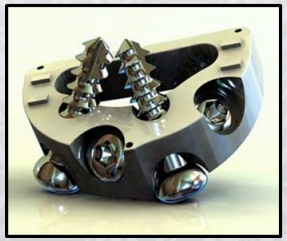
Implant Materials in Spine Surgery

- Titanium
  - Porous
  - Acid-Etched
- PEEK
- Ceramic
- Carbon Fiber
- HA Coated
- HA Infused







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The Ideal Interbody Material

- Facilitates bone growth
- Imaging capability
- Modulus similar to bone
- Biomechanical properties
- Cost effective

What is HA PEEK?

- Composite material of 80% PEEK, 20% Hydroxyapatite integration
- Structural and mechanical properties of PEEK combined with osteoconductive properties of HA
- No coatings or laminate
- Hydroxyapatite
  - Osteoconductive biomaterial used to enhance bone apposition
  - Chemical crystal structure similar to bone

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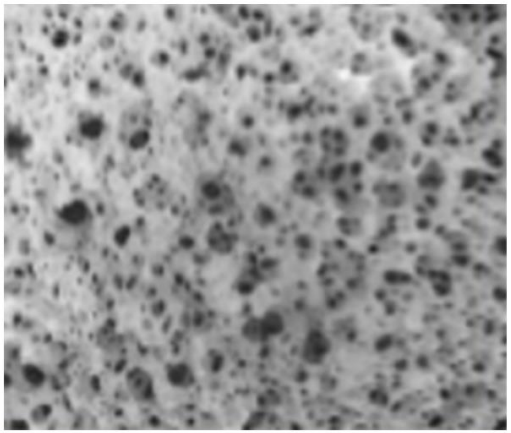
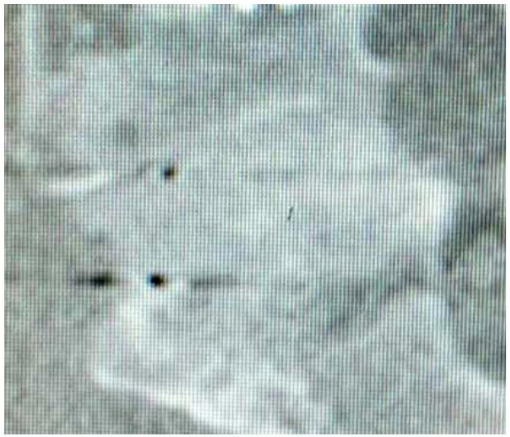
Proven HA PEEK Benefits

BONE LIKE STRUCTURE



With a modulus closer to bone^, PEEK-OPTIMA HA Enhanced reduces stress shielding at a higher rate than titanium^^

OSTEOCONDUCTIVE SURFACE

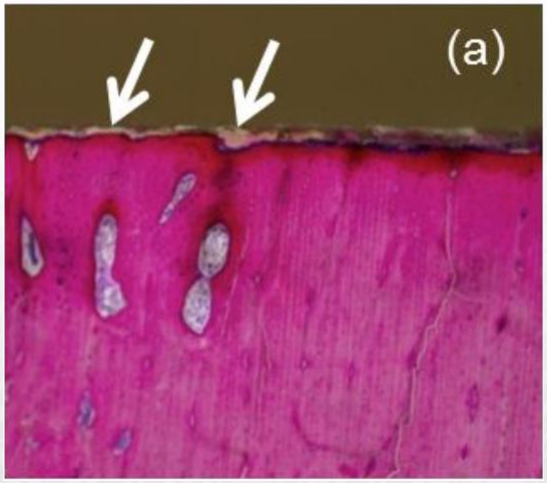


Fully integrated with hydroxyapatite on all surfaces for earlier bone ongrowth and greater new bone formation.*,**

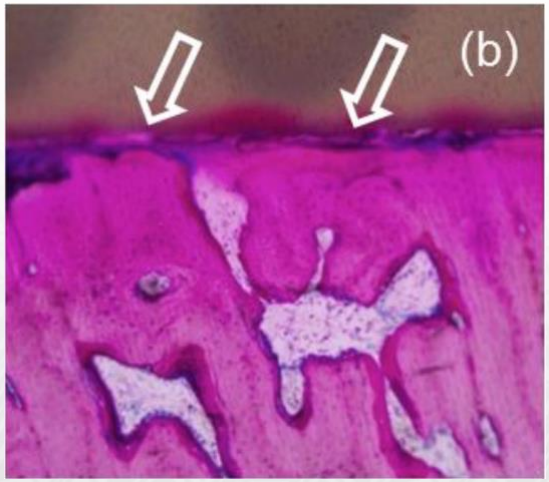
RADIOLUCENT IMAGING

PEEK-OPTIMA HA Enhanced is radiolucent for easy monitoring of the healing site with X-rays, CT or MRI.

