DISC PROSTHESES

CERVICAL DISC ARTHROPLASTY

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Disclosure

- I designed and developed the medical device included in this presentation.
- Currently the distributor trough Applied Veterinary Technology, LLC

Cervical Disc Arthroplasty “CDA”

Goals:

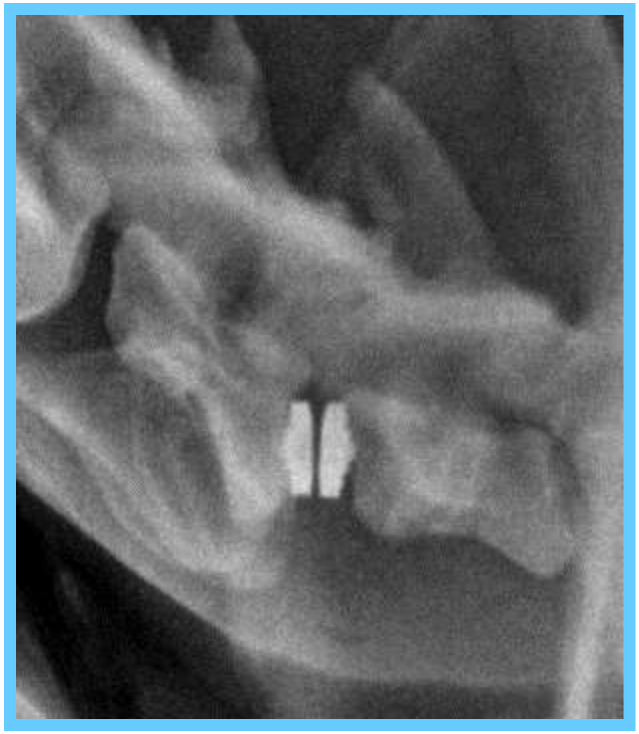
Preserve motion after neuronal decompression while providing distraction and stability

Potentials:

May prevent the occurrence of domino lesion

Advantages:

Treatment of multiples adjacent and not adjacent spaces



Cervical Disc Arthroplasty “CDA”

Indications

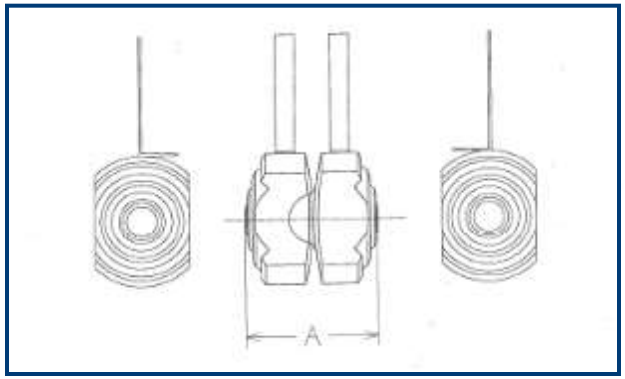
- ***Disc Associated Wobbler Syndrome***
- ***Cervical Disc herniation***

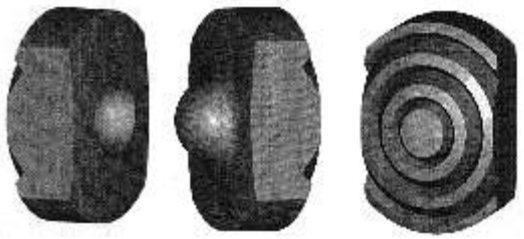
Copy of this presentation:

wobblersyndrome.com

History

- **Phase 1.**
  - **DESIGN**
    - *Madison, WI 2003*





- **Phase 2:**
  - **IN VITRO BIOMECHANICAL STUDY**
    - *Adamo, Kobayashi et al. Vet Surgery 2007*

4 Groups of 6 cervical spines (C5-C6)

a) **Arthroplasty,**
b) **Ventral Slot,**
c) **Pins+PMMA fixation,**
d) **and normal spine**

- ***The artificial disc was better able to mimic the behavior of intact spine compared with ventral slot and Pin+PMMA groups.***

Phase 3: Pilot clinical study in 2 owned clients dogs with DAWS

Adamo JAVMA, 239(6), 2011

- ***Results***
  - *Follow up to 3 ½ years post-op*
    - *Died for unrelated neurological diseases*
  - *MRI re-check 2 years post-op*
    - *No evidence of compression at the treated and adjacent sites*
- ***Conclusions***
  - *Cervical arthroplasty was well tolerated and provided excellent outcome in both dogs*
- ***Warranted further study:***
  - *Large number of patients*
  - *Longer follow-up*

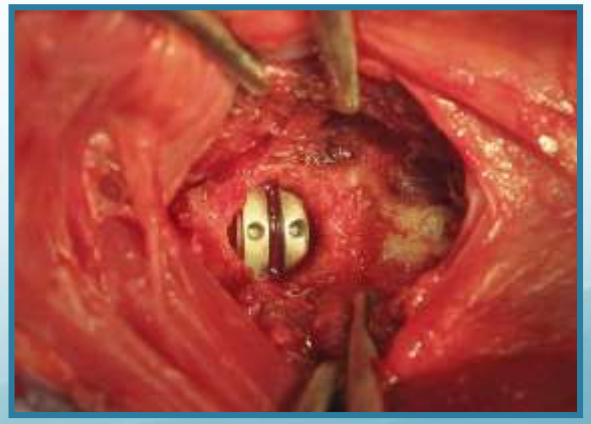
Titanium alloy

Cervical Disc Arthroplasty using the Adamo Spinal Disc® in 33 dogs affected by Disc Associated Wobbler Syndrome at Single and Multiple Levels.

