

## The role of infection in pseudoarthrosis

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| <b>University:</b> University of California San Francisco  |   |
| <b>PI and Co-PI name(s):</b> Sigurd Berven   | <b>Proposed Budget:</b><br>(includes 10% indirects): 39,600 |
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| <b>CDMI trainee name:</b> Daniel Beckerman   | <b>CDMI trainee title:</b> CRC                              |
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| <p><b>Need and Industrial Relevance:</b> Infection and pseudoarthrosis are widely understood to be common causes of revision surgery for the treatment of spinal pathologies. While patients who require revision surgery can still gain statistically relevant and clinically important improvements in their health status, it has been demonstrated in the literature that achieve worse outcomes than the subset of patients who do not require revision surgery. Furthermore, the financial impact of revision surgery can be burdensome – with the potential to meet or exceed the cost of a patient’s index operation. An article published by Theologis et al. demonstrated a 3.2 million dollar total direct cost for the revision of 57 consecutive thoracolumbar fusion surgeries.</p> <p>In light of this, much of clinical research in spine surgery has been focused on mitigating the need for early revision surgery. While infection and pseudoarthrosis rates are frequently discussed in outcomes based spine surgery literature, the role of infection as an etiology of pseudoarthrosis has not yet been described. The purpose of this study is to identify the prevalence of occult and overt infection as an etiology of pseudoarthrosis, and to define approaches to avoid infection-related pseudoarthrosis.</p> |   |
| <p><b>Project Aims (including Hypotheses):</b></p> <p>Aims:</p> <ol style="list-style-type: none"> <li>1. To define the role of infection in pseudoarthrosis</li> <li>2. To categorize predictors of both pseudoarthrosis and infection in spinal surgery as a whole and across specific etiologies of spinal disease</li> </ol> <p>Hypotheses:</p> <ol style="list-style-type: none"> <li>1. Infection plays a large role in pseudoarthrosis</li> <li>2. There are specific predictors of infection and pseudoarthrosis that can allow us to better anticipate/prevent the occurrence of adverse events in spine surgery.</li> </ol>  |   |
| <p><b>Methods:</b> Retrospective study of consecutive cases treated with revision surgery for the diagnosis of pseudoarthrosis</p> <ol style="list-style-type: none"> <li>1. A query of administrative and medical ontologies will be conducted to identify a consecutive series of revision surgeries with an associated diagnosis of pseudoarthrosis</li> </ol>  |   |

2. A chart review will be conducted to review intraoperative cultures to determine the prevalence of infection, and the microbiology in affected cases.
3. Predictor variables such as age, demographics, and comorbidities will be assessed to determine their predictive effect for the incidences of both infection and pseudoarthrosis.
4. A comparative analysis will be conducted to assess the financial burden of treating pseudoarthrosis secondary to infection vs. treating pseudoarthrosis as a primary dx.

**Milestones:**

- Obtain IRB Approval – Nov 30, 2016
- Finish cohort identification– Dec 31, 2016
- Finish collecting all data – July 31, 2017
- Finish data analysis – August 31, 2017

**Deliverables (must include):**

*Quarterly presentation updates:*

- *December 2016 – conference call*
- *Spring 2017 – Spring Symposium @ UT (conference call option for non-UT teams)*
- *June 2017 – conference call*
- *September 2017 – Fall Symposium @ UCSF (conference call option for non-UCSF teams)*

*Final written report including results - October 31, 2017*

*Specific work product (e.g. protocols, material, device, database)*

**General Budget Outline:**

Example:

|                      |    |        |
|----------------------|----|--------|
| Personnel            | \$ | 33,000 |
| Statistical Analysis | \$ | 3,000  |
| <hr/>                |    |        |
| Total Direct         | \$ | 36,000 |
| Indirects (10%)      | \$ | 3,600  |
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| Total                | \$ | 39,600 |

**Start Date:**

October 15, 2016

**End Date:**

Nov 15, 2017