

Ankle arthrodesis versus arthroplasty

Dr Bruce Sangeorzan is developing a novel research programme that aims to improve function and minimise pain experienced by patients following operations for end-stage ankle arthritis



Could you outline the background and goals of your research?

We are aiming to compare the functional outcomes of ankle arthrodesis and ankle arthroplasty as treatment options for end-stage ankle arthritis. Traditionally, ankle arthritis has been treated with bracing, cheilectomy (a surgical 'clean-up' of the joint), and realignment in its early stages. When the joint was no longer functional, ankle arthrodesis used to be the only option. However, there has since been an improvement in materials and understanding based on results from hip and knee replacements.

I began doing ankle replacement surgery in the 1990s for select patients who were not good candidates for ankle arthrodesis. As more ankle replacements became available for use in the US, their potential applications increased. The goal of this project is to determine by way of direct comparison the patient satisfaction and functional outcomes of the two treatments in matched populations.

Can you explain the difference between ankle arthrodesis and arthroplasty?

Both of these treatment options relieve pain caused by the arthritic ankle joint. Arthrodesis removes the joint itself as it bonds the talus and tibia together. When the joint and the motion are gone, the pain is gone. In contrast, arthroplasty works by removing the arthritic joint surfaces of the tibia and the talus, replacing them with metal components and then placing a plastic bearing surface between them. There is no longer any contact between the arthritic surfaces and pain is improved.

What do you hope will be the main benefits to patients following this research?

Improving function and relieving pain is what orthopaedic care is all about. This is a clinical trial with readily apparent translational value. We hope this research will identify strengths and weaknesses of each treatment that can be applied in patient and physician decision-making algorithms.

How did you come to join the VA Hospital Center of Excellence for Limb Loss Prevention and Prosthetic Engineering?

When I joined the faculty at the University of Washington, Drs Sigvard T Hansen and Ernest Burgess asked me to manage the amputee service at the VA Hospital. I had partnered with a mechanical engineer at the University by the name of Alan Tensor to investigate the mechanics of the lower leg and the ways in which trauma adversely affected those mechanics; we had received funding through the US Department of Veterans Affairs to study limb mechanics. When the VA determined it needed more medical evidence to manage patients with impending limb loss, the skillsets that we had developed together provided a good backdrop to answer the questions posed by the Veterans Administration.

Joseph Czerniecki, MD, a physical medicine and rehabilitation specialist with expertise in the rehabilitation of patients with limb loss, had been my co-director of the amputee care service. Along with Gayle Reiber, PhD, we formed a core investigator group to compete for funding at the VA Center.

How did you recruit for the project?

The cohort size was determined using pilot data from a prospective comparison funded by the Department of Veterans Affairs. The differences in outcome are relatively small so

we needed a large cohort to answer questions of effectiveness. The study is a little more than a year into active enrolment. We've enrolled about 150 patients in the first year of this National Institutes of Health (NIH) trial, and hope to enrol another ~400 patients. Along with approximately 300 patients from our pilot study, we think we will have adequate data to determine the patient self-reported outcomes in a valid way.

Other key collaborators for the NIH project come from five active participating clinical sites: Dr Michael Brage from the University of Washington; Dr Chris Coetzee from Twin Cities Orthopedics; Dr Michael Houghton from Orthopaedic and Spine Center of the Rockies; Dr Jim Davitt from Orthopedic and Fracture Specialists; and Drs Don Bohay, John Anderson and John Maskill from Orthopaedic Associates of Michigan.

What is next for the research?

We hope to follow our cohort longer than three years, as we estimate that enrolling sufficient patients to determine a difference would take about two and half years. While this particular research award only covers five years, we feel there will be great value in extending the award to follow the patients up to eight to 10 years. This is the traditional time when a joint replacement begins to break down. The value and cost-effectiveness of the treatment options will be clearer with a longer follow-up.



