Conversion-free survival rates after treatment with an implantable shock absorber (ISA) for medial knee OA

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Poster #25

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Disclosures and FDA Status

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As of April 5, 2023, the ISA is Investigational in the United States:

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.

Background

- Knee OA is a frequent cause of pain and disability
- 60% are working age
- Young, mild-moderate disease patients face dilemma:
  - Give up activity and lifestyle due to pain and symptoms
  - Give up joint and undergo early arthroplasty

1. Khan M, Adili A, Winemaker M, Bhandari M (2018) Management of osteoarthritis of the knee in younger patients. CMAJ 190(3):E72–E79.

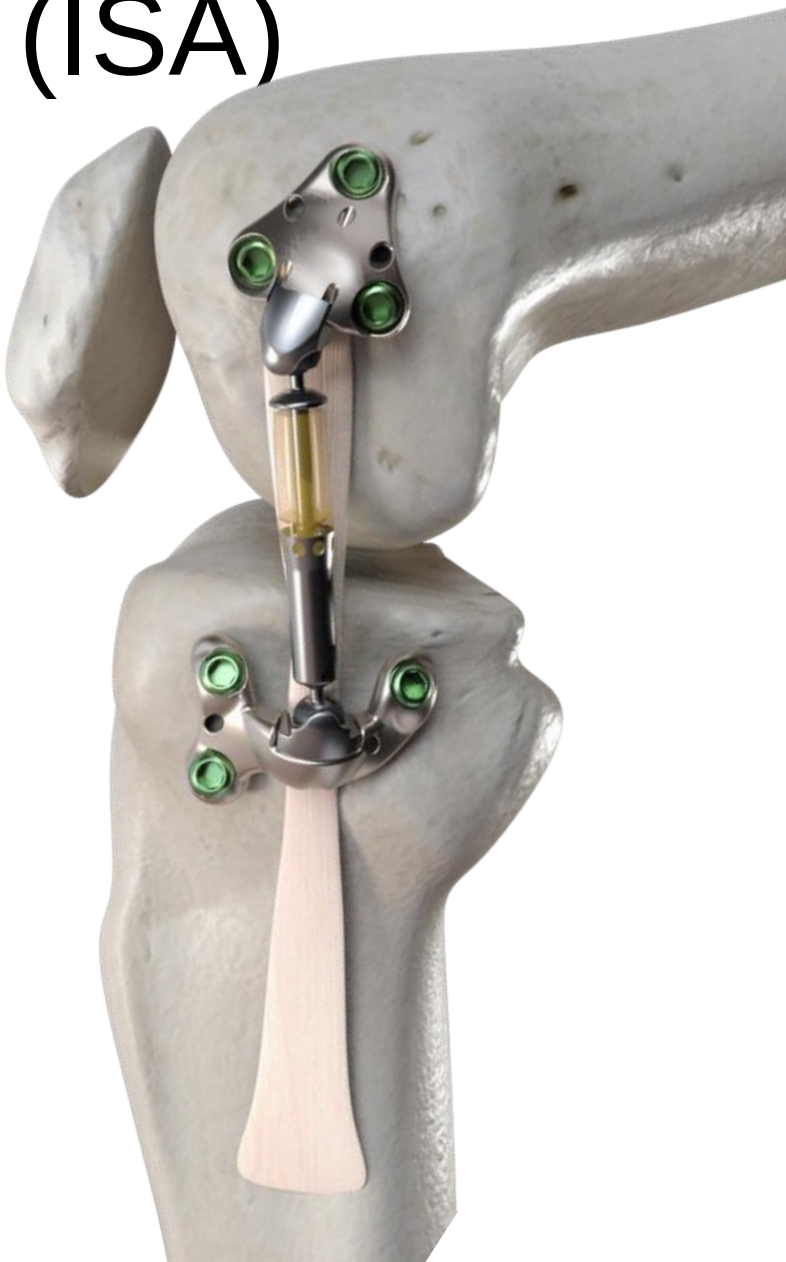
Objective

- Implantable shock absorber (ISA) developed to partially unload the knee
- Three clinical studies have evaluated this platform (polymer shock absorber) since 2014 (n=171)
- This analysis reports conversion-free survival rate of this platform

