ISSN 2473-0963

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY

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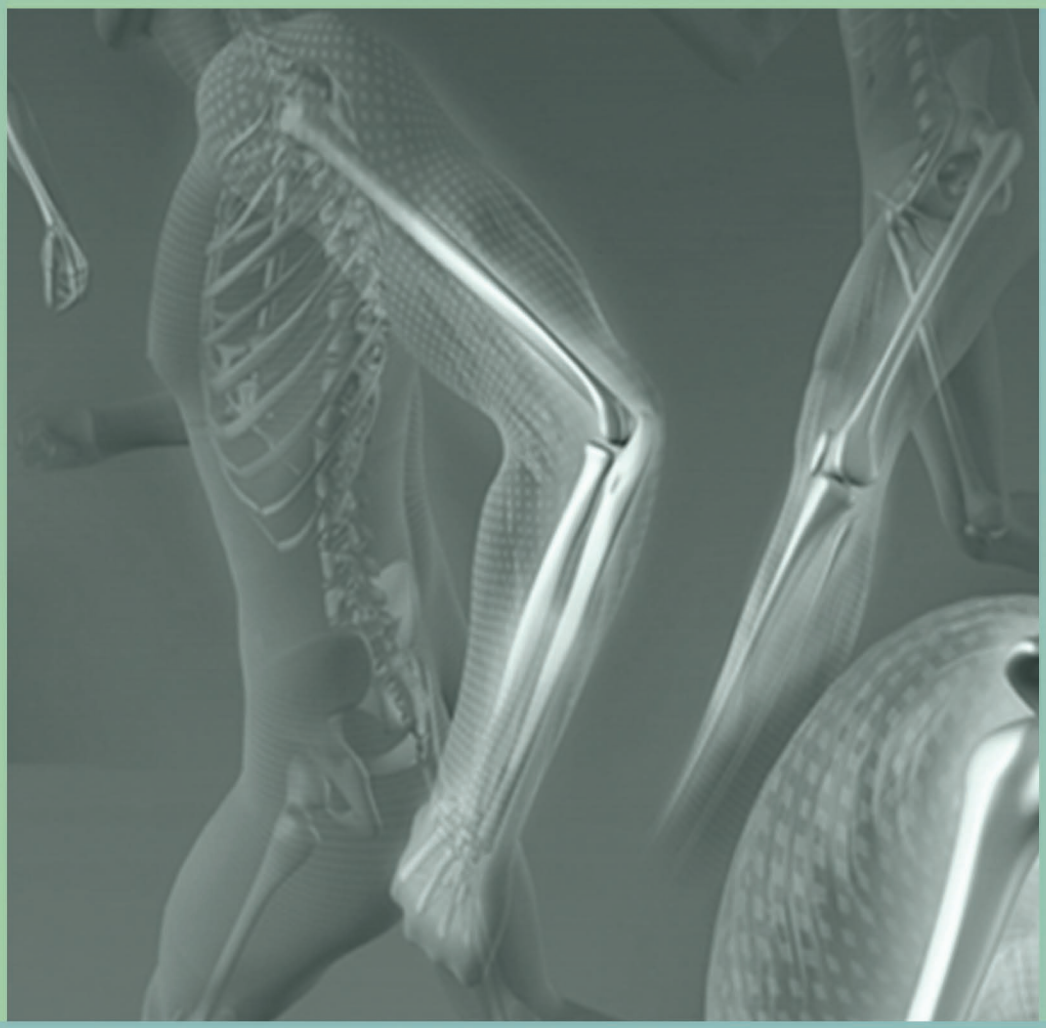

| May 2016 | Volume 1 | Issue 1 |

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ISSN 2473-0963

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-e001

Editorial

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Volume 1 : Issue 1
Article Ref. #: 1000ORTOJ1e001

Article History
Received: November 16th, 2015
Accepted: November 23rd, 2015
Published: November 24th, 2015

Citation
Gomez JA, Vitale MG, Lenke L. Coaching orthopaedic surgeons: can visiting professors be a valuable surgical coach? *Orthop Res Traumatol Open J*. 2015; 1(1): e1-e4. doi: 10.17140/ORTOJ-1-e001

Coaching Orthopaedic Surgeons: Can Visiting Professors be a Valuable Surgical Coach?

Jaime A. Gomez[1*], Michael G. Vitale[2] and Lawrence Lenke[2]

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Much has been discussed about coaching on different fields and medical training has not been left aside. Atul Gawande's article in *The New Yorker* back in 2002 was an eye opener for many regarding the fact that surgeons need and should be constantly coached.[1] Now-a-days, more than in the past surgeon's performance is being scrutinized and attempts to measure surgical skills have been in the cross hairs of public health entities.

Little has been said about coaching in the orthopaedic field, and although orthopaedic surgeon's clinical activities may include coaching on a daily basis we have to be aware of it and steps to improve and better characterize it should be undertaken by the academic as well as the non-academic orthopaedic surgeon. Just like every professional athlete uses a coach to carry and maintain them at the most proficient level possible within their discipline, surgeons should take this into consideration. Data supporting coaching in other areas is mainly based on expert's recommendation but on the field of education several randomized trials have demonstrated the importance and beneficial effects of coaching.[2]

These educational trials have demonstrated that the quality of a teacher has the biggest impact in how much students can learn and other variables such as class size or types of testing are not as influential in the ability to learn.[1] In an educational trial authors gave verbal instructions to a group of teachers and found that only 10% of teachers used the new skill. After modeling, practice, and feedback were added, the rate of adoption of the new skill by the teachers increased to 19%. But after the addition of peer coaching an astounding 95% of teachers utilized the new skill.[3]

We know coaching is important and much has also been written about the characteristics of a coach. "Partnership learning" is a termed coined by Jim Knight who has published remarkable papers on coaching. The idea is to provide "objective and constructive feedback on what he or she observes, helping the practitioner to recognize what is successful and what can be improved. Coaches do not judge or instruct; instead, they guide and facilitate. They act as collaborators and partners to assist practitioners to develop a better understanding of their own performance, and they help them to use their experience, knowledge, and abilities to provide the best care possible."[4] Knight has suggested that this approach is significantly more beneficial compared to the most traditional professional education/training seen in medicine denominated "dominator approach" (i.e. an expert giving a slideshow presentation to a group).[5]

Application of lessons learned elsewhere have been applied to medical coaching. Learning principals can be applied to medical training and, thus, to the development and improvement of surgical skills. Boonyasai, et al.[6] listed those principals in their 2007 publication which can be adapted to surgical training:

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- Enabling surgeon (trainee) to be an active participant.
- Providing content relating to the surgeon's current experiences.
- Assessing surgeon's needs and tailoring teaching to their past experience.
- Allowing surgeons to identify and pursue their own learning goals.
- Allowing surgeons to practice their learning.
- Supporting surgeons during self-directed learning.
- Providing feedback to surgeons.
- Facilitating surgeon's self-reflection.
- Role-modeling behaviors.

Recently at a children's hospital in New York a very interesting and rewarding coaching experience was conducted. This experience sparked the idea of writing this article in an attempt to bring more attention towards coaching of orthopaedic surgeons. Because we believe as other authors have pointed out that coaching can be valuable for surgeons at all stages of their career.[7] Dr. Lawrence Lenkea world leader in spinal deformity visited New York and accompanied a surgical team to the operating room for an observation/coaching initiative during a posterior spinal fusion for adolescent idiopathic scoliosis. The case was uneventful and during the procedure Dr. Lenke observed closely details including: positioning, surgical prepping, approach technique, instrumentation as well as correction maneuvers performed by Dr. Vitale and Dr. Gomez. After the procedure was completed Dr. Lenke went over his observations with the surgical team and wrote his raw comments, which were as follows:

- Smoke evacuator needed during exposure, as bovie smoke is toxic.
- X-ray verification – perform earlier in case as at least 10 times the levels were "counted" during exposure as uncertainty existed – limits excessive prox/distal dissection knowing proper levels as early as possible and less time trying to sort out.
- Continued exposure – consider curetting of posterior elements at end of exposure to finalize cleaning of bony elements and then avoid repetitive cleaning through rest of case.
- Not palpating medial wall – appeared that sounding probe was mainly feeling floor, with more challenging pedicles, careful medial wall palpation would be advisable.
- Suction crossing over hands – right-handed surgeon – left hand sucker. So may want to keep a 2nd sucker/tip at top of sterile field that the operating surgeon can easily grab with his left hand while holding other instruments simultaneously in right hand.
- 22 min spent on right T12 apical screw – discussed potential use of K-wires with cannulated taps to help salvage initial pedicle breaches.
- During fluoro-imaging, consider using one sheet to cover wound while cutting a small hole for imaging markers to be exposed through hole. Then just cut the drape longitudinally and let fall off either end when done. Keeps center of sterile field safer.
- Hard to crossover wound to place concave apical screw. Need to trust co-surgeon and assist by pulling up with a right angle clamp as we discussed as the steep angle is hard to maintain from the other side and the screw will routinely skive lateral.
- Overall nice derotation mechanism but trust distal lock of rod once appropriate Sagittal alignment of rod is achieved so the alignment of the rod isn't loosened again after the derotation. In larger curves, consider holding derotation until both rods seated.
- Overall great work – thanks for letting me observe!

As evidenced by Dr. Lenke's thoughtful comments and coaching qualities, we believe that coaching on the medical field is imperative. Dr. Lenke's comments were discussed within the group and since that coaching session many of his points were well taken and now routinely used during scoliosis cases.

Specifically within orthopaedic surgery the coach must be an experienced surgeon. The coaching surgeon must have a trusting relationship with the "mentee". The relationship must be flexible, thoughtful, respectful and constructive comments and feedback must always be present. In other areas such as consulting, the idea of an 'internal coach" within the organization has been proposed.[8] But in the medical field this should be seen differently, as previously proposed by Greenberg:[9] "coaches should not have administrative oversight for the surgeon they are coaching. This is to ensure that the content of coaching sessions remain focused on performance improvement and not on performance evaluations or career development." And this was clearly of great significance

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-e001

with our coaching experience.

Coaching can refine an orthopaedic surgeons' technical skill as well as enhance his intra-operative decision-making. As previously proposed in the education field cornerstone fundamentals to perform good coaching include: equality, choice, voice & dialogue, reflection and praxis.[10] Translating these fundamentals to the operating room, we've generated the following coaching guidelines.

- Allowing the "mentee" surgeon to choose voluntarily a case and setting of the session will generate a comfortable workspace for both surgeon and coach.
- The mentee should speak freely and feel comfortable about questioning the coach's comments. Assuring that the coach does not have direct administrative or practice relation with the mentee supports this issue.
- Intra-operative comments might distract and be deleterious for the coaching session and could be distractful for the surgeon. Contrary to that, we believe, as others that post-surgical reflection can be safer and likely more effective.
- Privacy and confidentiality are paramount as well.
- Surgeon's insight is another important fundamental; the mentee must be allowed to apply coaching suggestions on his own way and obviously depending on the resources available to him.