A Multi-Center Prospective Study

Study Authors

- F Adamo, DECVN
  - East Bay Vet Specialists – CA
- R Da Costa, DACVIM (Neurology)
  - The Ohio State University – OH
- R Kroll, DACVIM (Neurology)
  - VCA Northwest Vet Specialists – OR
- C Giovannella, DACVIM (Neurology)
  - Gulf Cost Vet Neurology / Neurosurgery – TX
- M Podell, DACVIM (Neurology)
  - Chicago Vet Specialty Group – IL
- P Brofman, DACVIM (Neurology)
  - Veterinary Specialty Care, SC



Objective

To evaluate the immediate postoperative recovery, and the short-, intermediate-, and long-term follow-up of dogs with one level and multi-level disc-associated-wobbler-syndrome (DAWS) treated with cervical disc arthroplasty (CDA).

Material & Methods

- Implant: similar to that described in the preliminary study, but with several modifications.

Adamo JAVMA, 239(6), 2011

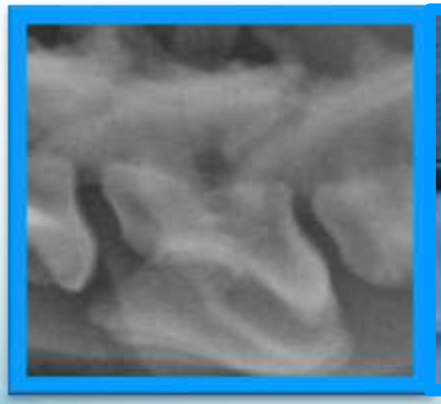
Adamo Spinal Disc 2nd and 3rd generation

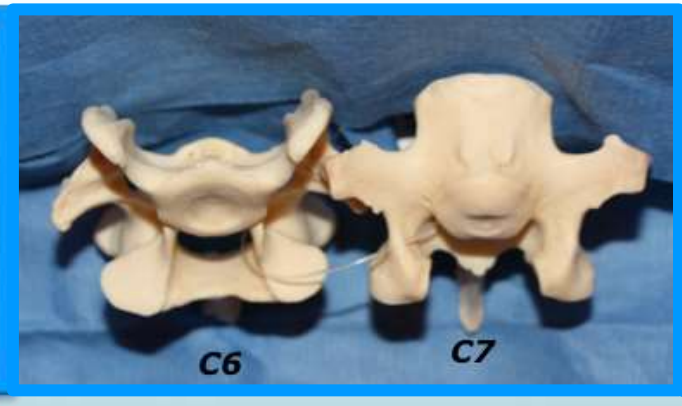
- Internal surfaces
  - Concavity is titanium
  - Convexity is PEEK
    - (PolyEther Ether Ketone)
      - Termoplastic polymer
      - Decreases friction
      - Prevent metallic debris from a metal to metal joint
  - Acts as a ball and the socket

Patent: US 8,496,707 B2

Implant

- External surface
  - Convex
    - To resemble natural concavity of vertebral end plates
    - To prevent implant migration

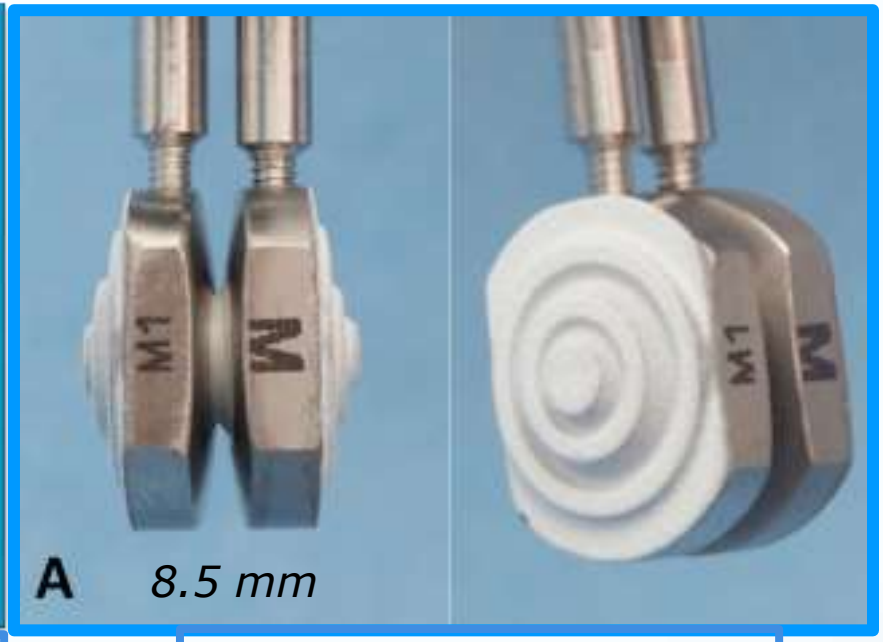




Implant

- External surface
  - Concentric grooves
    - To provide "grip"
    - To allow bone in-growth into the implant
    - 2nd Generation
      - Treated with Dual Acid Etch Bath
        - to promotes bone / implant incorporation
    - 3rd Generation
      - Treated with Hydroxyapatite
        - to better promotes bone / implant incorporation