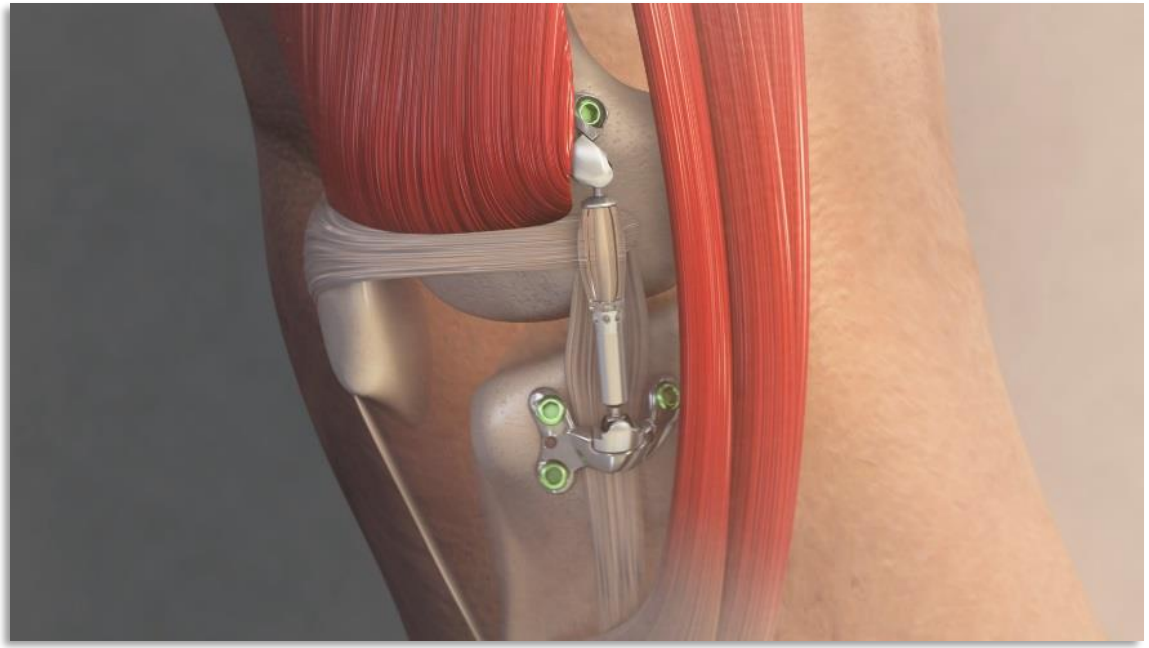
Implantable Shock Absorber (ISA)

For patients with medial compartment knee osteoarthritis that:

- Have failed to find relief in surgical and/or non-surgical treatment modalities
- Are still experiencing pain that interferes with activities of daily living
- Are also unwilling to undergo or ineligible for total knee replacement due to age or absence of advanced osteoarthritis



ISA Function: Partial Unloader



Extra-articular implant

Does not distract joint

Unloading comparable to HTO

Materials and Methods

- 171 subjects enrolled in three studies (2014 – 2020)
  - Similar versions of polymer shock absorber

- Kaplan-Meier arthroplasty-free survival analysis was performed, with conversion to HTO, UKA, or TKA deemed failure

Clinical History Since 2008

Study	Key Takeaways	Total Enrollment
Phantom Study	Proved concept	40
Atlas Study	Refined patient selection and surgical technique	50
Calypso Study	Generated pivotal clinical evidence of MISHA	81