Within different orthopaedic societies large interest has now been placed on surgical training and simulation such as during the International Pediatric Orthopaedic Society (IPOS) "Top Gun Competition". We believe that including coaching within these efforts is of major significance. Some efforts on demonstrating the importance of coaching have been published within the surgical[11] and orthopaedic literature, such as a cervical spine instrumentation study that demonstrated that coached residents had significant decreases in short-term technique error rates compared to non-coached residents.[12] The American Academy of Pediatrics (AAP) in the area of Attention Deficit Hyperactivity Disorder (ADHD)[13] and other groups have found positive results after including team coaching as part of their quality improvement initiatives. We believe that a very efficient way of instituting and achieving surgical coaching sessions could be to utilize visiting professors such as in our case example, as coaches. In our orthopaedic academic environment it is not uncommon to have a visiting professor for Grand Rounds on a weekly basis and reports have demonstrated their effectiveness.[14] We believe this is a tremendous opportunity for a coaching program to be instituted. Currently efforts to achieve this in a constant manner are being attempted at our institution.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-e002

Editorial

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Volume 1 : Issue 1
Article Ref. #: 1000ORTOJ1e002

Article History
Received: November 13th, 2015
Accepted: November 27th, 2015
Published: November 27th, 2015

Citation
Shaheen S. What can we expect from the ORTOJ? *Orthop Res Traumatol Open J*. 2015; 1(1): e5-e6. doi: 10.17140/ORTOJ-1-e002

What can we expect from the ORTOJ?

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The ORTOJ is being launched at a time when many of the existing journals publish articles relevant either to the developed world or the developing world. Thus a journal that addresses both worlds is much needed.

Indeed ORTOJ, with its wide vision, will be able to address all aspects of orthopedics and trauma, satisfying the interest of readers around the globe. We are aware that, different areas of the globe differ in their disease makeup, health care levels and systems. Although these differences apply for health disciplines in general, they are more obvious in orthopedics and trauma in particular. For instance in many areas in the developing world, Sudan as an example, seeing and managing neglected late presenting cases or cases seen by bone setters first is the rule. Even children disabilities are taken care of soon after birth by untrained personnel. Compared to other developed areas with good health system and people awareness were even tertiary care is available in a location accessible for almost all population. Thus researches addressing neglected cases although of little value at some parts of the developed world, is highly appreciated in the developing world. Indeed this difference in levels of the first care will affect publications and research topics. In most of European, American and other developed countries, a trained orthopedic and trauma surgeon will see the patient first, whereas a pediatric orthopedic unit will be usually the second if not the first level of health care, compared to developing countries where either a native bone setter or a general medical assistant is the first level of health care. Thus our training in such setup should be directed towards health personnel (paramedical staff), so that people will opt going to health centers and not to native bone setters if better service is offered by the available health personnel. In a study previously conducted in Sudan,[1] it was shown that clubfoot can be scored to comparable results when it is done by a pediatric orthopedic surgeon or an assistant physiotherapist (a nurse who had only on job training in physiotherapy). So we can trust these health personnel to deliver an acceptable quality service, because it will not be possible for the health system to make a trained orthopedic or pediatric orthopedic surgeon as it is in the developed part of the world. In such underdeveloped areas, even patient's follow up is a challenge due to lack of awareness and cultural issues related to how disability is looked at in such communities and poor health system setups, leave alone financial constraints.

Another point is that, surgery in general and orthopedic surgery in particular differs according to geography. For example Mycetoma is a health issue in many countries. It is particularly endemic between the latitudes of 15° South and 30° North in an area of vast forests and savannah, the so called Mycetoma Belt. These include Sudan, Somalia, Senegal, India, Yemen, Mexico and South America.[2] In Sudan for instance, Mycetoma has been found to be the third commonest cause of amputation.[3] Thus an article on Mycetoma can be welcomed in such a journal with global concerns heading towards being of international impact and observing principles of "Health for all".

Similarly, tuberculosis is of high concern in many areas of the world. In a recent study tuberculous adenitis was found in over 30% of patients examined for enlarged lymph nodes in the neck.[4] Indeed this would not be the case in Europe and Northern America. Many of the high impact journals that are concerned with western issues will find little interest in publishing articles looking at Mycetoma and Tuberculosis, two diseases that affect areas of the globe with the highest population rates.

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-e002

In conclusion, the ORTOJ is a promising journal, with high expectations and will carry that balance between the needs of these large underprivileged populations while having a strong impact on the fast developing art and science of Orthopedics and trauma taking care of the needs of readers all over the world.

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-101

Case Report

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Volume 1 : Issue 1
Article Ref. #: 1000ORTOJ1101

Article History
Received: November 9th, 2015
Accepted: January 21st, 2016
Published: February 9th, 2016

Citation
Tomecek FJ, Sapp M. A rare case of C8 radiculopathy due to cervical spine synovial cyst. *Orthop Res Traumatol Open J*. 2016; 1(1): 1-4. doi: 10.17140/ORTOJ-1-101

A Rare Case of C8 Radiculopathy Due to Cervical Spine Synovial Cyst

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ABSTRACT

Cervical spine synovial cysts are rare degenerative spinal abnormalities when compared to more frequently noticed degenerative cyst in the lumbar spine. Many times, cervical synovial cysts can be asymptomatic. However, as in the cervical spine, synovial cysts can cause nerve root compression and in the cervical spine can cause spinal cord compression, especially, when acute hemorrhage and/or a marked increase in the size of the cyst occurs, and thus, they can result in radiculopathy and/or myelopathy. The authors report a unique case of a 69-years-old female who presented with a right C7-T1 synovial cyst causing right C8 radiculopathy and early myelopathy. This case is felt to be unique, because the diagnosis of the right C8 radiculopathy was confirmed on Electromyography (EMG) testing. The patient was also found not to have any signs of carpal tunnel syndrome. In addition, the diagnosis was further supported by a myelogram Computed Tomography (CT) scan done after the Magnetic Resonance Imaging (MRI). The MRI showed multiple levels of degenerative spondylosis, namely at C4-5, C5-6, and C6-7 with the question of stenosis at C7-T1, wrose on the right. The myelogram CT scan showed a much more clear-cut synovial cyst causing right sided C8 neural impingement and foraminal encroachment. Flexion/extension x-rays and the myelogram showed that the patient had a very minimal subluxation and a synovial cyst in the cervicothoracic junction is treated with spinal fusion. The authors showed, in the case, that even with slight subluxation, it is safe to treat a patient with a more minimally invasive C7-T1 laminotomy, foraminotomy and post-operative Flexion/extension x-rays and showed no sign of cervical instability after she was treated for her synovial cyst. She had nearly complete resolution of symptoms post operatively and did not develop instability in the follow-up period.

KEYWORDS: Synovial cyst; Ligamentum flavum; Cervical spine; Subluxation; C8 radiculopathy.

ABBREVIATIONS: EMG: Electromyography; CT: Computed Tomography; MRI: Magnetic Resonance Imaging.

Cervical spine synovial cysts are rare.[1] Because they can be asymptomatic, the exact incidence is unknown. For example, they have been shown to become symptomatic with neurologic deficit only after an acute flexion-extension injury.[2] A retrospective report of patients at the Mayo clinic from 1984-1997 included nine with synovial cysts at C7-T1.[3] A recent study of seventeen cases of cervical synovial cysts at Johns Hopkins from 1991-2013 included ten cysts at C7-T1.[4] A meta-analysis published in conjuction with that report accounted for 23 additional cysts at C7-T1 for a total of thirty-three cases.

As in the lumbar spine, synovial cysts are associated with spinal segments that have increased mobility[3] and there has been documented evidence of related instability within the cervical spine as well, anywhere from the atlantoaxial junction[4] to C7/T1.[5] Generally accepted treatment for symptomatic synovial cysts is a posterior approach with laminectomy, hemilaminectomy, laminotomy, or foraminotomy, as the case requires to access and resect the cyst. In the case of symptomatic cysts without indication of instability, the debate is whether a fusion is

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-101

required to prevent subsequent instability and symptomatology.

The authors think this is a unique case because in the literature this patient unlike other reported cases had diffuse cervical pathology on MRI (Figure 1) and the final diagnosis required confirmation with Myelo/CT (Figure 2) and EMG in the face of diffuse degenerative cervical disc and spondylolisthesis. In fact, the exam and EMG were instrumental in establishing the diagnosis of a C8 radiculopathy and allowed the authors to perform a more minimally invasive approach, restricted to C7-T1. In addition, this paper has pathologic confirmation of a synovial cyst as the diagnosis (Figure 3).

A 69-year-old woman presented with complaints of neck pain with bilateral radiation of pain and numbness to her shoulders, arms and hands; the pain was worse on the right. She also was having frequent headaches and stabbing pain, especially in her left occipital region. She complained of poor balance and frequent falls. The patient had undergone treatment by a chiropractor as well as cervical epidural steroid injections without much relief.

Physical exam showed decreased grip strength on the right. The left-handed patient gripped with 60 foot pounds on the left and 30 foot pounds on the right. She had a positive Hoffman on the left and an ataxic gait, but no pathologic reflexes or clonus.

MRI showed multiple levels of degenerative changes with some amount of collapsed disc throughout her cervical spine. She also had very small subluxations at C2/3 and C3/4. There was some element of spondylosis and facet hypertrophy at multiple levels, with mild foraminal stenosis and C4/5, C5/6, and C6/7. EMG of the right upper extremity showed a C8 radic-

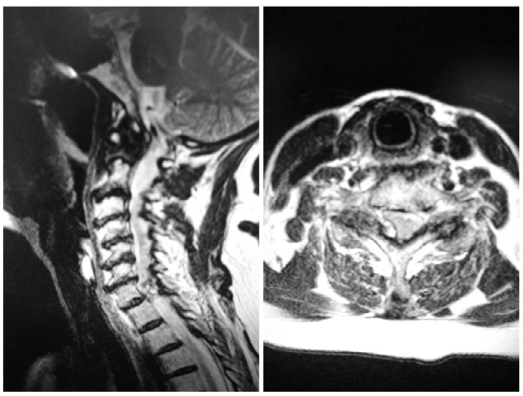

Figure 1: Sagittal and axial T2 MRI.

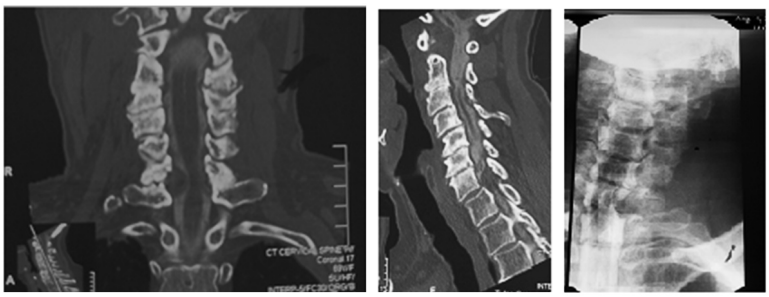

Figure 2: Myelogram and post-myelogram CT.

