

Kelly A. Van Schouwen (Frank), MS, ACRP-CP

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EXECUTIVE SUMMARY

Research professional with 9 years of experience in spine research. The ability to lead others to obtain successful results on a variety of clinical studies.

EDUCATIONAL BACKGROUND

Master of Science

University of Texas at Austin
Conferred: August 2012
Major Area: Kinesiology
Area of Concentration: Biomechanics

Bachelor of Science

University of Texas at Austin
Conferred: May 2001
Major Area: Architectural Engineering

SKILLS

- Successfully manage multiple clinical trials
- Knowledge of regulatory policies for clinical trials, including FDA, IRB and GCP
- Building long term successful working relationships
- Excellent communication skills, both with the internal team, external team, and with the public
- Background in engineering for data analysis and interpretation
- Accountability to drive a team to meet deadlines

PROFESSIONAL EXPERIENCE

RESEARCH SOURCE, Austin, Texas

Owner/Director of Clinical Research, June 2019-present

Clinical Site/s: Austin Neurosurgeons, Arise Medical Center, Texas Spine Care

SPINE INSTITUTE OF LOUISIANA, Shreveport, Louisiana

Associate Director of Clinical Research, January 2015-June 2019

UNIVERSITY OF TEXAS AT AUSTIN

Lecturer of Biomechanics, Department of Kinesiology, January 2016- May 2017

LDR SPINE

Clinical Research Manager, May 2012-December 2014

UNIVERSITY OF TEXAS

Teaching Assistant, Kinesiology Department, August 2010-August 2012

SPIRE CONSULTING GROUP

Senior Consultant of Construction Services, February 2007- December 2012

CLINICAL TRIALS

An Assessment of P-15L Bone Graft in Transforaminal Lumbar Interbody Fusion with Instrumentation

Safety and Effectiveness of Bio2 Vitrium® Cervical Cage in Anterior Cervical Discectomy and Fusion. A Randomized, Controlled, Non-inferiority, Pivotal Study.

A 2 and 5 year comparative evaluation of clinical outcomes in the treatment of degenerative spinal stenosis with concomitant low back pain by decompression with and without additional stabilization using the coflex® Interlaminar Technology for FDA Real Conditions of Use Study

A Multi-Center, Open-Label Prospective Study of CervicalStim device™ as Adjunctive Treatment following Cervical Fusion

A Multi-Center, Open-Label, Prospective Study of SpinalStim™ (MOP-SS) as Adjunctive Care following Lumbar Fusion Surgery

A Prospective Clinical Evaluation of the Centinel Spine™ STALIF C® No Profile® Integrated Interbody Fusion™ Device

A Prospective, Post Market, Multi-center, Open Label, Non-Randomized Clinical Study of the Efficacy of using Trinity ELITE® in Lumbar Fusion Surgery

The Rampart Duo Clinical (RaDical) Study: An Exempt Minimal Risk Post-Market Evaluation of Clinical Outcomes for a Novel Hybrid Device in Instrumented Lateral Lumbar Interbody Fusion

Prospective, Multi-Center Minimally Invasive Adult Spinal Deformity Outcomes Database Registry

Clinical Study Protocol for the Investigation of the Two Level Simplify Cervical Artificial Disc

A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Staphylococcus Aureus 4-Antigen Vaccine (SA4Ag) In Adults Undergoing Elective Posterior Instrumented Lumbar Spinal Fusion Procedures

A Prospective, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of a Single Injection of rexlemestrocel-L Alone or combined with Hyaluronic Acid (HA) in Subjects with Chronic Discogenic Lumbar Back Pain Through 12 Months

Clinical Study Protocol for the Investigation of the Simplify Cervical Artificial Disc

SCOUT (Spineology Clinical Outcomes Trial) An Investigational Device Exemption Performance Goal Clinical Investigation

Prospective, Concurrently Controlled, Multi-Center Study to Evaluate the Safety and Effectiveness of the Spinal Kinetics™ M6-C Artificial Cervical Disc Compared to Anterior Cervical Discectomy and Fusion (ACDF) for the Treatment of Symptomatic Cervical Radiculopathy

A single-arm, prospective, multi-center study of Nucel® in patients receiving interbody fusion for one and two level degenerative disease of the lumbar spine

Prospective, Multi-Center Minimally Invasive Adult Spinal Deformity Outcomes Database Registry

A Multicenter, Randomized, Double-blind, Controlled, Comparative Study of SI-6603 in Patients with Lumbar Disc Herniation (Phase III)

A Multicenter, Open-label Study of SI-6603 in Patients with Lumbar Disc Herniation (Phase III)

A Multi-Center, Prospective, Randomized, Controlled Clinical Trial Comparing the Safety and Effectiveness of the Mobi-C® Prosthesis to Conventional Anterior Cervical Discectomy and Fusion in the Treatment of Symptomatic Degenerative Disc Disease (DDD) in the Cervical Spine

DATA ANALYSIS AND PUBLICATIONS

Nunley P, **Frank K**, Stone M. Patient Selection in Cervical Disc Arthroplasty. Int J Spine Surgery.2020;12:s2:S29-S35.