Osteoconductive Surface



Natural PEEK



HA PEEK

The above images compare the two products showing a 4 week histology in sheep of (a) Natural PEEK, and (b) HA infused PEEK. Solid and open arrows show gaps and areas of direct bone contact respectively.
With the HA infused PEEK (b), a more consistent and continuous degree of direct bone contact is observed.

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Jerry about to go hammer mode in the snackcountry

#nosnacksleftbehind #cheeseballsFTB#powermove // @improbablereality

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Why a registry?

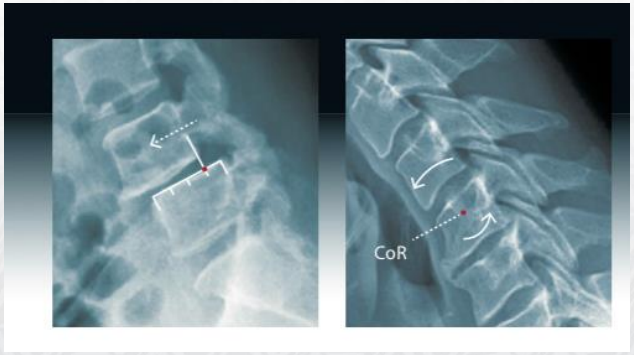
- Analogy: Change in your life -> feedback?
  - A new diet and never weigh yourself or look in the mirror?
- Most implant companies do not do this with new technology.
  - A rep told me the other day that they didn't need to study a new technology bc they already knew it worked…

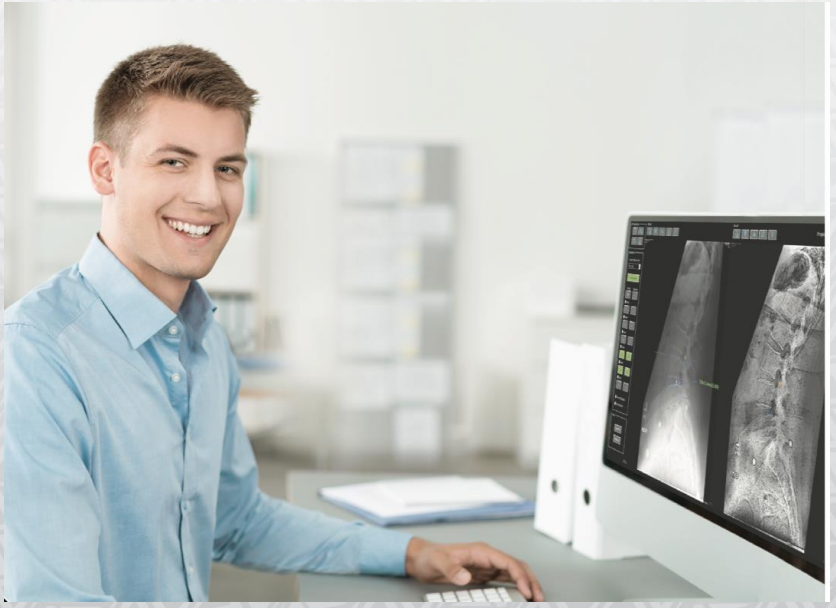
Why a registry?

- Have to study new technology!
- Tremendous respect for Innovasis in setting up this registry to find out how effective HA PEEK really is.
- Helps us as surgeons to track our patients. Helps the spine community by scientifically analyzing a new technology.