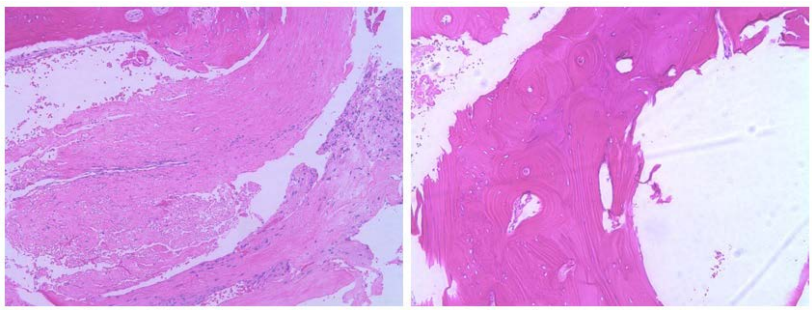

Figure 3: Pathology confirmed the diagnosis of synovial cyst.

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-101

ulopathy and no significant carpal tunnel syndrome. Myelogram CT scan was most remarkable for right C7-T1 neural impingement and cord deviation caused by an epidural mass, thought most likely to be a synovial cyst or atypical far-right lateral herniated disc. Other degenerative changes consistent with the MRI were noted, but the right-sided mass at C7/T1 was consistent with her C8 radiculopathy found on EMG.

The patient was treated with a right C7 laminotomy, T1 hemilaminectomy, and C7/T1 foraminotomy with resection of a synovial cyst. The facet was somewhat disrupted and the thecal sac was displaced from right to left. Pathology report measured the cyst at 2.0×1.8×0.3 cm. Postoperatively she was neurologically intact and by post-op day 1 she had improvement in her subjective right hand numbness.

By her final post-op visit at 5 months, after several months of physical therapy, she had no arm/hand numbness, equal and full upper extremity strength, increased range of motion in her neck, and mild upper neck pain which was dramatically better than prior to surgery.

This case report also demonstrates that when appropriate pre-op testing is done to assess stability, such as the flexion extension myelogram done here, that a C7-T1 synovial cyst can be approached safely and effectively by a unilateral posterior decompression and synovial cyst resection. Care should be taken to partially preserve the facet joint.

Synovial cysts are generally considered degenerative, but likely can have other causes such as trauma.[6] They are not symptomatic unless they cause neural impingement, and can become symptomatic with structural changes in the spine.[2] Cysts are the result of increased mobility but can contribute to joint disruption and pain.

A recent meta-analysis and case report indicated that patients treated with decompression and subaxial synovial cyst resection without fusion improved post-operative Nurick scores greater than patients who were also treated with fusion. For both groups the recurrence rate at time of report was 0%. However, the authors point out that a longer follow-up time could reveal other group difference with regard to recurrence and symptomatology.[4] The literature is divided on whether a fusion is required after cyst resection with removal of all or a portion of a cervical lamina, particularly at C7/T1. It has been argued that because of the flexibility differences between the cervical and thoracic spine, that decompression at C7/T1 should include a fusion due to increased concern of instability.[7] In the current case, the patient, a 69-year-old woman with multiple levels of cervical spine degenerative chances, present with both neck pain and radiculopathy. She had resolution of neurologic symptoms and near-complete resolution of neck pain after localized surgical resection without fusion, indicating that she had not become unstable at 5 months post-op (Figure 4).

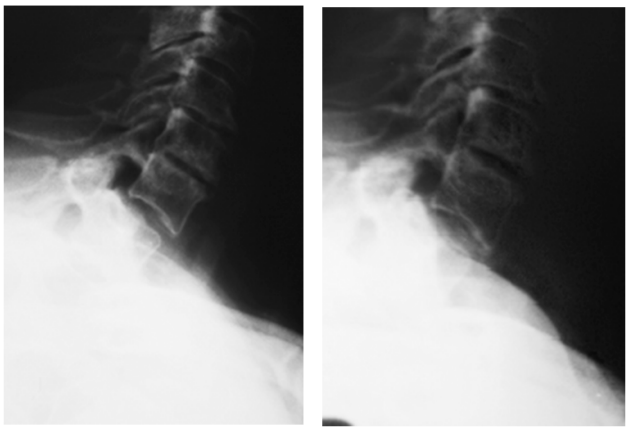

Figure 4: No evidence of instability on post-operative flexion/extension x-rays.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

CONSENT

Consent is not required for article publication, this article is a case report and not a study.

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-101

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-102

Research

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Volume 1 : Issue 1
Article Ref. #: 1000ORTOJ1102

Article History
Received: February 12th, 2016
Accepted: February 23rd, 2016
Published: February 23rd, 2016

Citation
Johnston BR, Biercevicz AM, Koruprolu SC, Terek RM, Born CT. A Biomechanical Comparison of a Novel Expandable Photodynamic Intramedullary System to a Metal Plate and Screw System in Humerus and Femur Osteotomy Models. *Orthop Res Traumatol Open J*. 2016; 1(1): 5-13. doi: 10.17140/ORTOJ-1-102

A Biomechanical Comparison of a Novel Expandable Photodynamic Intramedullary System to a Metal Plate and Screw System in Humerus and Femur Osteotomy Models

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ABSTRACT

The biomechanical performance of a locking compression plate system was compared to an intramedullary photodynamic bone stabilization system in a femur and humerus osteotomy model. The photodynamic bone stabilization system utilizes an angioplasty-like balloon that is introduced into the intramedullary canal of a fractured bone, filled with monomer that is then polymerized and hardened by visible blue light delivered through an optical fiber. This system has been in clinical use since 2010. Synthetic bones engineered to mimic the biomechanical properties of natural bone were cut to produce a 10 mm defect mid-shaft, and two groups of specimens were stabilized by either the compression plate or intramedullary photodynamic bone stabilization system. For each bone model, one locking compression plate system was used, and three different diameter intramedullary photodynamic bone stabilization implants were used. Experimental groups were tested for stiffness, peak load, yield load, peak displacement and yield displacement when a load was applied. Additional samples per experimental group were tested for long-term dynamic stability by cyclically loading until failure. It was found that in all biomechanical parameters measured, the 17 mm intramedullary photodynamic bone stabilization system exceeded the mechanical strength and durability of the locking compression plate system in the femur osteotomy model. It was found that in all biomechanical parameters measured, the 15 mm intramedullary photodynamic bone stabilization system performed equivalently or exceeded the mechanical strength and durability of the locking compression plate system. This testing combined with long-term clinical use, and *in vivo* data from a large animal model, suggest that femur fixation by an intramedullary photodynamic bone stabilization system will provide equivalent biomechanical properties to a locking compression plate once implanted.

KEYWORDS: Humerus; Femur;Fracture; Intramedullary devices; Biomechanics.

INTRODUCTION

Internal plate fixation and intramedullary nailing are long-standing methods to provide fixation of fractures of the femoral and humeral shaft.[1,2] These techniques are also used for fracture non-unions, osteotomy and bulk allograft stabilization.[1,2] Internal fixation needs to provide enough rigidity, compression, and have adequate durability (fatigue life) to promote bone healing.[2,3] Intramedullary rods are implanted along the axis of the center of mass and provide better durability than plates, but are not as rigid.[4] Implanted metal plates are fixed to cortical bone with screws, and can provide compression and better rigidity under conditions of good

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-102

bone contact. The differences between these two fixation methods have different biomechanical and clinical outcome considerations.[1-5] Intramedullary rods have become the preferred clinical choice for femoral shaft non-union.[2,3] A rod with improved durability might be useful for situations with prolonged healing such as bulk allografts, and severe bone defects as is seen with high-energy trauma and metastatic bone disease. Intramedullary rods are typically metal and are traditionally a fixed size that stabilizes the fracture by using distal and proximal cross-locking screws.[3,4,6] A recently developed Intramedullary system (IS) that utilizes a photodynamic monomer offers the potential to completely fill the intramedullary canal and provide better stabilization of a fracture or an osteotomy.[7,8] The implantation process begins with clearance of the soft tissue of the medullary canal by a flexible, cannulated, drill bit guided by a wire.[7,8] An angioplasty-like balloon adapted for this system is then inserted down the canal and filled with a liquid photodynamic monomer until the balloon is expanded and conforms to the inner cortical walls.[7,8] Finally, an optical fiber inserted down the cannulated balloon delivers visible blue light (436 nm) to polymerize the liquid monomer and thus hardening the implant.[7,8] Each implant is expandable to ensure a conformal fit between the implant and the canal and could potentially offer improved biomechanics. This technology has shown promising results in a large animal model and in clinical use.[9-11] As a first step in evaluating the mechanical properties of this new rod, we compared the following biomechanical properties of three IS diameter sizes to a locking compression plate appropriately sized for either the humerus osteotomy or femur osteotomy model. For the humerus, three IS diameter sizes (11 mm, 13 mm, 15 mm) were compared to a 3.5 mm Locking Compression Plate (LCP) and screw system.[12,13] For the femur, three IS diameter sizes (13 mm, 15 mm, 17 mm) were compared to a 4.5 mm Locking Compression Plate (LCP) and screw system.[7-9] Using a bone surrogate model we evaluated these implants using biomechanical parameters: stiffness, yield load, peak load, yield displacement, peak displacement, and finally cycles to failure under axial load.[5-10,14] In both models, previous biomechanical testing of plates and intramedullary rods provided a suitable predicate.[1,4,5,10,12-20] An osteotomy model was chosen for both models because of the biomechanical demand such a defect places on a fixation system.[5] Understanding the biomechanical performance of these two implant systems could be beneficial in directing clinical decisions when the two systems might be considered for the same indication.

MATERIALS AND METHODS

Humerus Osteotomy

Humerus Experimental Groups: The static and dynamic mechanical properties of three different diameter IS implants and an LCP implant were compared in four humerus experimental groups: (1) 11 mm, (2) 13 mm, (3) 15 mm diameter IS implants (IlluminOss Medical, East Providence, RI, USA), and (4) 3.5 mm titanium Locking Compression Plate (LCP) (7 hole, 98 mmx11 mm) with 3.5×30 mm titanium locking screws (Synthes, Westchester, PA, USA). Six constructs per group were built and tested for the static parameters and an additional three constructs per treatment group were built for the dynamic testing.

Humerus Model and Fabrication of Constructs: A synthetic humerus bone model (Sawbones Product #3404 - Sawbones, Vashon, WA, USA), which has been shown to exhibit similar mechanical properties to bone, was cut at the midpoint with an additional 5 mm removed from the cut ends to create a 10 mm defect.[16,17] The remaining segments of the synthetic bone were removed 95 mm away from the center cut. A custom-made jig was built to hold both sections of the synthetic bone while a drill press was used to widen the intramedullary canal to the final diameter (11 mm, 13 mm, 15 mm). Synthetic bone constructs were assembled with a 10 mm spacer inserted at the midline to preserve the spacing and alignment (Figure 1).