Nunley P, Kerr E, Cavanaugh D, Utter PD, Campbell P, Wadhwa R, **Frank K**, Marshall K, Stone M. Adjacent Segment Pathology After Treatment With Cervical Disc Arthroplasty or Anterior Cervical Discectomy and Fusion, Part 1: Radiographic Results at 7-Year Follow-Up. Int J Spine Surgery.2020;14:3:278-285.

Nunley P, Kerr E, Cavanaugh D, Utter PD, Campbell P, Wadhwa R, **Frank K**, Marshall K, Stone M. Adjacent Segment Pathology After Treatment With Cervical Disc Arthroplasty or Anterior Cervical Discectomy and Fusion, Part 2: Clinical Results at 7-Year Follow-Up. Int J Spine Surgery.2020;14:3:278-285.

Campbell PG, Nunley PD, Cavanaugh D, Kerr E, Utter P, **Frank K**, Stone M. Short-term outcomes of lateral lumbar interbody fusion without decompression for the treatment of symptomatic degenerative spondylolisthesis at L4-5. *Neurosurg Focus*. 2018;44:E6

Nunley P, Cavanaugh D, Kerr E, Utter P, Campbell P, **Frank K**, Marshall K, Stone M. Heterotopic Ossification after Cervical Total Disc Replacement at 7 Years - Prevalence, Progression, Clinical Implications, and Risk Factors. *Int J Spine Surg*.2018;12:1-10.

Nunley P, Coric D, **Frank K**, Stone M. Cervical Disc Arthroplasty: Current Evidence and Real World Application. *Neurosurgery*. 2018.

Nunley P, Mundis G, Fessler R, Park P, Zavatsky J, Uribe J, Eastlack R, Chou D, Wang M, Anand N, **Frank K**, Stone M, Kanter A, Shaffrey C, Mummaneni P, ISSG. Impact of case type, length of stay, institution type, and comorbidities on Medicare DRG reimbursement for adult spinal deformity surgery. *Neurosurgical Focus*.2017;43(6): 1-5.

Nunley PD, Kerr EJ, Utter PA, Cavanaugh, D, **Frank K**, Moody D, McManus B, Stone M. Preliminary Results of Bioactive Amniotic Suspension with Allograft for Achieving One and Two-Level Lumbar Interbody Fusion. *Int J Spine Surg*.2016;10:12.

Nunley P, Sandhu F, **Frank K**, Stone M. Neurological Complications after Lateral Transposas Approach to Anterior Interbody Fusion with a Novel Flat-Blade Spine-Fixed Retractor. *Biomed Res Int*. 2016;2016:8450712.

Davis RJ, Nunley PD, Kim KD, Hisey MS, Jackson RJ, Bae HW, Hoffman GA, Gaede SE, Danielson GO 3rd, Gordon C, Stone MB. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. *J Neurosurg Spine*. 2015;22(1):15-25.

Ament JD, Yang Z, Nunley P, Stone MB, Kim KD. Cost-effectiveness of cervical total disc replacement vs fusion for the treatment of 2-level symptomatic degenerative disc disease. *JAMA Surg*. 2014;149(12):1231-9.

Hisey MS, Bae HW, Davis R, Gaede S, Hoffman G, Kim K, Nunley PD, Peterson D, Rashbaum RF, Stokes J, Ohnmeiss DD; Texas Back Institute Research Foundation. Prospective, Randomized Comparison of Cervical Total Disc Replacement versus Anterior Cervical Fusion: Results at 48 Months Follow-up. *J Spinal Disord Tech*. 2015;28(4):E237-243

Hisey, M. S., Bae, H. W., Davis, R., Gaede, S., Hoffman, G., Kim, K., Nunley P.D., Peterson D., Rashbaum R., Stokes J. & Ohnmeiss, D. D. (2014). Multi-center, Prospective, Randomized, Controlled Investigational Device Exemption Clinical Trial Comparing Mobi-C Cervical Artificial Disc to Anterior Discectomy and Fusion in the Treatment of Symptomatic

Degenerative Disc Disease in the Cervical Spine. *International Journal of Spine Surgery*, 8(1), 7-7.

Davis, R., Nunley, P. D., Kim, K., Hisey, M., Bae, H., Hoffman, G., & Gaede, S. (2014). Two-level total disc replacement with Mobi-C® over 3-years. *Coluna/Columna*, 13(2), 97-103.