Implant Design Modification



1st generation

2nd generation
- Ball in PEEK
- Thinner size

3rd generation
- Ball in PEEK
- Thinner size
- Hydroxyapatite Coating

Implant Design Modification

- 6 different disc sizes

- Set of dedicated tools

Implant Design Modification

- 6 different disc sizes

- Set of dedicated tools

CDA Disc Placement

CDA Disc Placement

- Visit: http://youtu.be/DaFRzcvjyXY

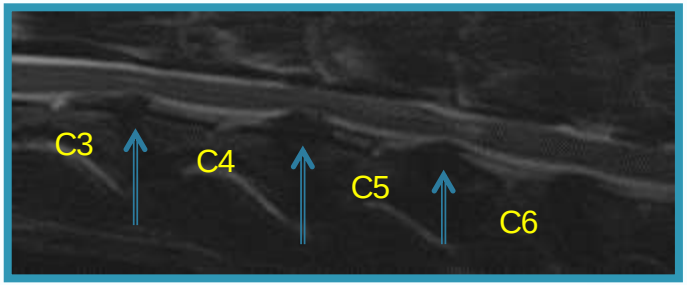
Including Criteria

- Sample population:
  - First 33 clients-owned dogs w / over 2 mo. history of DAWS
  - Diagnosed by MRI or CT myelo
  - Weight over 23 kg, but one (12.2 Kg)

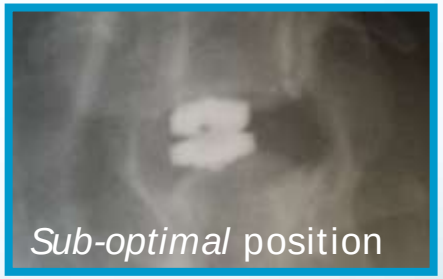
- Neurologically and radiologically evaluated
  - Prior to surgery
  - Shortly after surgery
    - within 24 hrs
  - At 2 wks & 3, 6, 12 & 24 mo. after surgery

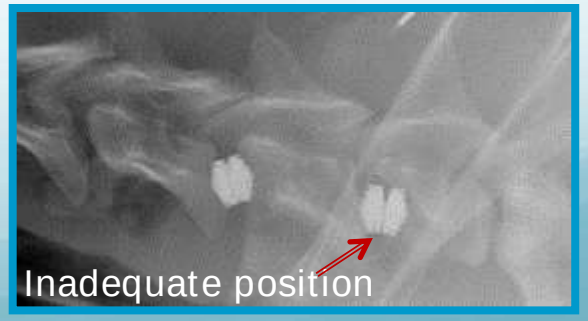
Material and Methods

- Total = 50 disc sites treated
  - Single, two and three level lesions
- Neurological Assessment
  - Grade 0 to 6
    - De Decker, et al. J Am Vet Med Assoc 2012; 240:848–857



- **Implant Position**
  - Optimal
    - Well centered in lateral and VD
  - Sub-optimal
    - Off midline on VD
  - Inadequate
    - Not seated in the center on lateral view

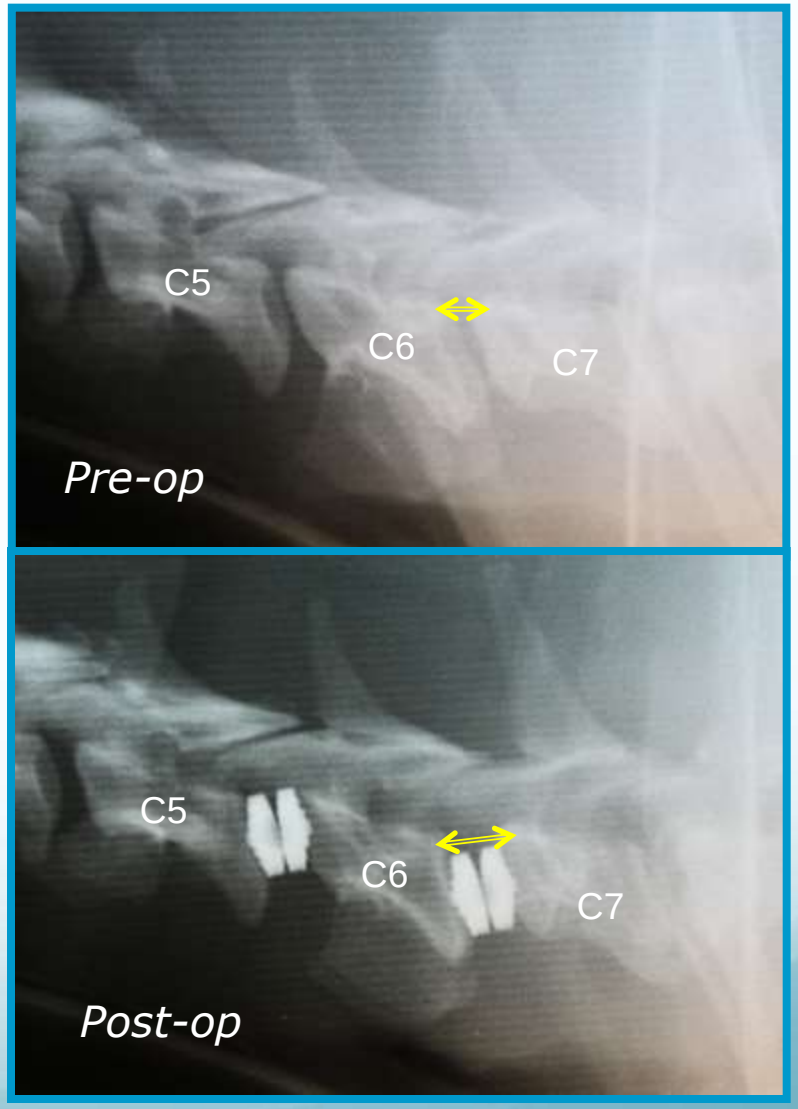




Distraction

- Relative Distraction ratio (RDR):
  - Ratio between post-op and pre-op width at the treated space
  - Adequate / Ideal*
    - RDR > 1.7 and < 2