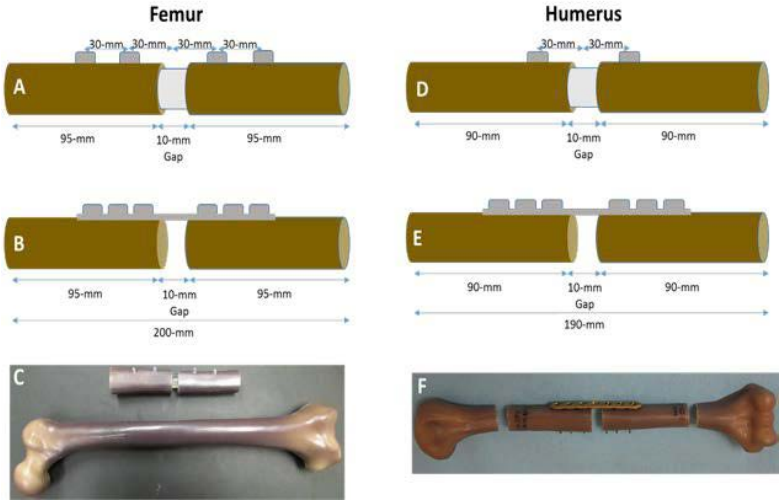

Figure 1: Dimensions for the IS construct A) femur and D) humerus, respectively. Dimensions for LCP construct B) femur and E) humerus, respectively. Picture of final construct in the sawbones C) femur and F) humerus, respectively.

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-102

For the humerus IS implants, a 180 mm long deflated and wrapped polyethylene terephthalate (the material used in Dacron® fiber) balloon with either an 11 mm, 13 mm, or 15 mm diameter was inserted down the intramedullary canal and filled with liquid monomer. The monomer was polymerized for 500, 600, and 700 seconds for the 11 mm, 13 mm and 15 mm balloons, respectively using 436 nm visible light delivered by an optical fiber (Figure 2). The hardened, polymerized IS was further secured in the construct by two 3.5×28 mm self-tapping screws (DSS, Inc. Fresno, CA, USA) into pre-drilled pilot holes 30 mm from the center of the construct on either side of the osteotomy.

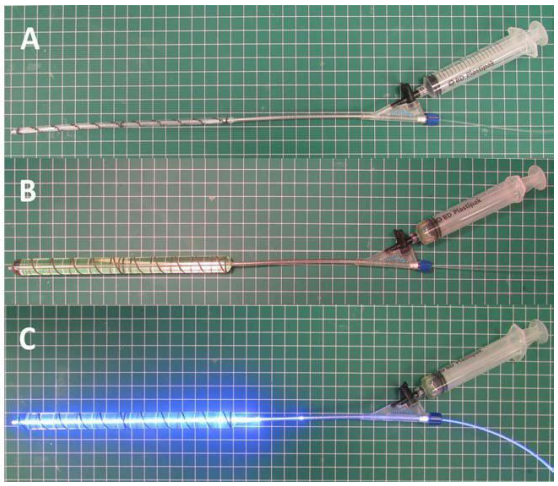

Figure 2: Fabrication of expandable photodynamic intramedullary system (IS). A: angioplasty-like balloon connected to syringe and light fiber. B: injection of photodynamic monomer to expand the angioplasty-like balloon. C: polymerization and hardening of photodynamic monomer by 436 nm visible light delivered by an optical fiber.

The LCP construct was prepared using the same custom jig as the IS construct. After cutting to the proper length, the plate was aligned on the lateral aspect of the synthetic bone and pilot holes were pre-drilled. Six 3.5×30 mm titanium locking screws were screwed into the plate by hand. The middle hole on the 7 hole LCP was left open above the osteotomy.

Humerus Cantilever Bend Mechanical Testing: All static and dynamic testing was performed using ASTM F382-99 as a nominal guide (Standard Specification and Test Method for Metallic Bone Plates).[14,18] For static testing, each construct was loaded in custom fixtures that allowed unrestricted bending when subjected to a transverse compressive load in the anterior to posterior direction (Figure 3A). All testing was completed in a servo-hydraulic materials testing machine (Instron 8521S, Instron, Norwood, MA). All specimens were loaded at a rate of 25.4 mm/min and the test was stopped before the humerus constructs were deflected beyond a functional limit (>30 mm).

For dynamic testing, the same custom fixtures as static testing were used to apply a cyclic sinusoidal compressive load along the transverse axis of the humerus (anterior to posterior direction) at a rate of 5 Hz (MTS model 810, MTS Corp., Eden Prairie, MN, USA). Three samples were tested at each of the three loading conditions (33N, 66N, 99N) with an R ratio of 10 for 1,000,000 cycles or until the construct was permanently deformed (10 mm total displacement). Samples that completed 1,000,000 cycles without being permanently deformed in a given loading condition were then stepped up to the next loading condition for additional 1,000,000 cycles until the final loading condition (99N) was complete. The loading conditions were determined from *in vivo* reports of a 120° bending moment on the humerus during Activities of Daily Living (ADLs).[19,20] To achieve a bending moment of 4.6 nm seen on the humerus during ADLs, the minimum load of 33 N was applied with a moment arm of 140 mm. The additional loading conditions (66 and 99 N) were included to encompass three factors beyond typical ADLs. For the 3.5 mm plate constructs, the orientation of the plate was antero-medial. After dynamic testing, the constructs were visually inspected for defects.

Femur Osteotomy

Femur Experimental Groups: For the femur model, the biomechanical properties of four experimental groups were evaluated: (1) 13 mm, (2) 15 mm, (3) 17 mm diameter IS implants (IlluminOss Medical, East Providence, RI, USA), and (4) PERI-LOC 4.5 mm Locking Compression Plate (LCP) (Smith and Nephew, 8-hole, 4.5 mm × 157 mm, stainless steel, Part #71809308) with six 4.5x40 mm PERI-LOC self-tapping cortex screws and two locking buttons (Smith and Nephew, Memphis, TN, USA Part#3826040). Three constructs per IS group were built and compared to six LCP samples previously tested in Tompkins et al.[15]

Femur Model and Fabrication of Constructs: A synthetic femur bone model (Sawbones Product #3403 - Sawbones, Vashon, WA, USA), which has been shown to exhibit similar mechanical properties to bone, was cut at the midpoint with an additional 5 mm removed from the cut ends to create a 10 mm defect.[9,21] A large femur model was used for the 17 mm IS and LCP groups, whereas a medium femur model was used for the 15 mm and 13 mm IS groups. The femur model sizes were chosen to accommodate the relative size of the large diameter (17 mm) IS and LCP constructs. The remaining segments of the synthetic bone were removed 100 mm away from the center cut. Similar to the humerus model, a custom-made jig was built to hold both sections of the synthetic bone while a drill press was used to widen the intramedullary canal to the final diameter (13 mm, 15 mm, 17 mm). Synthetic bone constructs were assembled with a 10 mm spacer inserted at the midline to preserve the spacing and alignment.

For the IS implants, a 180 mm long deflated and wrapped polyethylene terephthalate (the material used in Dacron® fiber) balloon with either an 13 mm, 15 mm, or 17 mm diameter was inserted down the intramedullary canal and filled with liquid monomer. The monomer was polymerized for 600, 700, and 800 seconds for the 13 mm, 15 mm and 17 mm balloons, respectively using 436 nm visible light delivered by an

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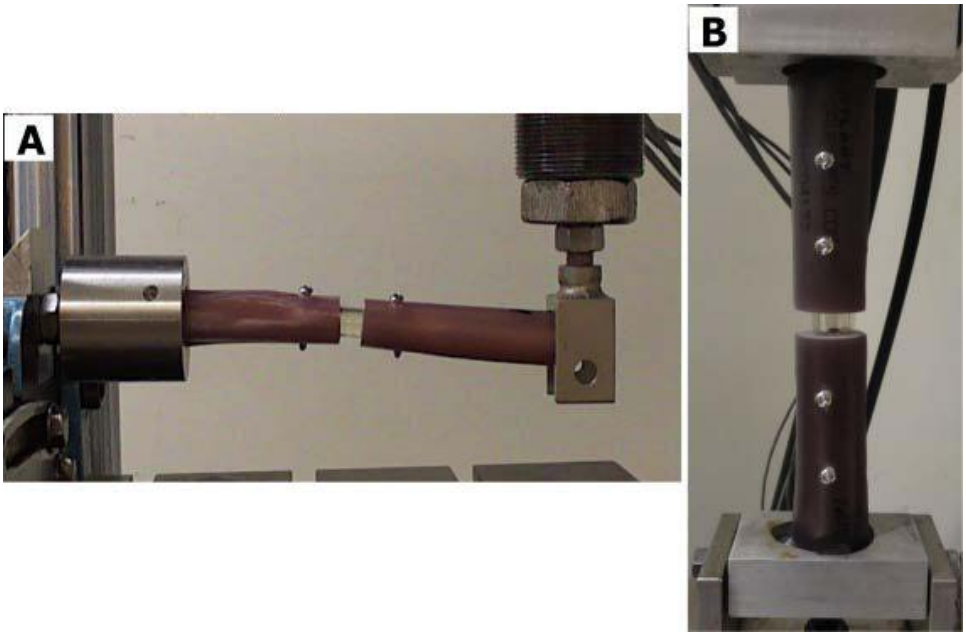

Figure 3: Picture of IS construct in the A) humerus model in the cantilever bend test and the B) femur model in the compressive axial load test in mechanical testing frame.

optical fiber (Figure 2). The hardened, polymerized IS was further secured in the construct by a total of four 3.5×40 mm self-tapping large cortical screws (Part#204840 Diverse Surgical Solutions, Fresno, CA, USA) drilled 30 mm and 60 mm from the center of the construct on either side of the simulated osteotomy.

The LCP constructs were prepared using the same custom jig as the IS construct. However, after cutting to the proper length, the intramedullary canal was filled with polymethylmethacrylate (PMMA) bone cement to increase the purchase of the screws. The plate was aligned on the lateral aspect of the synthetic bone and pilot holes were drilled. Six 4.5×40 mm large, cortex, self-tapping screws were screwed into the plate by hand (tightened to a torque of 35 inch-pounds). The two middle holes on the 8-hole LCP were filled with locking buttons which have been shown to improve the fatigue life.[15]

Femur Axial Compression Mechanical Testing: All static and dynamic testing was performed using ASTM F382-99 as a nominal guide (Standard Specification and Test Method for Metallic Bone Plates).[15,22] For static testing, each construct was loaded in custom fixtures that allowed unrestricted bending when subjected to a compressive axial load. All biomechanical testing was completed in a servo-hydraulic materials testing machine (Instron 8521S, Instron, Norwood, MA, USA). All specimens were loaded in axial compression at a rate of 25.4 mm/min and the test was stopped before the femur constructs were deflected beyond a functional limit (>30 mm) (Figure 3B).