HA PEEK Registry

A quality assessment service provided by Innovasis





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Registry Objective

- To provide a simple, secure, confidential method for data collection and utility
- To allow investigators to access data on a real-time basis and track patient-reported outcomes and radiographic outcomes against aggregate peer data
- To provide resource to assess data for use in podiums, posters and training presentations

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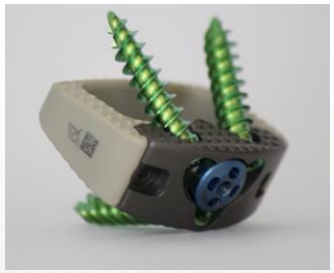
Registry Product Scope

- ALIF



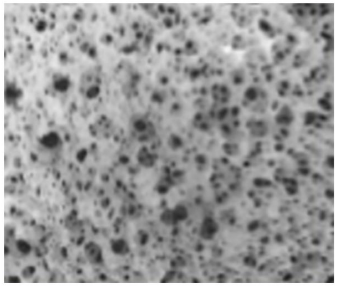
- PLIF

- ACDF

- TLIF

HA PEEK

BONE LIKE STRUCTURE



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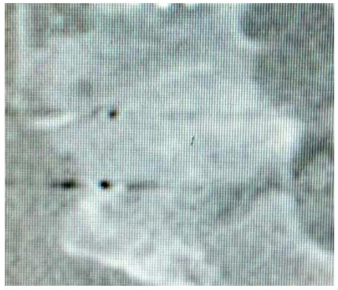

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Registry Summary

- Study type: Prospective, Observational, Patient outcome registry
- Study Population: Patients with DDD
- Inclusion Criteria: Adults receiving HA PEEK device
- Enrollment Period: 12 months
- Follow up Period: 24 months
- Patients: >100
- Sites: >10
- Data collection periods: Preop, Surgery, 6 wks, 3, 6, 12, and 24 months

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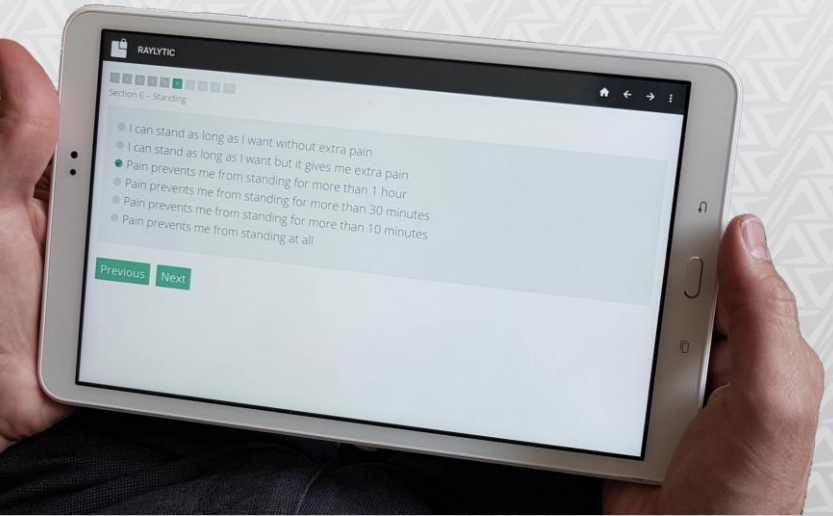
Patient Outcome Measures

- ✓CRF
- ✓ODI/NDI
- ✓VAS
- ✓EQ-5D
- ✓Patient Satisfaction

- Web-Portal based electronic questionnaires
- Secure, password protected access
- Desktop computer- and tablet-friendly app
- Electronically stored and accessible files
- Customizable follow-up notifications



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Radiographic Outcome Measures

- Radiographs will be analyzed by an independent core lab (Raylytic Inc.) assessing fusion:
  - Radiolucency around device
  - Segmental ROM
  - Segmental translational motion or instability
  - Disc Height
  - Device migration or subsidence