      * Equivalent to a distraction of 2-3 mm
  - Under distraction
    - RDR < 1.7
  - Over-distraction
    - RDR > 2

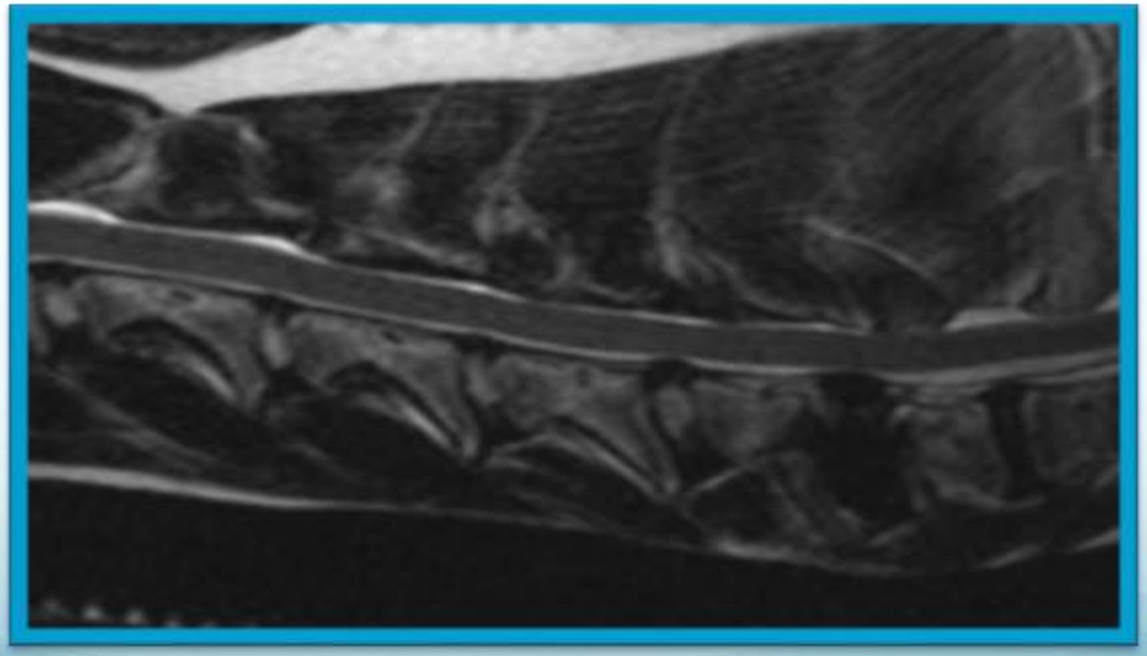


Mobility

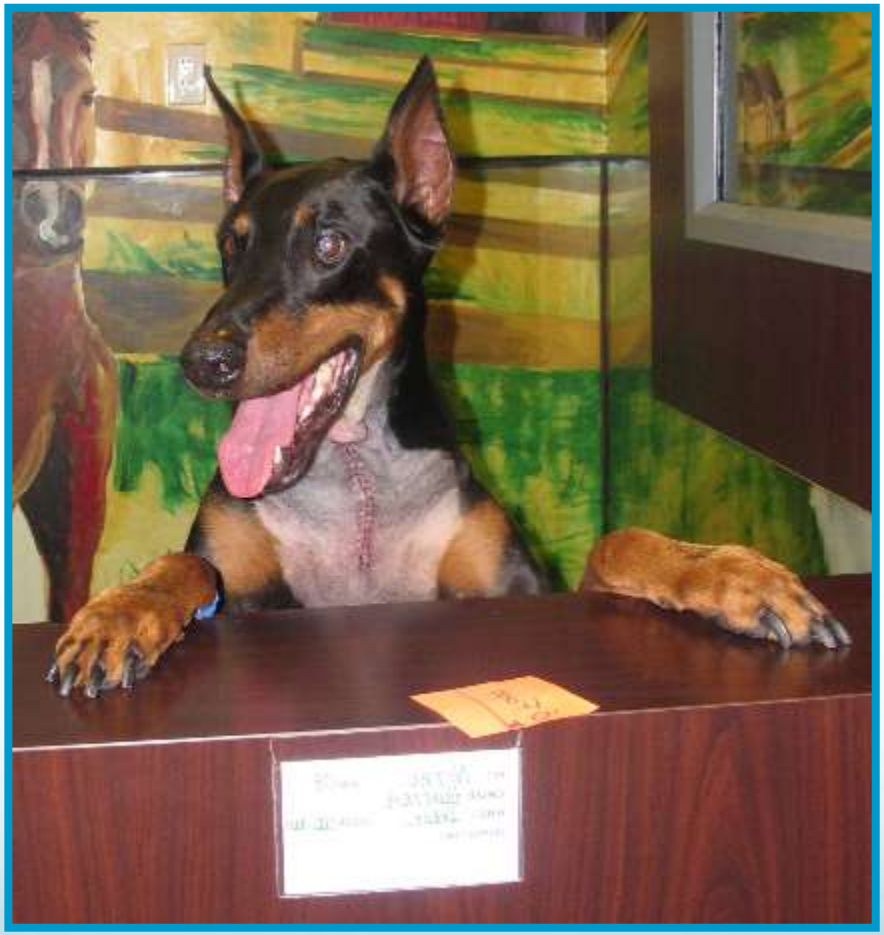
- Distance between dorsal and ventral edge of the 2 faces of the implant in neutral and stressed views
  - Present
  - Lost or Not detectable