For dynamic testing, the same custom fixtures used for static testing were used to apply a cyclic sinusoidal compressive axial load at a rate of 5 Hz (MTS model 810, MTS Corp., Eden Prairie, MN, USA). Samples were tested at each of the three loading conditions (689 N, 798 N, 900 N) with an R ratio of 10 for 1,000,000 cycles or until the construct was permanently deformed (10 mm total displacement). Samples that completed 1,000,000 cycles without being permanently deformed in a given loading condition were then stepped up to the next loading condition for additional 1,000,000 cycles until the final loading condition (900 N) was complete. The loading conditions were determined from published reports on the number of cycles equivalent to one year of walking.[23] The applied load parameters were determined from previously published mechanical testing data (yield load 1060 N) of a plate and compression screw construct test using similar methods (quasi-static compression. 65%, 75%, and ultimately 85% (698 N, 798 N, 900 N) of yield load was applied to simulate three patients of varying weight (70 kg, 81 kg, and 92 kg) standing on one leg with an implant.[15] The dynamic testing was performed on the femur IS constructs and compared to previously tested and published specimens from Tompkins et al.[15]

Statistical Analysis

Differences in biomechanical parameters between interventions (stiffness, yield load, peak load, yield displacement, peak displacement, and cycles to failure) were tested statistically using a one-way analysis of variance (ANOVA) with a Tukey's multiple comparisons test to evaluate differences between treatment groups for the humerus (11 mm, 13 mm, 15 mm IS, and LCP) and the femur seperately (13 mm, 15 mm, 17 mm IS, and LCP) (GraphPad Prism, La Jolla, CA, USA). In all cases, statistical significance was set to $p<0.05$ *a priori*. Treatment group sample sizes were estimated based on previously published reports of static and dynamic testing of locking plates and pilot testing.[15,24]

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RESULTS

Humerus Osteotomy

Humerus Stiffness: The 15 mm IS construct group had the highest average stiffness (15 mm IS 11.67 N/mm, SD 1.280; LCP – 9.983 N/mm, SD 2.26; 13 mm IS 7.367 N/mm, SD 1.299; 11 mm IS 4.617, SD 0.4309) (Figure 4A). There was a significant difference in stiffness between the treatment groups (F=26.50, *p value*=<0.0001). The 15 mm IS construct was not significantly different from the plate LCP construct (Dunnet's Multiple Comparisons Test, Mean Diff=1.683 N/mm; *p value*=0.1468). The 13 mm and 11 mm IS constructs were significantly less stiff than the plate construct (13 mm *vs.* Plate, Mean Diff=-2.617, *p value*=0.0155; 11 mm *vs.* Plate, Mean Diff=-5.367, *p value*=<0.0001).

Humerus Peak and Yield Load: The 15 mm IS construct group had the highest average peak and yield load (276.8 N, SD 21.05; 191.4 N, SD 68.15 respectively) (Figure 4B and 4C, respectively). There was a significant difference in peak and yield load between the groups (F=56.22, *p value*=<0.0001; F=5.135, *p value*=0.0085 respectively). The 15 mm IS construct had a significantly larger peak load when compared to all experimental groups (Dunnet's Multiple Comparisons Test, Mean Diff =54.10 N; *p value*=0.0029) (Figure 4B). The 15 mm IS construct also had the highest yield load, but there were no significant differences in yield load between the IS experimental groups and the LCP group (15 mm IS *vs.* LCP, Mean Diff=39.5 N, *p value*=0.4407; 13 mm IS *vs.* LCP, Mean Diff=-58.35 N, *p value*=0.1657; 11 mm IS *vs.* LCP, Mean Diff=-61.42, *p value*=0.1381) (Figure 4C).

Humerus Peak and Yield Displacement: The 15 mm IS construct had the highest peak and yield displacement (17.87 mm and 31.90, respectively) of the construct groups (Figure 5A and 5B). There was no significant difference between the any of the IS constructs and the LCP group for either peak or yield displacement (Peak Displacement, 15 mm IS *vs.* LCP, Mean Diff=1.733 N, *p value*=0.9422; 13 mm IS *vs.* LCP, Mean Diff=-2.283 N, *p value*=0.8821; 11 mm IS *vs.* LCP, Mean Diff=4.3, *p*

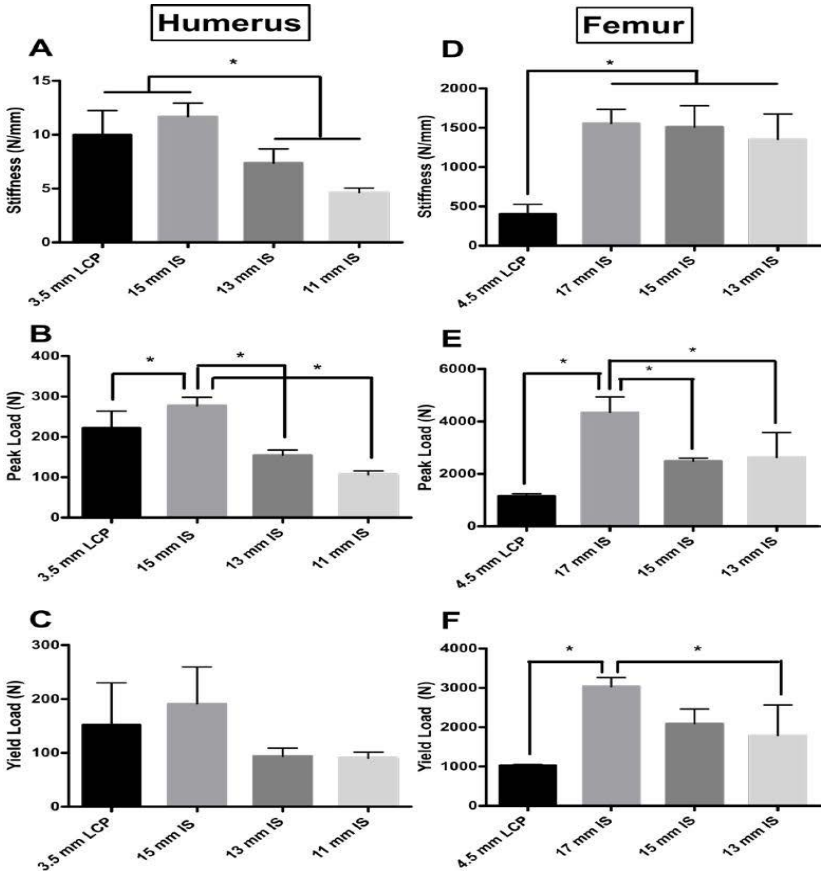

Figure 4: Stiffness (N/mm) of the four treatment groups for the A) humerus and D) femur model. For the A) humerus model, a non-significant difference was found between the 3.5 mm plate and the 15 mm IS construct. Also for the humerus model a significant difference was found between the 15 mm IS and LCP constructs and the 13 mm and 11 mm IS constructs. For the D) femur model, a non-significant difference was found between the 17 mm, 15 mm, and 13 mm IS constructs. Also in the femur model, a significant difference was found between the 17 mm, 15 mm, 13 mm IS and LCP constructs (*p value*<0.05). Peak load (N) for the four treatment groups for the B) humerus and E) femur model. The 17 mm IS construct had significantly greater peak load than the other experimental groups for both the B) humerus and E) femur models. Yield load (N) of the four treatment groups for the C) humerus and F) femur model. In the femur model B3), a significant difference (indicated by asterisk) in yield was observed between the 17 mm IS group and the LCP and 13 mm IS group (*p value*<0.05). Asterisk indicates a significant difference between groups.

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value=0.5536; Yield Displacement, 15 mm IS *vs.* LCP, Mean Diff=0.9833 N, *p value*=0.9842; 13 mm IS *vs.* LCP, Mean Diff=-3.983 N, *p value*=0.5349; 11 mm IS *vs.* LCP, Mean Diff=-2.0, *p value*=0.8908) (Figure 5A and 5B).

Humerus Dynamic Fatigue Testing: In the humerus model, for both the 15 mm IS construct and plate group all samples were intact after 3,000,000 cycles. The average number of cycles to failure for the 13 mm and 11 mm IS groups were 2,285,000 and 1,140,000 cycles respectively. There was no significant difference for cycles to failure between the LCP and the 15 mm and 13 mm IS constructs (Figure 6A). The 11 mm IS construct had significantly less cycles to failure than the LCP and 15 mm IS construct.

Femur Osteotomy

Femur Stiffness: For the femur model, the 17 mm IS construct group had the highest average stiffness (17 mm IS 1554 N/mm, SD 178; LCP – 402.4 N/mm, SD 12.3; 15 mm IS 1510 N/mm, SD 271.4; 13 mm IS 1351 N/mm, SD 322.5). There was a significant difference in stiffness between the treatment groups (F=15.68, *p value*=0.001). The 13 mm, 15 mm, and 17 mm groups were not significantly different (Tukey's Multiple Comparisons Test, *p values*>0.05). The LCP constructs were significantly less stiff than the IS constructs (17 mm *vs.* LCP, Mean Diff=1152 N/mm, *p value*=0.00155; 15 mm *vs.* Plate, Mean Diff=1107 N/mm, *p value*=0.002; 13 mm *vs.* LCP, Mean Diff=948.5, *p value*=0.0052) (Figure 4D).

Femur Peak and Yield Load: The 17 mm IS construct group had the highest average peak and yield load (4344 N, SD 591.1; 3035 N, SD 230.4 respectively). There was a significant difference in peak and yield load between the groups (F=16.2, *p value*=0.0009; F=10.41, *p value*=0.0039, respectively) (Figure 4E). The 17 mm IS construct had a significantly larger peak load when compared to all experimental groups (Tukey's Multiple Comparisons Test, *p values*<0.05) (Figure 4E). The 17 mm IS construct also had the highest yield load, and this was significantly higher than the 13 mm IS experimental group and the LCP group groups (Tukey's Multiple Comparisons Test, *p values*<0.05) (Figure 4F).

Femur Peak and Yield Displacement: The 4.5 mm LCP constructs had the highest peak and yield displacement (mean: 5.4 mm and 3.6 mm, respectively) of the construct groups. All groups tested had significantly different peak displacements except for the 17 mm and 15 mm IS constructs (Peak Displacement, 17 mm IS *vs.* LCP, Mean Diff=-2.467 mm, *p value*=0.0023; 15 mm IS *vs.* LCP, Mean Diff=-2.400 N, *p value*=0.0028; 13 mm IS *vs.* LCP, Mean Diff=-3.977, *p value*=<0.0001; 15 mm IS *vs.* 13 mm IS, Mean Diff=-1.577, *p value*=0.0300; 13 mm *vs.* 17 mm IS, Mean Diff=-1.510, *p value*=0.0370) (Figure 5C). Although the LCP construct group had the highest yield displacement, it was only significantly higher than the 13 mm IS construct group (Mean Diff=-2.653, *p value*=0.0222) (Figure 5D).