Key Inclusion / Exclusion Criteria

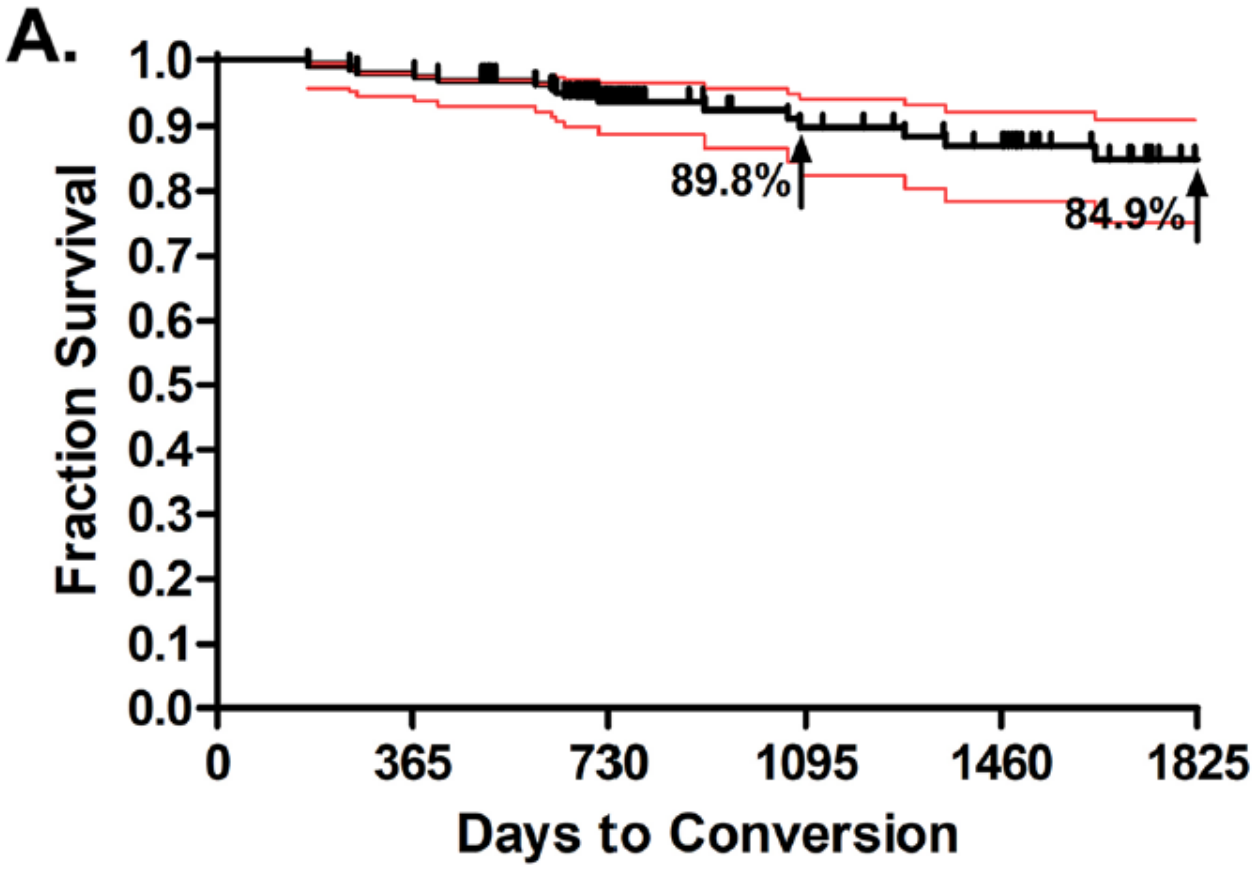
- Inclusion
  - Age 25 – 65
  - Radiographic evidence of medial OA
  - ≥ 6 months failed conservative care
  - BMI < 35, Weight < 300lbs
  - WOMAC pain ≥ 40
- Exclusion
  - Large (> grade 2) marginal osteophytes that could interfere with device function
  - Lateral OA > KL 2
  - PF OA > KL 3
  - Alignment < -10° (varus)
  - Flexion contracture >10°