MRI re-evaluation

- 2 years post-op when possible
- As needed, in the event of recurrence of clinical signs



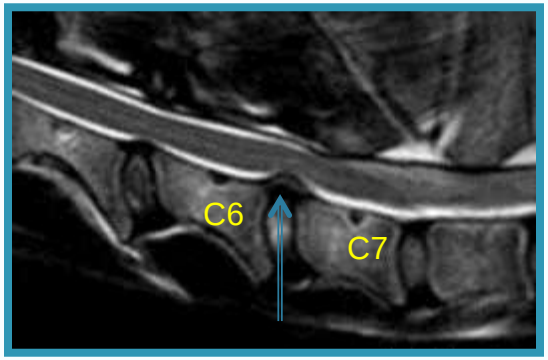
Results



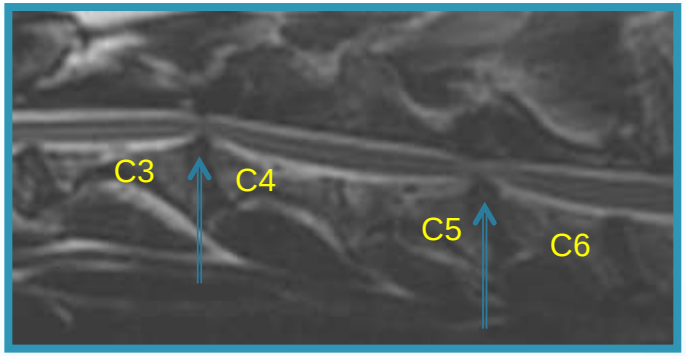
- Breeds:
  - 17 Doberman Pinchers (50%)
  - 3 Dalmatians
  - 2 Labrador
  - 2 Bernese Mountain dog
  - 1 Standard Poodle
  - 1 Weimeraner
  - 1 Boxer
  - 1 Greyhound
  - 5 Mix
- Sex:
  - 21 M; 12 F
- Age:
  - 4 - 13 y; Mean 8.3 y
  - 27% over 10 y old

Lesion Localization

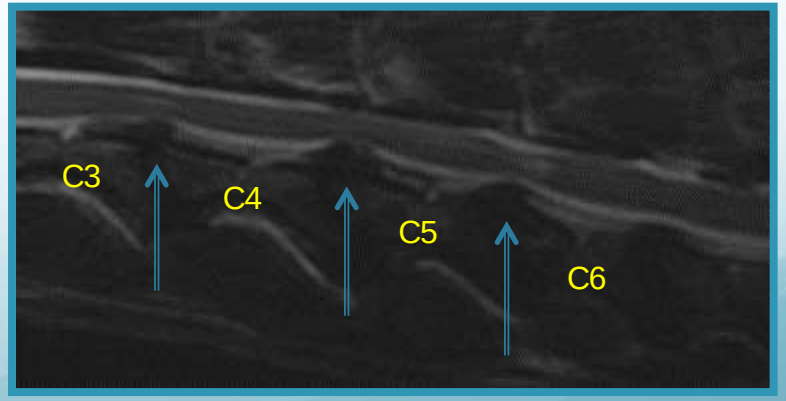
- Single level: 19 dogs
  - C6-C7 (13 dogs)
  - C5-C6 (5 dogs)
  - C3–C4 (1 dog)



- Two levels: 10 dogs
  - C5-C6 & C6-C7 (8 dogs)
  - C4-C5 & C5-C6 (1 dog)
  - C3-C4 & C5-C6 (1 dog)



- Three levels: 3 dogs
  - C3-C4, C5-C6 & C6-C7 (2 dogs)
  - C2-C3, C5-C6 & C6-C7 (1 dog)

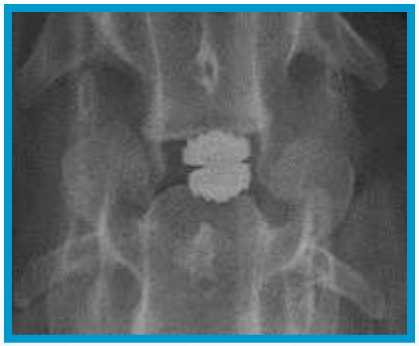


TOTAL: 50 Spaces treated

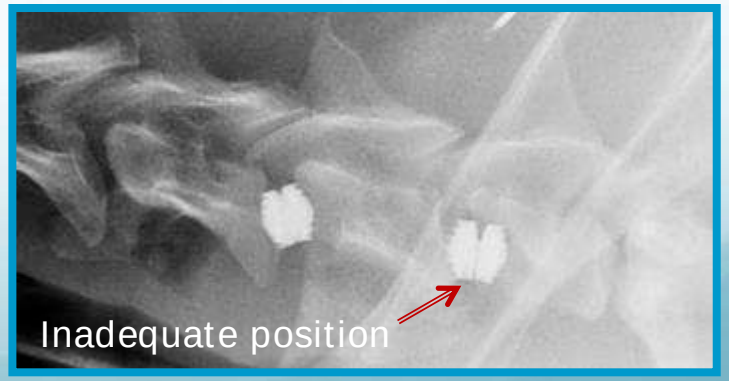
Immediate Post-op Radiographs

- Implant position:
  - Optimal (40 / 48 sites)