Step by step

A multi-centre research initiative led by the VA Center of Excellence for Limb Loss Prevention and Prosthetic Engineering is helping US Veterans to rebuild their lives and independence following loss of limbs or limb function

A STUDY BY the US Congressional Research Service reported that between 2001 and 2010, 1,126 US Veterans experienced major limb loss due to injuries sustained during combat. For those Veterans who underwent lower limb amputation surgery, or for those who are still at risk, the VA Center of Excellence for Limb Loss Prevention and Prosthetic Engineering is a vital source of hope and rehabilitation. At the heart of the Center's mission is its aim to improve the quality of life of Veterans at risk of lower extremity amputation, through a variety of means: quantitative comparison of different treatment options for foot deformities that can lead to loss of limb function; insight into the pathomechanics of diabetic foot ulcer formation; development of pioneering new prostheses; and the creation of novel research tools that can be employed in a wide range of clinical studies.

Center Director Dr Bruce Sangeorzan has been working in the field of ankle osteoarthritis since the early 1990s and is only too familiar with the agony suffered by so many Veterans, often under traumatic circumstances: "Although injury and arthritis contribute less than many other afflictions to mortality, they contribute more to disability," he comments. "In particular, the number of years for which people are affected are very high for trauma because it affects younger people. I believe that both arthritis and trauma rank in the top 10 for impact on the American population."

THE NEED FOR ACTION

It is apparent to researchers working alongside Dr Sangeorzan that US military action in the Middle East region has greatly heightened the VA's need for advanced expertise in limb injury, limb loss and improved prosthetic components, and a range of innovative research programmes has been developed in response. As well as catering for the young combat-injured Veterans from Operation Iraqi Freedom (OIF)

and Operation Enduring Freedom (OEF), the Center also helps many Veterans of the Vietnam War and other armed conflicts spanning many decades. With this in mind, they have been able to develop strategies to analyse and compare the frequency of treatable conditions in these populations from different age groups and how patients variously respond to the available therapies and/or prosthetic solutions.

The breadth of research conducted by Dr Sangeorzan's group is such that they necessarily recruit experts from a diverse set of medical backgrounds. The investigative team includes orthopaedic surgeons, physiatrists, engineers, psychologists, human motion biomechanists, foot/ankle biomechanists, epidemiologists and prosthetists, all of whom work with collaboration in mind. The three focal areas under exploration at the Center are limb loss prevention, prosthetic engineering and translational research, each of which has its own unique challenges requiring state-of-the-art solutions.

AREAS OF EXPERTISE

Limb loss prevention research – this tranche of study aims to reduce functional and anatomical limb loss by exploring the disease processes that lead to aberrant limb function and by developing novel technologies for studying the foot. Scientists investigate Veterans who have particular musculoskeletal impairment of the foot and ankle which causes them significant pain and restricts mobility. They also look at those Veterans at risk of amputation caused by diabetes and foot ulceration.

Prosthetic engineering research – this area is producing some of the most exciting and life-changing results for lower limb amputees of all age ranges, from the young, active Veterans of OIF and OEF to the ageing Vietnam Veteran. These studies not only aim to improve the functionality of prosthetics but also to enhance standards of care and thereby vastly improve the experience of the prosthetic user. Under Dr Sangeorzan's direction, the Center is currently testing a system which can make use of electrical activation signals from residual muscles without the need for surgical intervention: "This system has the ability to detect user objectives, such as walking on level ground

and up and down stairs, with over 98 per cent accuracy,” he reveals. Another study looking at sweat production inside the prosthesis has tested a Dynamic Air Exchange Prosthesis that provides evaporative cooling inside the prosthesis and enables the expulsion of sweat. “This system could have far-reaching effects on comfort for users, and dramatically increase the ability of amputees to exercise without the need to remove their prosthetic limbs to empty the build-up of sweat,” enthuses Dr Sangeorzan.

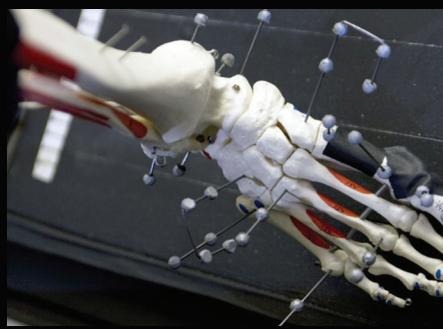
Translational research – the Center bases its translational approach on a conceptual biopsychosocial framework. “This model recognises that outcome is ultimately related to amputees’ medical status and associated co-morbidities, as well as their psychological status and the social environment in which they live and function,” Dr Sangeorzan elucidates. For example, alongside the development of learning strategies that prosthetic users can adopt to help them train with their new limb, one area of research is looking to reduce the incidence of depression following amputation by engaging patients more closely in their own medical care. Moreover, the emphasis on combining translational research with advances in limb loss prevention and prosthetic engineering provides a holistic approach to patient care that greatly enhances outcomes for Veteran amputees.