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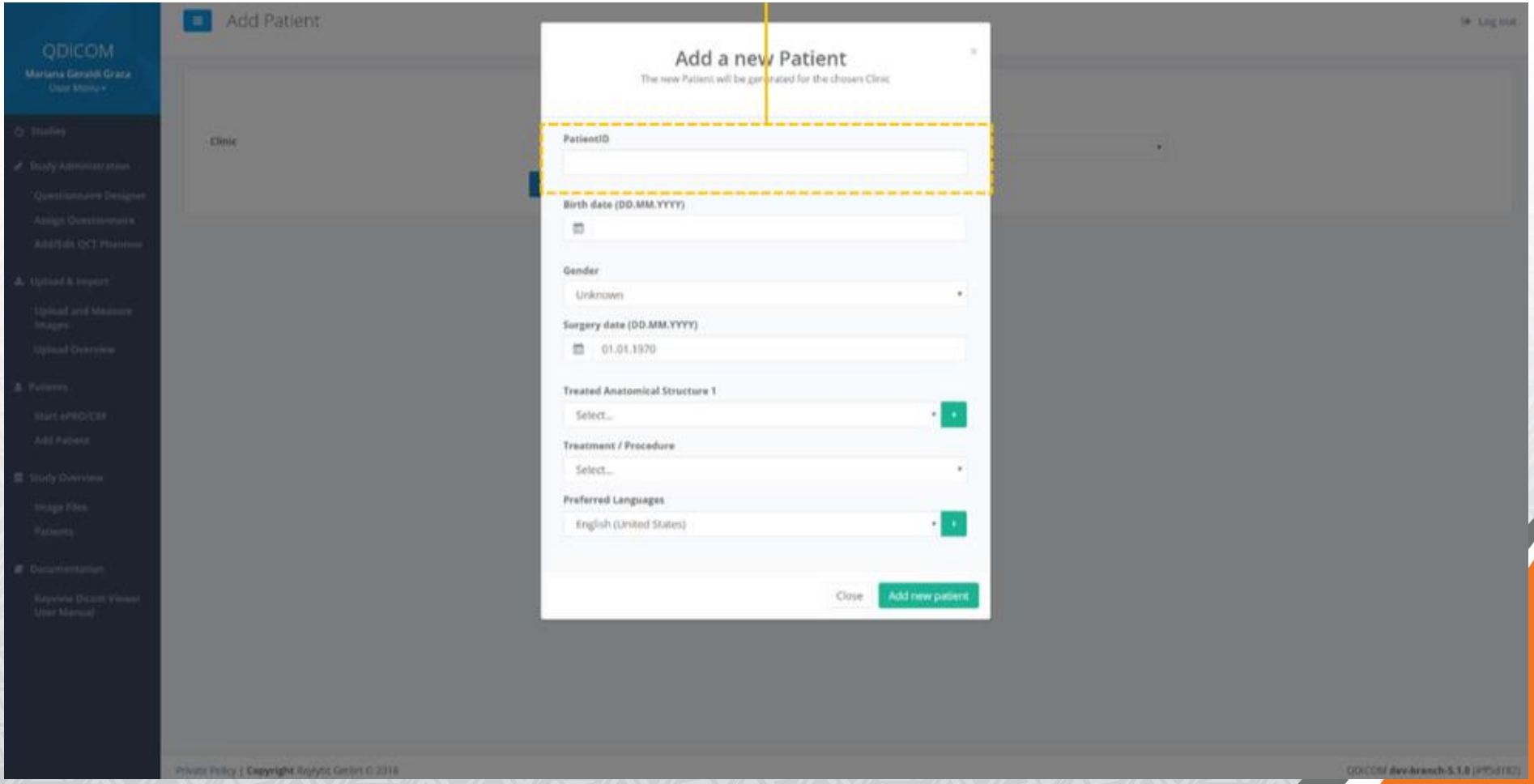
Real Time Registry: Adding a Pt



Real Time Registry: Outcomes

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Real Time Registry: Xray Upload