  - Sub-optimal (7 / 48 sites)
    - Off midline on VD

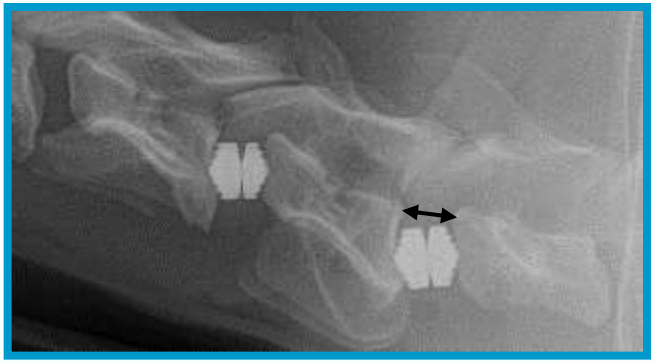


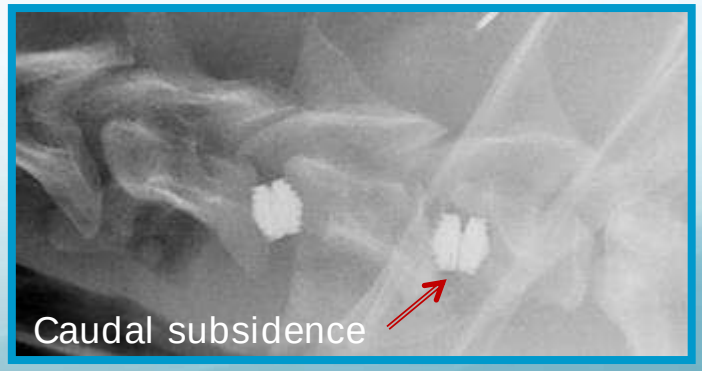
  - Inadequate (1 / 48 sites)
    - Improper technique
      - Excessive burring of caudal endplate
      - immediate subsidence



Immediate Post-op Radiographs

- Distraction:
  - Over-distraction (15/50 sites)
    - Mostly with 1st generation (thicker) implant
  - Adequate distraction (34/50 sites)
    - Mostly with 2nd & 3rd generation (thinner) implant
  - Under-distraction: (1/50 sites)
    - Improper technique
      - Excessive burring of caudal endplate – immediate subsidence





Serial Radiographic Assessment

- Minor Subsidence

  Distraction lost compared to immediate post-op, but maintained when compared to pre-op

  - All sites
    - More pronounced with 1st generation (thicker) implant
    - Less pronounced with 2nd and 3rd generation (thinner) implant

- Severe Subsidence

  Distraction lost compared to pre-op

  - 7/50 sites (14%)

- Ventral Osteophytes
  - 2 sites in one dog

Serial Radiographic Assessment

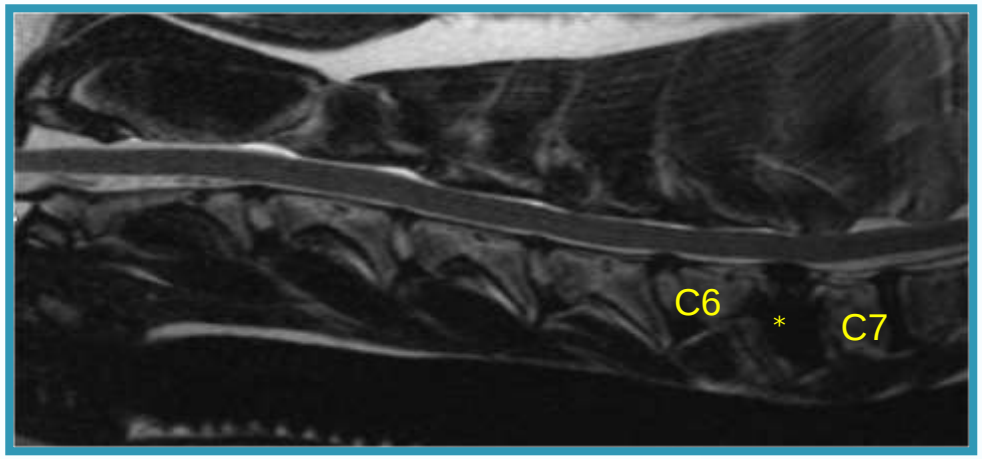
- Mobility
  - Present:
    - at 2 wks post-op in 88% in 24 dogs examined
    - at 6 mo post-op in 23% in 14 dogs examined

♫ In 7 dogs where dynamic study was performed immediately after surgery: mobility although expected was not detectable in 5/10 of the treated spaces

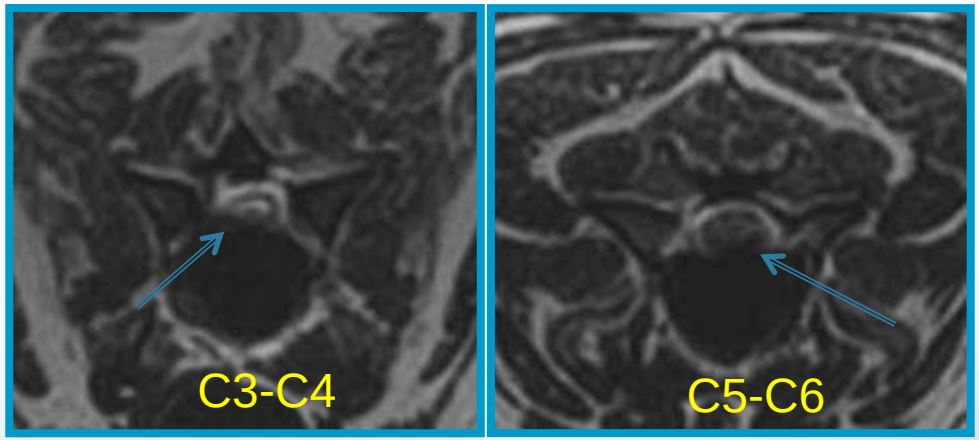
- No Implant migration
- No Implant infection