Patient Demographics

Population: Young with Mild-Moderate Medial Knee OA

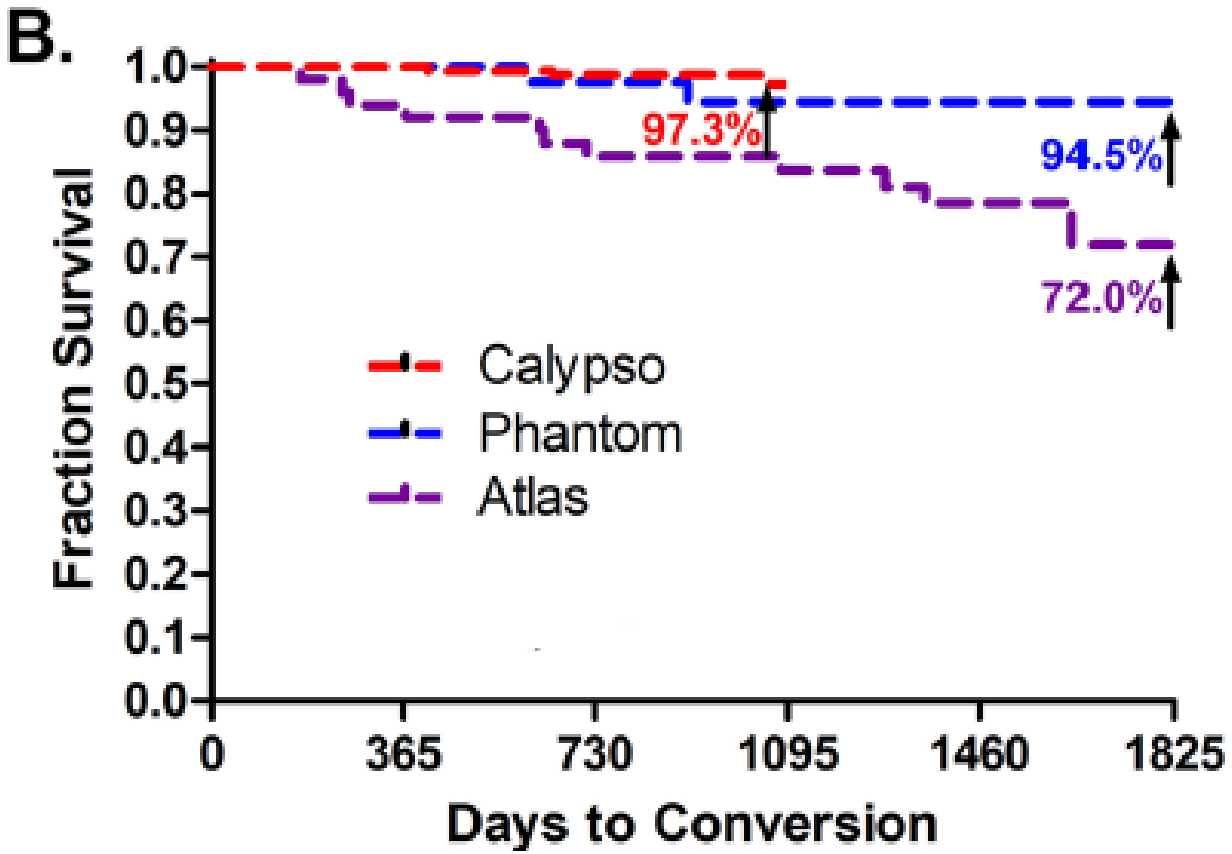
	Calypso ($n=81$ at 4 sites)		Atlas ($n=50$ at 9 sites)		Phantom ($n=40$ at 10 sites)	
	Mean	SD	Mean	SD	Mean	SD
Parameter						
Age, years	51.2	7.7	49.4	10.9	50.8	8.9
Height, inches	68.4	3.7	68.8	4.1	68.0	3.6
Weight, lbs	189.5	30.7	195.6	36.4	185.9	24.7
BMI, kg/m^2	28.4	3.4	28.8	3.6	28.3	3.5
Clinical Scores						
K-L Grade	2.5	0.9	2.9	1.0	2.9	0.7
WOMAC Pain	60.6	12.3	57.2	13.0	52.1	12.2
WOMAC Function	60.1	16.0	51.9	18.5	50.6	17.9

Kaplan-Meier Survival, all studies



- Mean follow-up 3.2 ± 1.6 years
- 85% 5-year K-M point estimate for survival
- 90% 3-year K-M point estimate for survival

Kaplan-Meier Survival, by study



- Median 3-year survival estimates by study:
  - Phantom: 95%
  - Atlas: 84%
  - Calypso: 97%
- Patient selection and surgical technique contributed most to improved survival in Calypso Study

Pain and Function Outcomes

Dramatically Improved Pain and Function Across All Studies

	Calypso ($n=78$)			Atlas ($n=39$)			Phantom ($n=38$)			Total analysis* ($N=155$)		
Pain	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range
Baseline	60.6	12.3	40–90	57.2	13.0	40–85	52.1	12.2	10–70	57.6	12.9	10–90
Last Follow-up	13.8	16.3	0–55	22.9	21.3	0–75	13.6	11.5	0–40	16.0	17.1	0–75
Change from Baseline, %	− 76.5%			− 59.1%			− 71.2%			− 70.9%		
p-value	<0.0001			<0.0001			<0.0001			<0.0001		
Function	Calypso ($n=78$)			Atlas ($n=39$)			Phantom ($n=38$)			Total Analysis ($N=155$)		
Baseline	60.1	16.0	31–96	51.9	18.5	12–87	50.6	17.9	7–85	55.7	17.6	7–96
Last Follow-up	15.1	17.3	0–62	20.8	18.7	0–59	16.6	15.0	0–50	16.9	17.2	0–62
Change from Baseline, %	− 74.2%			− 58.6%			− 66.9%			− 68.5%		
p-value	<0.0001			<0.0001			<0.0001			<0.0001		

*N-values were censored for patients who underwent conversion because their last follow-up score would have been influenced by the subsequent treatment, *i.e.*, arthroplasty or HTO

Conclusions

- 85% survival from arthroplasty at 5-years in a younger, mild-moderate OA population

- Pivotal (Calypso) Study incorporated evolved indications and technique, with 2-year data suggesting that the latest ISA version may outperform the aggregate survival rate

Significance of the Findings

- ISA may be effective treatment option for young, mild-moderate disease, working-age patients who are not eligible for arthroplasty