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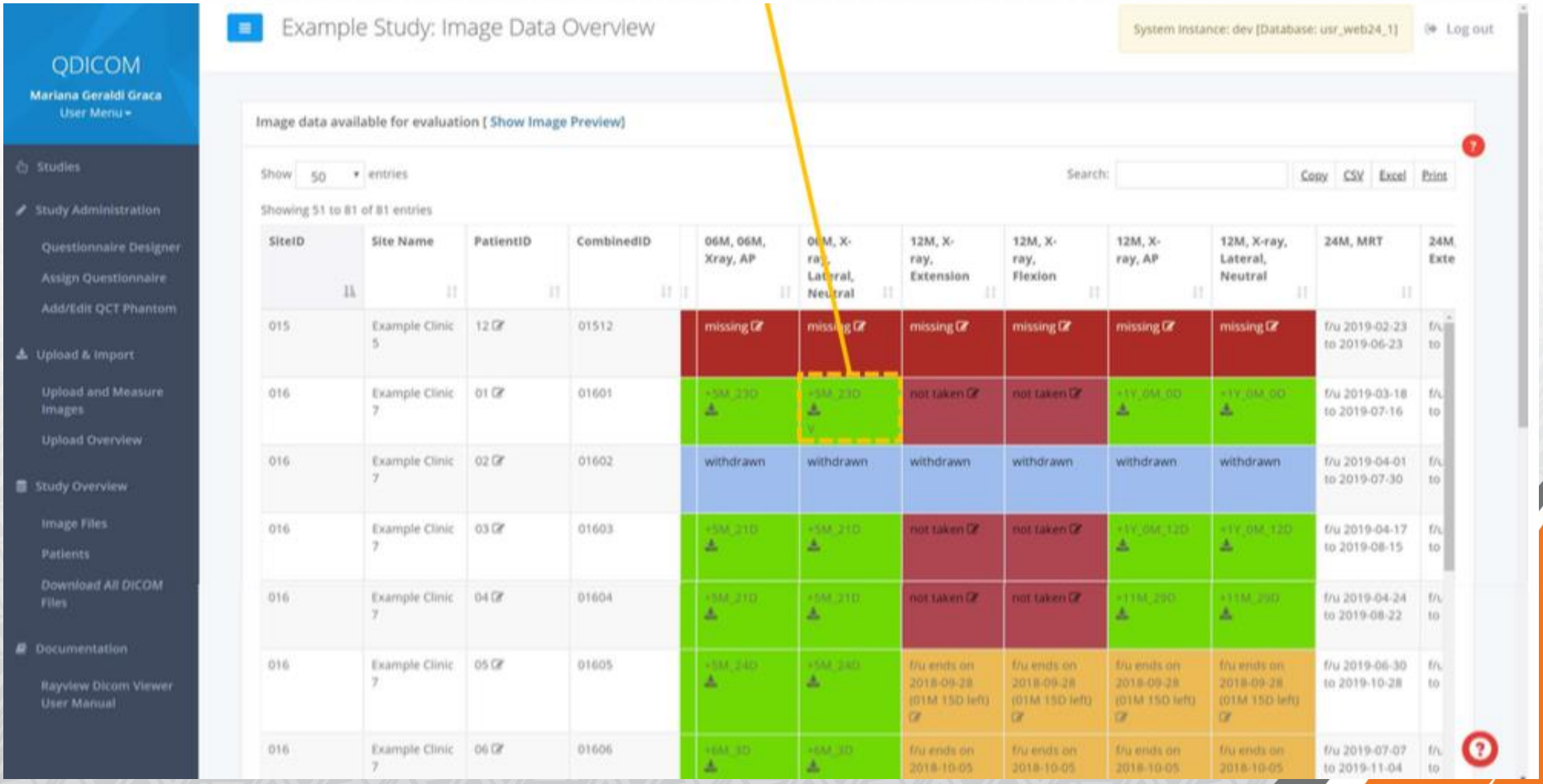
Real Time Registry: Tracking Xrays



Assessment Schedule

ID	Outcome Measure Type	Preop (0M-2M/+0M)	Surgery (0M 0M+12D)	6 Weeks (42D -7D/+7D)	3 Months (3M -14D/+14D)	6 Months (6M -1M/+1M)	12 Months (12M -1M/+1M)	24 Months (24M -2M/+2M)
		Assessment Procedure						
1	Lateral Neutral	X		X	X	X	X	X
2	AP Neutral	X		X	X	X	X	X
3	Flexion	X				X	X	X
4	Extension	X				X	X	X
5	Patient Survey and Op Report*	X	X	X	X	X	X	X
	Outcome Assessment	**Assessment Period**						
	Radiolucency around device (device loosening)					1	1	1
	Range of motion (degrees)	3, 4				3, 4	3, 4	3, 4
	Translational AP-motion or instability	3, 4				3, 4	3, 4	3, 4
	Fusion in disc space anterior to device			1, 2	1, 2	1, 2	1, 2	1, 2
	Fusion in disc space posterior to device			1, 2	1, 2	1, 2	1, 2	1, 2
	Absence of graft subsidence or migration			1		1	1	1
	eCRF	5	5	5	5	5	5	5
	Visual Analogue Scale (VAS)	5		5	5	5	5	5
	NDI or ODI	5		5	5	5	5	5
	EQ-5D	5		5	5	5	5	5
	PROMIS	5		5	5	5	5	5
	Patient Satisfaction			5	5	5	5	5

*Patient reported outcome measures will be determined by Participant and Innovasis.

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Thank you