MRI Re-assessment

- 20-24 mo. post-op (4 dogs)
  - 2 dogs: No signs of disc degeneration or compression at treated and adjacent sites



  - 2 dogs: New osteophites or eterotopic ossification.
    - 1st and 2nd generation implant



- In all dogs the implant **didn't affect the spinal** cord visibility

Clinical Assessment

- Post-op recovery time
  - Immediate in all dogs
  - Neurological status unchanged compared to pre-op status in all dogs

- Post-op hospitalization time *
  - Discharged same day: 5 dogs
  - 1 and 3 days : 25 dogs
  - 4 and 5 days: 2 dogs
    - Based on the severity of the neurological status pre-surgery

Clinical Assessment

Follow-up: Mean 23 mo, (range 2 wks - 42 mo)

- 22 dogs still alive
- 11 dogs deceased
  - 9 for non-neurological diseases
  - 2 euthanasia: insufficient improvement and complications

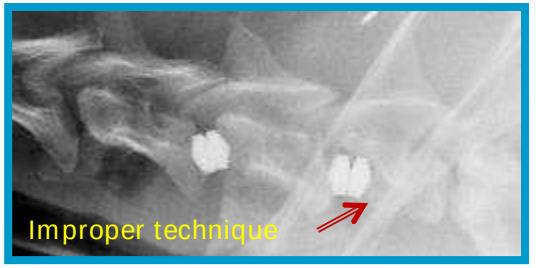
Patient Outcome

- 91% have shown improvement of at least 1+ neurological grade
  - Satisfactory to Excellent: 30 dogs
  - Unsatisfactory: 1 dog
  - Poor: 2 dogs
- No Domino lesions during the observation period
  - Better: mild and short duration of signs on presentation
  - Worse: chronic non-ambulatory paraparesis + extensor rigidity of front legs not resolving under general anesthesia

Complications

- Vertebral fissure fracture during distraction: 2 dogs
  - Improper Caspar pins placement
    - → didn't affect the outcome

- Immediate subsidence: 1 dog
  - Improper technique: over-burring.
    - → improved after surgical revision



- Vertebral fracture with ventral implant displacement: 1 dog
  - Sheltie Mix, F, 12.4 y old, weight 12.2 kg
  - 4 years ambulatory ataxia,
  - 6 month prior to referral non ambulatory tetraparesis with extensor rigidity all 4 legs, not resolving under anesthesia
  - Overdistraction (RDR 3.2; normal > 1.7 and < 2)
    - → euth 2 wks after surgery