ARTHRODESIS VERSUS ARTHROPLASTY RESEARCH

Dr Sangeorzan’s cutting-edge research on arthrodesis and arthroplasty for end-stage ankle arthritis is making exciting progress in limb loss prevention. The comparison between arthrodesis – traditionally considered the ‘gold standard’ of treatment – and arthroplasty has provided vital insight into the efficacy of each option in terms of both physical and psychological gains.

In preliminary analysis from Dr Sangeorzan’s VA-funded pilot study, 269 arthrodesis and arthroplasty patients were followed both during their surgery and throughout their post-operative recovery for up to 36 months, to determine if there was any significant difference in the recovery rates or experiences of patients. They were examined at regular intervals, completing Musculoskeletal Functional Assessments (MFA) and SF-36 Health Assessments at each stage, while their activity levels were assessed using StepWatch3™ Activity Monitors which recorded step activity across a 14-day period.

“Average step activity at a high activity level (>40 steps per minute) significantly increased across the overall study period with the greatest average change of 424 bilateral steps occurring between baseline and 12 months,” reflects Dr Sangeorzan. “Sustained activity measures generated by the StepWatch™ software revealed significant improvement from baseline to 12, 24 and 36 months. Neither surgery significantly improved the total number of daily steps over the course of the study. Self-reported function did not differ by surgery type. However, MFA scores decreased strongly for arthrodesis



Top: foot markers on a model used for gait simulation in laboratory testing. **Bottom:** front and side images of an ankle joint replacement.

and arthroplasty across all follow-up periods, indicating increased function.”

Data revealed dramatic improvements in both ankle arthrodesis and arthroplasty, and the data were used to formulate the power analysis for the prospective trial comparing the two treatments, which is funded by the National Institute for Arthritis and Musculoskeletal and Skin Diseases.

RESULTS

In addition to the physical benefits described by increased step activity in both arthrodesis and arthroplasty patients, Dr Sangeorzan was able to identify some pre-operative baseline differences between patients undergoing arthrodesis and arthroplasty. He believes identifying pre-operative functional differences could enhance surgical decision making and aid in the assessment of post-surgical treatment efficacy.

Findings from the ongoing study indicate self-reported pain reduction and improved gait function after surgery for both treatments. Additionally, Dr Sangeorzan and his colleagues learned that the raw numbers of step counts were not particularly useful in determining differences in activity, but further analysis is needed to look at specific sustained activity measurements generated by the StepWatch™. Moving forward, his team has a better idea of how to analyse the activity variables and look for specific benefits from treatment. They continue to follow patients in the VA-funded study through a three-year follow-up and have plans for further data analysis at the conclusion of the study, while continuing his research through the National Institutes of Health-funded trial. This knowledge will be invaluable in the treatment of related conditions and looks set to help significantly improve the lives of patients for years to come.

INTELLIGENCE

COMPARING ANKLE ARTHRODESIS TO ANKLE ARTHROPLASTY

OBJECTIVES

To conduct a randomised controlled trial (RCT) with a back door for patient preference enrolment comparing ankle arthroplasty to ankle arthrodesis for treatment of end-stage ankle arthritis. The project will compare subjects’ pain, mobility and general health before and after each surgery, and will also determine whether certain patient characteristics are associated with more successful outcomes.

KEY COLLABORATORS

VA Center of Excellence for Limb Loss Prevention and Prosthetic Engineering, Seattle, WA • Harborview Medical Center, UW Medicine, Seattle, WA • Orthopedic and Fracture Specialists, Portland, OR • Twin Cities Orthopedics, Minneapolis, MN • Orthopaedic Associates of Michigan, Grand Rapids, MI • Orthopaedic and Spine Center of the Rockies, Fort Collins, CO

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