Davis RJ, Kim KD, Hisey MS, Hoffman GA, Bae HW, Gaede SE, Rashbaum RF, Nunley PD, Peterson DL, Stokes JK. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial: clinical article. *J Neurosurg Spine*. 2013 Nov;19(5):532-45

PRESENTATIONS

Campbell P, Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Treatment of symptomatic degenerative spondylolisthesis at L4/L5 with LLIF without decompression. *Proceedings from the 86th American Association of Neurological Surgeons (AANS) Annual Scientific Meeting*. April 28 - May 2, 2018, New Orleans, LA.

Cavanaugh D, Nunley P, Kerr E, Utter A, Campbell P, **Frank K**, Stone M. Heterotopic Ossification, Is it Clinically Relevant? Clinical Implications and Risk Factors after Cervical Total Disc Replacement at 7-Years. *Proceedings from the 86th American Association of Neurological Surgeons (AANS) Annual Scientific Meeting*. April 28 - May 2, 2018, New Orleans, LA.

Nunley P, Cavanaugh D, Utter A, Kerr E, Campbell P, **Frank K**, Stone M. Current Worldwide Evidence, Application, and Future of Cervical Total Disc Replacement. *Proceedings from the 43rd Louisiana Neurological Society (LANS) Annual Meeting*. January 12-13, 2018, Shreveport, LA.

Campbell P, Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Symptomatic degenerative spondylolisthesis at L4/L5 treated with LLIF without decompression. *Proceedings from the 43rd Louisiana Neurological Society (LANS) Annual Meeting*. January 12-13, 2018, Shreveport, LA.

Utter A, Nunley P, Mundis G, Fessler R, Park P, Zavatsky J, Uribe J, Eastlack R, Chou D, Wang M, Anand N, **Frank K**, Stone M, Kanter A, Shaffrey A, Mummaneni P. Medicare DRG Reimbursement for Adult Spinal Deformity Surgery--The Impact of Case Type, Length of Stay, Institution Type, and Comorbidities *Proceedings from the 43rd Louisiana Neurological Society (LANS) Annual Meeting*. January 12-13, 2018, Shreveport, LA.

Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Prevalence, Progression, and Clinical Implications of Heterotopic Ossification after Cervical Disc Arthroplasty at 7 Years. *Proceedings from the 17th International Society for the Advancement of Spine Surgery (ISASS) Annual Conference*. April 12-15, 2017, Boca Raton, FL.

Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Radiographic adjacent segment pathology following treatment with CDA or ACDF at one or two levels: a prospective, randomized, controlled FDA clinical trial at seven years. *Proceedings from the 17th International Society for the Advancement of Spine Surgery (ISASS) Annual Conference*. April 12-15, 2017, Boca Raton, FL.

Cavanaugh D, Nunley P, Kerr E, Utter A, **Frank K**, Stone M. Seven-Year Follow-Up of One-Level vs Two-Level Treatment with Cervical Disc Arthroplasty and Anterior Cervical Discectomy and Fusion. *Proceedings from the 30th Annual Neurosurgery in the Rockies Annual Meeting*. February 26-March 2, 2017, Beaver Creek, CO.

Nunley P, Cavanaugh D, Utter A, Kerr E, **Frank K**, Stone M. Seven-Year Follow-up of One-Level vs. Two-Level Treatment with Cervical Disc Arthroplasty and Anterior Cervical Discectomy and Fusion. *Proceedings from the North American Spine Society (NASS) Annual Spine Summit*. February 23-25, 2017, Park City, UT.

Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Radiographic Adjacent Segment Pathology after Treatment with CDA or ACDF at One or Two Levels at Seven-Years. *Proceedings from the North American Spine Society (NASS) Annual Spine Summit*. February 23-25, 2017, Park City, UT.

Cavanaugh D, Nunley P, Kerr E, Utter A, **Frank K**, Stone M. Seven-Year Clinical Results from an FDA Clinical Trial of Single and Multilevel Treatment of Cervical Degenerative Disc Disease: Cervical Disc Replacement versus ACDF. *Proceedings from the 42nd Louisiana Neurological Society (LANS) Annual Meeting*. January 13-14, 2017, New Orleans, LA.

Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Cervical Disc Replacement versus ACDF for Single and Multilevel Treatment of Cervical Degenerative Disc Disease: Seven-Year Clinical results from an FDA Clinical Trial. *Proceedings from the 42nd Louisiana Neurological Society (LANS) Annual Meeting*. January 13-14, 2017, New Orleans, LA.

Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Cervical Disc Replacement vs ACDF for Single and Multilevel Treatment of Cervical Degenerative Disc Disease: Seven-Year clinical Results from a FDA Clinical Trial. *Proceedings from the 44th Cervical Spine Research Society (CSRS) Annual Meeting*. November 29 – December 2, 2016, Toronto, Ontario.