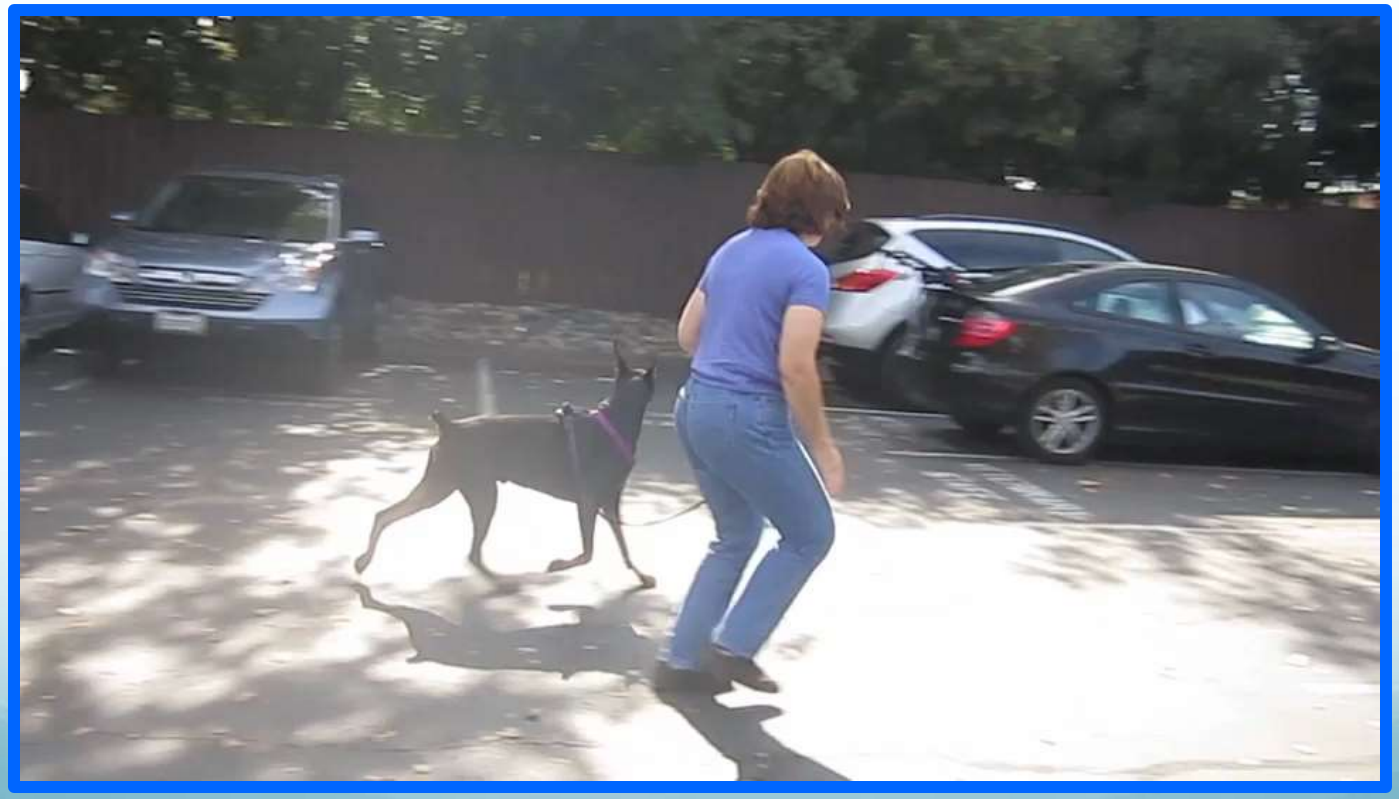
Patch: 6 y old MN Dalmatian

6 mo ataxia/ tetraparesis worsening 2 mo prior to presentation

- **Case study:** Visit: http://youtu.be/evMKCX4UDHg

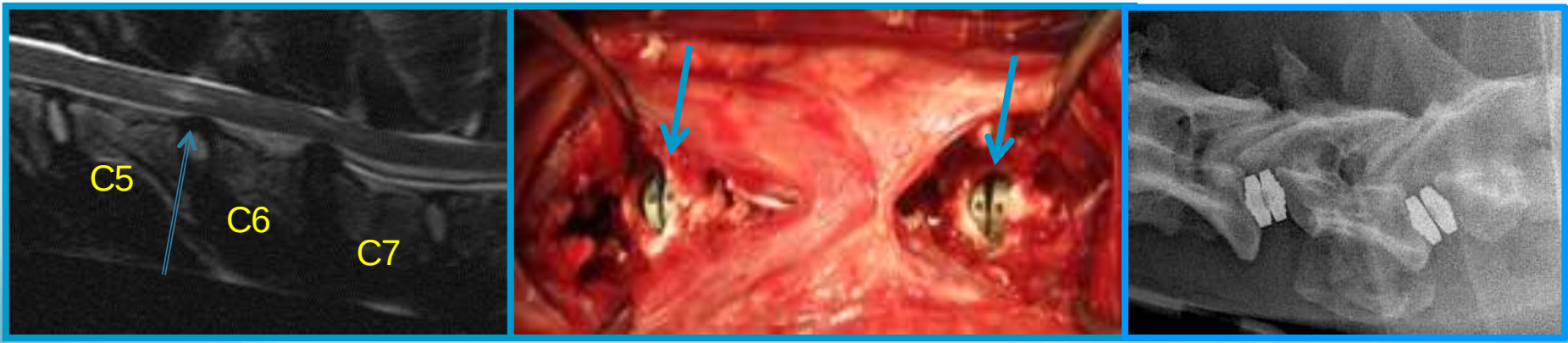
Sonny: 8 y old MN Doberman,
presented with 1y ataxia/ tetraparesis, and acute tetraplegic

6 months post-op Visit:
http://youtu.be/9OPx6tFcKmU



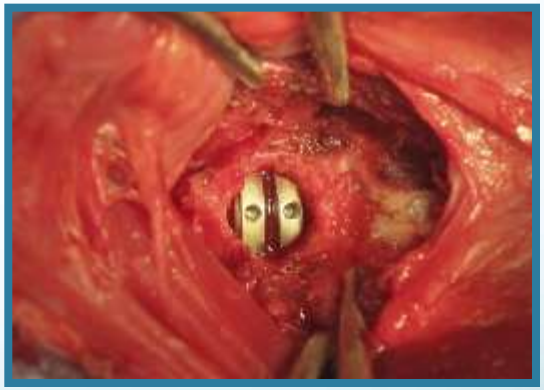
Advantages of CDA

- Less invasive than traditional surgeries
- Rapid post-surgical recovery
- Can be performed on a out-patient basis
- Treatment of multiple lesions at adjacent or non-adjacent sites
- Prophylactically for "Incipient lesions"
- May prevent "Domino lesions"



Conclusions

- CDA using this prosthesis appears to be safe and effective
- Suitable for medium and large breed dogs
- Rapid post-surgical recovery
- Ideal for treating multiple levels
- Not technically difficult and easy to master
- **Dog's owners more prone to pursuing surgery**



As for any other surgery: CEC.: Case selection , Early Intervention and Correct execution of the surgical technique may be critical factors for the outcome

"Case selection is King,
…. technique is the Prince"

- **number 6 of the most commonly cited attributes of a "great" surgeon!**

Dr. Zelman column

Future Directions

- Central Axis of Rotation of the Normal Disc
- Other materials surfaces or coating to promote bone-implant osseo-integration
- Other modules to improve elasticity of the implant which may help to reduce subsidence
- Longer term clinical studies

Acknowledgments

- Colleagues whose cases are represented here
- Pet owners who placed hope and trust in the application of this technology for their dogs

Questions?

Contact:

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Second practical CDA Course

- **December 6, 2014**
  - **Las Vegas, Oquendo Center**