Femur Dynamic Fatigue Testing: For both the 17 mm and 15 mm IS constructs all samples were intact after 3,000,000 cycles. The

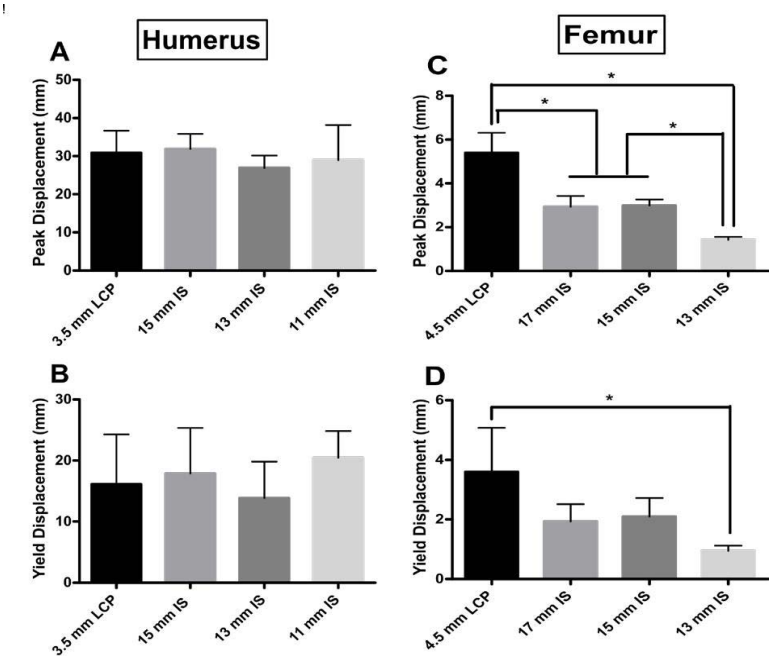

Figure 5: Peak displacement (mm) for the four experimental groups for both the A) humerus and C) femur models. Yield displacement (mm) for the four experimental groups for both the B) humerus and D) femur models. For the A) humerus group, no significant difference was observed for peak displacement between groups. Also for the B) humerus group, no significant difference in yield displacement was observed. For peak displacement in the femur group, all groups performed significantly differently (*p value*<0.05, indicated by asterisk); except for the 17 mm and 15 mm IS groups (*p value*=9987). For yield displacement in the femur model, only the LCP and the 13 mm IS groups performed significantly differently (*p value*<0.05, indicated by asterisk).

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average number of cycles to failure for the 13 mm IS and LCP groups were 1,733,000 and 1,297,000 cycles respectively. The 17 mm and 15 mm IS constructs withstood significantly higher cycles of fatigue testing compared to the LCP (*p value*=0.0052), but there was not a significant difference between the 13 mm IS construct and the 15 mm and 17 mm IS constructs (*p values*>0.05) (Figure 6B).

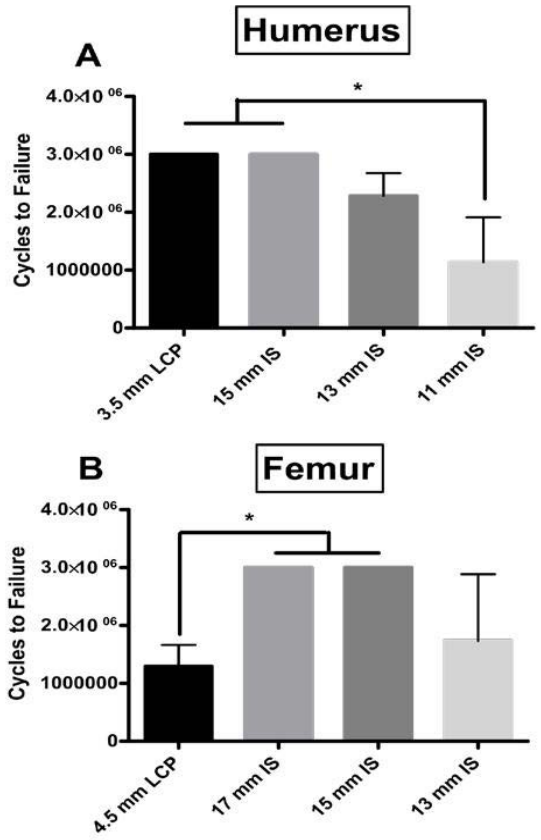

Figure 6: For the A) humerus group, the cumulative number of cycles to failure in three successive applied loads (33N for 1M cycles, 66N 1M cycles, 99N for 1M cycles). All plate and 15 mm samples were intact after 3,000,000 cycles (1M at 33N, 1M at 66N, 1M at 99N). Asterisk indicates a significant difference between the both the 15 mm IS and LCP groups and the 11 mm IS group. For the B) femur group the cumulative number of cycles to failure in three successive applied loads (689 N for 1M cycles, 798 N 1M cycles, 900 N for 1M cycles). All 17 mm and 15 mm IS samples were intact after 3,000,000 cycles (1M at 689 N, 1M at 798 N, 1M at 900 N). Asterisk indicates a significant difference between the both the 17 mm and 15 mm IS groups and the LCP group. The results from the LCP group are from the previously published Tompkins et al.[15]

DISCUSSION

The purpose of this study was to compare the biomechanical performance of three different diameters of the IS implant against a traditional metal plate fixation (LCP) system in both humerus and femur osteotomy defect models. We sought to determine whether an IS implant would perform in a biomechanically equivalent manner to the LCP for these indications.

For the humerus osteotomy model, we have demonstrated that a 15 mm diameter IS implant exhibited comparable stiffness (11.67 *vs.* 9.983 N/mm), peak load (276.8 *vs.* 222.7 N), yield load (191.4 *vs.* 151.0 N), peak displacement (17.87 *vs.* 16.13 mm), yield displacement (31.9 *vs.* 30.92 mm), and cycles to failure (3,000,000 *vs.* 3,000,000) to the 3.5 mm LCP. These results show the 15 mm IS system had similar biomechanical performance to the 3.5 mm LCP across the parameters investigated, and this indicates that the two methods could have similar mechanical performance for the same clinical indication with the IS method offering the added benefit of a less invasive surgical procedure.

For the femur osteotomy model, have demonstrated that the 17 mm diameter IS implant exhibited significantly higher average stiffness (1554 *vs.* 402.4 N/mm), peak load (4344 *vs.* 1156 N), yield load (3035 *vs.* 1023 N), and cycles to failure (3,000,000 *vs.* 1,297,000) compared to the 4.5 mm LCP.[15] The higher mechanical properties of the 17 mm IS suggests that the IS could have equivalent or increased mechanical performance in the clinical setting.

We acknowledge limitations to this investigation. A surrogate humerus and femur rather than a real human cadaver samples may be somewhat unrepresentative of clinical values because the surrogate bones are standardized. We believe this substitution was justified following published studies confirming the robust biomechanical performance of Sawbones constructs.[21,25] The synthetic 4th generation Sawbones were developed using ASTM standards D-638 and D-695 to mimic the properties of bone, and have the added benefit of limiting variability found in cadaver samples.[9,21,25,26] The 10 mm defect simulated may have been larger than is typically seen clinically, but provided a balance between isolating the implant sufficiently and avoiding the bone ends from coming into contact when flexed. Our decision to test for 3,000,000 cycles and up to 900 N of applied load may not have been sufficient to recapitulate the demands of the implant *in vivo*, but appears to have adequately captured the differences between the experimental groups, and was chosen based on estimates of repetitive loading during normal locomotion.[23] We chose relatively small sample sizes for our experimental groups due to the fact that early pilot testing had shown large effect sizes.[15,24] Lastly, the static and dynamic tests chosen may not fully represent the forces delivered during an *in vivo* situation. However, these tests were guided by the ASTM standards (F382-99) that are meant to ensure medical devices tested *in vitro* perform to clinical standards.[22] Additionally, we submit that benchmarking the IS to the LCP implant, which is currently in clinical use, indicates that the two systems would perform similarly in a clinical environment with the added benefit of the IS implant able to offer a custom conforming fit. In a cadaver or live bone the internal geometry varies, and thus a conforming fit may serve as an advantage when compared to fixed diameter rods. This work compared conforming intramedullary rods to plates and screws and lays the foundation for additional comparisons to fixed-diameter intramedullary rods.

Large bone defects are a challenging clinical scenario

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-102

that necessitate durable, reliable hardware fixation. Using biomechanical outcomes, this study compared the less invasive IS implant against a current clinical option (LCP) to determine if the novel IS would show similar performance. We hypothesized that equivalency could be found by testing various diameters of the IS implant. The 17 mm IS implant had significantly higher biomechanical performance when compared to the LCP system. The 15 mm and 13 mm IS implants were not consistently statistically superior, but for most parameters had higher values than the LCP system. This evidence coupled with clinical use, and *in vivo* data from a large animal model suggest that femur fixation by the IS will provide equivalent biomechanical properties to an LCP once implanted, with the added benefit that there will be less damage to adjacent tissue during implantation.[7,8,20,27]

ACKNOWLEDGMENTS

All authors contributed equally to this work. BRJ and AMB analyzed the data and wrote the manuscript. AMB and SCK designed and preformed experiments. RMT and CTB were responsible for study concept and critical revisions. The authors wish to acknowledge the staff of the Rhode Island Hospital Orthopedic Foundation for the assistance in completing this testing. The authors report IlluminOss, Inc. provided the test samples and funding for mechanical testing.

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-103

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Volume 1 : Issue 1
Article Ref. #: 1000ORTOJ1103

Article History
Received: February 9th, 2016
Accepted: March 17th, 2016
Published: March 22nd, 2016

Citation
ADA Mustafa A, Aydin T, Yavuz F, Yanmis İ, Yildiz Y. Isokinetic Muscle Strength in Recreational Athletes With Partial ACL Lesions Treated with Surgical Reconstruction. *Orthop Res Traumatol Open J*. 2016; 1(1): 14-19. doi: 10.17140/ORTOJ-1-103

Isokinetic Muscle Strength in Recreational Athletes with Partial ACL Lesions Treated with Surgical Reconstruction

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ABSTRACT

Background: Surgery that spares the intact portion of the ACL seems to be more favorable. This surgical technique has a positive effect on joint stability, joint position sense and functional scores in patients with partial ACL lesions.
Aim: This study aimed to assess isokinetic muscle strength following surgical reconstruction of partial ACL lesions.
Materials and Methods: The study included 13 recreational athletes with partial ACL lesions that underwent surgical reconstruction. In all ACL reconstructions the remnant ACL was preserved and reinforced with hamstring autografting. The primary outcome parameter was isokinetic muscle strength of the knee muscles. The secondary outcome parameters were Single Leg Stance Test (SLST) score and the Cincinnati knee-rating score. The clinical outcomes were compared between the treated knees and non-treated (contralateral) knees.
Results: There wasn't a significant difference in peak isokinetic torque of the knee flexors at 60° s^{-1} and 180° s^{-1} between the treated and non-treated knees (p>0.05); however, there was a significant difference in peak isokinetic torque of the knee extensors at 60° s^{-1} and 180° s^{-1} between the knees (p=0.03). The mean SLST score for the treated and non-treated knees was 3.90±1.29 and 3.62±1.47, respectively; the difference was not significant (p=0.44).
Conclusion: The present findings show that the surgical technique described had a positive effect on isokinetic muscle strength of the knee flexors and joint postural stability during the early post surgery period.