Nunley P, Cavanaugh D, Utter A, Kerr E, **Frank K**, Stone M. Clinical Implications of Heterotopic Ossification After Cervical Disc Arthroplasty At 7 Years. *Proceedings from the 44th Cervical Spine Research Society (CSRS) Annual Meeting*. November 29 – December 2, 2016, Toronto, Ontario

Nunley P, Kerr E, Cavanaugh D, Utter A, **Frank K**, Stone M. Prevalence, Progression, and Clinical Implications of Heterotopic Ossification after Cervical Disc Arthroplasty at 7

Years. *Proceedings from the 31st North American Spine Society (NASS) Annual Meeting*. October 26-29, 2016, Boston, MA.

Nunley P, Kerr E, Cavanaugh D, Utter A, **Frank K**, Stone M. Seven-Year Radiographic Adjacent Segment Pathology after Treatment with TDR or ACDF at One or Two Levels. *Proceedings from the 31st North American Spine Society (NASS) Annual Meeting*. October 26-29, 2016, Boston, MA.

Utter A, Nunley P, Cavanaugh D, Kerr E, **Frank K**, Stone M. One-Level and Two-level Treatments for Degenerative Disc Disease: Cervical Disc Arthroplasty and Anterior Cervical Discectomy and Fusion. *Proceedings from the 16th European Congress of Neurosurgery (EANS) Annual Meeting*. September 4-8, 2016, Athens, Greece.

Utter A, Nunley P, Cavanaugh D, Kerr E, **Frank K**, Stone M. Radiographic Adjacent Segment Pathology after Treatment with CDA or ACDF at One or Two Levels. *Proceedings from the 16th European Congress of Neurosurgery (EANS) Annual Meeting*. September 4-8, 2016, Athens, Greece.

Cavanaugh D, Nunley P, Kerr E, Utter A, **Frank K**, Stone M. Comparison of One-Level and Two-Level treatments for Cervical Disc Arthroplasty and Anterior Cervical Discectomy and Fusion. *Proceedings from the 84th American Association of Neurological Surgeons (AANS) Annual Scientific Meeting*. April 30-May 4, 2016, Chicago, IL.

Cavanaugh D, Nunley P, Kerr E, Utter A, **Frank K**, Stone M. Preoperative Predictors of Patient Outcomes at 60 Months Following Single Level Cervical Surgery with CDA or ACDF. *Proceedings from the 84th American Association of Neurological Surgeons (AANS) Annual Scientific Meeting*, April 30-May 4, 2016, Chicago, IL.

Nunley P, Small J, **Frank K**, Stone M. Spine Surgeons' Perceptions of the Incidence and Impact of Third Party Payers' Delay or Denial of Coverage in the Pre-Authorization of Surgical Procedures and Subsequent Payment. *Proceedings from 16th International Society for the Advancement of Spine Surgery (ISASS) Annual Meeting*. April 6-8, 2016, Las Vegas, NV.

Nunley P, Kerr E, Cavanaugh D, Utter A, **Frank K**, Stone M. Factors Predictive of Return to Work Time after Cervical Disc Arthroplasty and ACDF: A Multivariable Analysis. *Proceedings from 16th International Society for the Advancement of Spine Surgery (ISASS) Annual Meeting*. April 6-8, 2016, Las Vegas, NV.

Nunley P, Kerr E, Cavanaugh D, Utter A, **Frank K**, Stone M. SF-12 PCS and VAS Neck as Preoperative Predictors of Patient Success at 60 Months Following Single Level Cervical Surgery with TDR or ACDF. *Proceedings from 16th International Society for the Advancement of Spine Surgery (ISASS) Annual Meeting*. April 6-8, 2016, Las Vegas, NV.

Cavanaugh D, Nunley P, Kerr E, Utter A, **Frank K**, Stone M. Comparison of One-Level and Two-Level treatments for Cervical Disc Arthroplasty and Anterior Cervical Discectomy and

Fusion. *Proceedings from the 67th Southern Neurosurgical Society (SNS) Annual Meeting*. March 2-5, 2016, San Antonio, Texas.

Cavanaugh D, Nunley P, Kerr E, Utter A, **Frank K**, Stone M. One-Level versus Two-Level treatments for Cervical Degenerative Disc Disease using Cervical Disc Arthroplasty and Anterior Cervical Discectomy and Fusion. *Proceedings from the 41st Louisiana Neurosurgical Society (LANS) Annual Meeting*. January 15-17, 2016, New Orleans, LA.

Nunley P, Cavanaugh D, Kerr E, Utter A, **Frank K**, Stone M. Heterotopic Ossification and Endplate Coverage in One-Level CDA Patients. *Proceedings from the 30th North American Spine Society (NASS) Annual Meeting*. October 14-17, 2015, Chicago, IL.