KEYWORDS: Anterior cruciate ligament; Reconstruction; Remnant; Muscle strength.

INTRODUCTION

Partial lesions of the Anterior Cruciate Ligament (ACL) that involve complete tearing of 1 of the 2 bundles—anteromedial (AM) and posterolateral (PL)—or an increase in vascularity of the ACL fibers (as in intrasubstance ruptures) can cause significant knee instability, especially in young patients with high functional demands.[1] The reported rate of ACL partial tears ranges from 10% to 35%.[2] The treatment of partial ACL lesions is usually conservative; however, surgical treatment may be required in cases of persistent symptomatic instability, especially in young patients with high functional demands.[3]

Although different surgical techniques are described in the literature, that which spares the intact portion of the ACL is viewed more positively. In this surgical technique the remnant ACL is preserved and reinforced *via* hamstring autografting. The advantages of this surgical technique include the following: a) the intact remnant may protect the autograft and

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-103

maintain its blood supply, providing support for the healing process in the autograft; b) sparing the intact portion of the ACL fibers may maintain some proprioceptive innervation of the ACL, thus providing faster and safer return to sports activity.[4-6]

Earlier studies have shown that sparing the intact portion of the ACL has a positive effect on joint stability, joint position sense, and functional scores in patients that undergo surgical reconstruction of partial ACL lesions[1,7-9]; however, no study has examined the ability of this surgical technique to restore isokinetic muscle strength in patients with partial ACL lesions. As such, the present study aimed to assess isokinetic muscle strength following surgical reconstruction of partial ACL lesions. It was hypothesized that this surgical procedure would result in optimal isokinetic muscle strength.

MATERIALS AND METHODS

Patient Selection

This prospective, controlled clinical study was conducted between January 2010 and January 2012 at a tertiary care hospital, and included 13 recreational athletes with partial ACL lesions scheduled to undergo surgical reconstruction. All of the surgical reconstructions were performed by the same orthopedic surgeon using knee arthroscopy. In all ACL reconstructions the remnant ACL was preserved and reinforced *via* hamstring autografting. The study protocol was approved by the Local Ethics Committee and all the patients provided written informed consent to participate in the study.

Patients that were diagnosed with partial ACL tear based on physical examination including lachmann test, anterior drawer test and pivot shift test, and MRI. The patients with an ACL with >50% of its integrity preserved, bridging the tibia and femur according to arthroscopic evaluation were included. The patients with a history of knee surgery or fracture in the affected and contralateral knee, and those with Posterior Cruciate Ligament (PCL) lesion and meniscus tears in the affected knee were excluded.

Surgical technique

In all cases after sterile preparing and draping we exsanguinate the leg and inflate the tourniquet established inferolateral and inferomedial portals touching the edges of patella tendon starting 1 cm distal to the inferior pole of patella. The medial portal must touch the edge of the patella tendon because if it is placed more medial, the tibial guide may not stay seated in the intercondylar notch with the knee in full extension. An optional outflow portal can be established superiorly.

After a diagnostic arthroscopy we identified and removed the torn remnant AM bundle. It is not necessary to denude the tibial insertion of the native AC tissue. Infact, retaining the insertion of the native ACL helps seal the edges of the ACL graft at the joint line and does not result in roof impingement if the tibial tunnel has been appropriately positioned. Then we removed the synovium and soft tissue in the notch to expose the lateral edge of the PCL and removed any of the ACL origin from the over-the-top position using an angled curette and shaver.

We inserted the tibial guide through the medial portal to advance the guide into the intercondylar notch. The tip of the guide was 9.5 mm wide (If the guide makes contact and deforms the PCL as it enters the intercondylar notch, perform a lateral wall plasty). We removed bone in 1 to 2 mm wides livers from the lateral wall until the tip of the guide passes into the notch without deforming the PCL, which creates a wide enough area for an 8 to 10 mm wide graft. We attentioned not to remove any bone from the intercondylar roof since the roof anatomy is crucial for proper positioning of the tibial guide-pin in the sagittal plane using the 55 degree tibial guide.

In fully extend the knee we inserted the 55 degree tibial guide through the anteromedial portal that touches the medial edge of the patella tendon into the intercondylar notch between the PCL and lateral femoral condyle to ensure adequate width of the notch for the ACL graft. We visualized that the tip of the guide was captured inside the notch and that the arm of the 55 degree tibial guide contacted the trochlea groove.

We drilled the tibial guide-pin through the lateral hole in the bullet until it striked the guide intraarticularly then removed the bullet from the tibial guide and remove the guide from the notch then tapped the guide-pin into the notch and assess its position.

The tibial guide-pin was properly positioned in the coronal plane when it enters the notch mid way between the lateral edge of the PCL and the lateral femoral condyle and the guide-pin aims 8 mm front of the PCL, 8 mm nearby the posterior horn of lateral meniscus.

We prepared the tibial tunnel and reamed the tibial cortex with a reamer with the same diameter as the prepared ACL graft. We checked for PCL impingement by placing the knee in 90 degrees of flexion and inserting the impingement rod into the notch and checked for roof impingement by placing the knee in full extension.

For the femoral tunnel, we inserted the size specific femoral aimer through the tibial tunnel with the knee in flexion in 90 degrees. The size of the "off-set" of the femoral aimer was based on the diameter of the ACL graft and was designed to create a femoral tunnel with a 1 mm back wall. We extended the knee and hook the tip of the femoral aimer in the over-the-top position. Allow gravity to flex the knee until the femoral guide seats on the femur. Rotate the femoral aimer a quarter turn lateral away from the PCL, which positions the femoral guide-pin farther down the lateral wall of the notch minimizing PCL impingement then we drilled a pilot hole in the femur through the aimer and removed femoral aimer, knee was still at flexion at 90

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-103

degrees.

Then we drilled the guide-pin through the anterolateral femoral cortex passed a cannulated reamer the same diameter as the ACL graft over the guide-pin and reamed the femoral tunnel and confirmed the back wall of the femoral aimer is only 1 mm thick and the center of the femoral tunnel is midway between the apex and base of the lateral half of the notch. A femoral tunnel placed correctly down the side wall does not allow room for a second posterolateral tunnel. In femoral drilling firtst of we drilled the endobutton drill to the cortex and measured then we drilled the femoral hole according to the lenght of the tendon greft. At last we passed the tendon from tibial hole to femoral hole with the proprior endobutton.

Study Protocol

Following surgical reconstruction, all of the patients underwent the same rehabilitation and exercise program for 2-3 months. In the first 2 weeks post-surgery, the patients were instructed to use crutches and braces. Patients underwent a home-based exercise program for the first 2 weeks post surgery, and then full weight bearing was allowed without the brace. The patients began rehabilitation by performing closed-chain kinetic exercises during postoperative weeks 3 and 4, cycling after week 6, and straight flat-surface running after 12 weeks.

Patient Evaluation

The primary outcome parameter was isokinetic muscle strength of the knee muscles, and secondary outcome parameters were single leg stance test (SLST) and the Cincinnati knee-rating scores. These outcome parameters were recorded before surgery and at 3 months post-surgery, and clinical outcome was compared between the treated knee and non-treated (contralateral) knee. Isokinetic muscle strength of the knee muscles was tested using a Biodex isokinetic dynamometer (Biodex Corp., Shirley, New York, USA) at 2 angular velocities for the knee extensor and flexor groups during isometric contraction. Isokinetic knee strength at 60° s^{-1} and 180° s^{-1} was measured in both knees. All of the participants completed 5 maximal repetitions at 60° s^{-1} and after 30-60 s of rest the participants completed 5 maximal repetitions at 180° s^{-1}. The peak torque (Nm) for knee extension and knee flexion for each leg at each of the 2 speeds was tested and recorded. SLST score was measured using a Biodex Balance System SD (BBS) (Biodex, Shirley, NY, USA), which is designed to measure postural stability on a stable or unstable surface. The BBS includes a circular platform that is free to move in the anterior-posterior and medial-lateral axes simultaneously. This device was designed to measure the degree of tilt in each axis, providing an average sway score. It consists of 8 springs located underneath the outer edge of the circular platform, which provide resistance to movement. Resistance levels range from 8 (most stable) to 1 (least stable). The participants stood on the BBS platform supported on 1 leg and looking at the display. All trials were performed without shoes. This test consisted of 3 trials 20 s in duration for each leg, with a 1 min rest between trials.

The Cincinnati knee-rating scale[10] was originally designed to assess ACL injuries and consists of symptom rating subscales for pain, swelling, and a sense of instability, physical examination, laxity of the knee on instrumented testing, daily activities, sports activity level, and radiographic findings. Maximum subscale scores are as follows: symptoms: 20; functional daily and sports activities: 15; physical examination (knee effusion, range of motion, tibiofemoral, and patellofemoral crepitus): 25; knee stability (arthrometer and pivot-shift): 20; radiographic findings: 10; and functional testing: 10. The total score ranges from 0 to 100 and is the sum of all subscale scores. Higher scores indicate higher levels of knee function. This scale is reliable, valid, and responsive to clinical changes.

Statistical Analysis

Statistical analysis was performed using SPSS v.15.0 (SPSS Inc., Chicago, IL, USA). Qualitative variables are presented as proportion and percentage. Quantitative variables are presented as mean ±SD (range). Comparisons between the treated knee and non-treated (contralateral) knee were performed using the Mann-Whitney U test (non-parametric test). The sample size 13 patients per treatment group was based upon a sample size calculation, with an anticipated mean difference of 7 in Cincinnati knee-rating scores between the groups, and a standard deviation of 4, allowing for a p-value of 0.05 and power of 0.72.

RESULTS

The study included 13 recreational athletes with a mean age 32.92±7.11 years. The mean time from trauma to ACL reconstruction was 2.73±3.05 years. In all, 7(53.8%) surgeries were performed on right knees, *versus* 6(46.2%) on left knee. All the injuries were sustained while player soccer (n=11) or basketball (n=2). No postoperative complications were observed.

Peak isokinetic torque of the knee extensors at 60° s^{-1} was 151.38±55.13 Nm in the treated knees, *versus* 210.07±61.60 Nm in the non-treated knees. Peak isokinetic torque of the knee extensors at 180° s^{-1} was 115.76±37.13 Nm in the treated knee, *versus* 142.0±41.97 Nm in the non-treated knees. Peak isokinetic torque of the knee extensors at 60° s^{-1} and 180° s^{-1} did differ significantly between the treated and non-treated knees (p=0.03). Peak isokinetic torque of the knee flexors at 60° s^{-1} was 82.46±29.74 Nm in the treated knees, *versus* 104.15±29.74 Nm in the non-treated knees. Peak isokinetic torque of the knee flexors at 180° s^{-1} was 73.38±22.73 Nm in the treated knees, *versus* 82.76±24.53 Nm in the non-treated knees. Peak isokinetic torque of the knee flexors at 60° s^{-1} and 180° s^{-1} did not differ significantly between the treated and non-treated knees (p>0.05) (Table 1). Compared to the non-treated knees at 3 months post surgery, isokinetic knee flexion at 60° s^{-1} and 180° s^{-1} in the

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treated knees exhibited 78.8% and 89% recovery, respectively. At 60° s^{-1} and 180◦/° s^{-1} isokinetic knee extension in the treated knees exhibited 71.9% and 80.9% recovery, respectively.

SLST scores for the treated and non-treated knees were 3.90±1.29 and 3.62±1.47, respectively; the difference was not significant (p=0.44). Cincinnati knee-rating scores for the treated and non-treated knees were 91.61±6.92 and 98.57±4.32, respectively, and the difference was significant (p=0.01) (Table 2). Comparison of preoperative and postoperative results—including the primary and secondary outcome parameters—showed that the knee flexors and SLST scores exhibited significant improvement (p<0.05), whereas knee extensors and the Cincinnati knee-rating scores did not improve significantly p<0.05) (Table 3).

DISCUSSION

To the best of our knowledge the present study is the first to investigate the ability of ACL remnant-preserving surgery to restore isokinetic muscle performance in patients with partial ACL lesions. The present findings show that the surgical technique described herein for the treatment of partial ACL lesions had a positive effect on knee flexor isokinetic muscle strength and joint postural stability in the early post surgical period; however, a positive effect on knee extensor isokinetic muscle strength was not observed.

Definitive indications for ACL remnant-preserving surgical techniques have not been reported; however, such indications as a partial rupture of the AM and PL bundle, an ACL remnant bridging the femur and tibia with a thickness of >50% of the native ACL, and laxity of <5 mm have been suggested.[8,11,12] In the present study all the participants had an ACL with ≥50% of its integrity preserved bridging the tibia and femur, based on arthroscopic screening for the remnant-preserving surgical technique.

	Knee Extansors		*p* Value	Knee Flexors		*p* Value
Peak Isokinetic Torque	Operated Knee	Non-operated Knee		Operated Knee	Non-operated Knee	
at 60◦/s (Nm)	151.38±55.13	210.07±61.60	0.03	82.46±29.74	104.15±29.74	0.23
at 180◦/s (Nm)	115.76±37.13	142.0±41.97	0.03	73.38±22.73	82.76±24.53	0.14

Bold values indicate a *p* value <0.05.

Table 1: Comparison of the peak isokinetic torque of the knee flexors and extansors between the operated and non-operated knees *at third months after the surgery.*

	Operated knee	Non-operated knee	*p* value
SLST score	3.90±1.29	3.62±1.47	0.44
Cincinnati knee-rating score	91.61±6.92	98.57±4.32	0.01

Bold values indicate a *p* value <0.05.

Table 2: Comparison of the SLST and the *Cincinnati knee-rating scores* between the operated and non-operated knees *at third months after the surgery.*

	Before Surgery	At 3rd months after surgery	*p* value
Peak Isokinetic Torque			
Knee extansors at 60◦/s (Nm)	135.62±68.21	151.38±55.13	0.13
Knee extansors at 180◦/s (Nm)	98.1542.25	115.76±37.13	0.08
Knee flexors at 60◦/s (Nm)	60.23±25.84	82.46±29.74	0.02
Knee flexors at 180◦/s (Nm)	52.54±27.35	73.38±22.73	0.04
SLST score	1.90±1.02	3.90±1.29	0.03
Cincinnati knee-rating score	75.21±8.95	91.61±6.92	0.12

Bold values indicate a *p* value <0.05.

Table 3: Comparison of the primary and secondary outcome parameters between the before surgery and *at third months after the surgery.*

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-103

Numerous studies have indicated that ACL reconstruction with remnant preservation will yield better clinical outcomes, including proprioception, revascularization, and knee stability, than the standard ACL reconstruction procedure.[13,14] The primary aim of ACL reconstruction is to restore the biomechanical stability of the knee joint. The positive affect on knee stability in response to remnant-preserving surgery for partial ACL lesions has been reported.[11,15,16] In the present study preoperative and postoperative knee joint postural stability in patients with partial ACL tear were compared. The patients that underwent ACL reconstruction using the remnant-preserving technique had significantly higher SLST scores after the surgery than before. In addition, there was a non-significant difference in the SLST scores between the treated and non-treated knees 3 months post surgery.

Saving ACL remnants during ACL reconstruction may have some advantages for knee muscle strength. ACL remnants can be beneficial during the start of post-surgical rehabilitation by providing additional mechanical strength while the graft is healing; thusly, the recovery of muscle strength can occur more rapidly and easily. Earlier studies reported that quadriceps strength recovered more slowly than hamstring strength after ACL reconstruction. Rosenberg et al[17] reported that quadriceps strength recovered to 82% and hamstring strength to 90% at 12-24 months post ACL reconstruction. Kobayashi et al[18] reported that quadriceps muscle strength recovered to approximately 90% of the level of the non-treated side at 24 months post ACL reconstruction, whereas hamstring muscle strength had already recovered to approximately 90% at 6 months. In the present study hamstring strength almost recovered to 80%-90% and quadriceps strength almost recovered to 70%-80% of the level of the non-treated side 3 months post surgery. Saving ACL remnants might have accelerated the healing process in the knee muscles, as reported in the above-mentioned studies.

Earlier studies reported that quadriceps muscle deficit was greater than hamstring muscle deficit following standard ACL reconstruction. Natri et al[19] reported quadriceps deficit of 15% and hamstring deficit of 9% in patients with ACL reconstruction a mean 4.3 years post surgery. Kobayashi et al[18] reported quadriceps muscle deficit of 12-27% at 12 months post ACL reconstruction, *versus* hamstring muscle deficit of 7-9%. In the present study muscle strength between the treated and non-treated knees was compared 3 months post surgery and there wasn't a significant difference in hamstring muscle strength between sides; however, quadriceps muscle strength was significantly lower in the treated knees. In agreement with the studies mentioned above, in the present study quadriceps muscle deficit was greater than hamstring muscle deficit in patients that underwent remnant-preserving surgery for partial ACL lesions. Because of the synergistic action between the ACL and hamstring muscle, the hamstring muscle plays a major role in the muscle activity that is required to maintain stabilization of knees with ACL lesions, which is why the hamstring muscle group may have less deficit the than quadriceps muscle group.

Some studies reported data for patients with ACL reconstruction based on such functional knee rating scales as the International Knee Documentation Committee (IKDC) Scale, Lysholm Scale, and Tegner Scale, all of which reported that there wasn't a significant difference at final follow-up between the patients that underwent remnant-preserving surgery and standard surgery.[11,15,20,21] however, one study reported that the Lysholm score in patients that underwent remnant-preserving surgery was significantly higher at final follow-up than in those treated *via* standard surgery.[22] In the present study the Cincinnati Knee-Rating Scale, which is the most sensitive test for evaluating functional limitations due to ACL injuries, was used for functional assessment. Cincinnati knee-rating scores were significantly lower in the treated knees than in the non-treated knees; however, the Cincinnati knee-rating scores were higher post surgery than before surgery.

ACL remnant-preserving surgery can increase the risk of developing cyclops lesions and loss of knee range of motion.[6] In the present study none of the patients had cyclops lesion formation or loss of knee range of motion following surgery. The present study has some limitations, of which the most important is the lack of a control group of patients that underwent standard ACL reconstruction. In addition, the patient population was small and only short-term follow-up was employed.

CONCLUSIONS

Based on the present findings, we think that the surgical techniques described herein, which spares the intact portion of the ACL, can have a positive effect on isokinetic muscle strength of the knee flexors and on joint postural stability during the early post surgery period; however, the long-term outcome of this technique on isokinetic muscle strength, knee stability, and functional knee scores must be determined *via* additional research.

CONFLICTS OF INTEREST: None.

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-103

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-104

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Volume 1 : Issue 1
Article Ref. #: 1000ORTOJ1104

Article History
Received: March 24th, 2016
Accepted: April 20th, 2016
Published: April 20th, 2016

Citation
Alobiad A. The use of navigation in minimal invasive spine surgery (MIS). *Orthop Res Traumatol Open J*. 2016; 1(1): 20-21. doi: 10.17140/ORTOJ-1-104

The Use of Navigation In Minimal Invasive Spine Surgery (MIS)

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Spine surgery is among the surgical specialities that is evolving tremendously and rapidly. The advancements in technology and diagnostic tools opened new era of spine surgery. The rapid growth in the implant industry delivered novel techniques, at the same time more confusion on the proper choice of surgical technique or implant. Although there is no consensus on the gold standard on many spine procedures, it's acceptable to say that the conventional open techniques are the most widely used by spine surgeons. One of the issues of spine instrumentations is screw mal position that was as high as 42% in some reports.[1]

The advancement of spine surgery and the better knowledge in spine anatomy, biomechanics, imaging, and implants introduced a new concept of less invasive "key hole surgery" that's called minimal invasive spine surgery "MIS". The newer techniques promises less soft tissue injury during surgery and faster post-operative recovery. One of the major concerns with MIS is the increasing radiation exposure for both the staff and the patient.[2] to overcome this concern, computer-assisted navigation was introduced not only for reducing radiation exposure, but also to improve accuracy of implant position. Navigation has been used for brain surgery in the early 1990s.[3] This technology utilizes stereotactic technique where the surgical instruments are guided to the pathologic target and it was frame-based navigation. The advancement of technology delivered frame-less systems, when combined to MIS techniques it should lower the radiation exposure and increases accuracy.[4,5] In a systematic literature review and meta-analysis,[6] it was clearly shown that the use of computer-assisted navigation significantly lowers the risk of pedicle perforation for the navigated screw insertion compared with non-navigated insertion for all spinal regions.[7]

There are different techniques of navigation, but in general it utilizes a real-time three dimensional visualization of patient's spinal anatomy. To achieve this, a meticulous exposure of the bone is required for better accuracy. However, if this technique is done utilizing intra-operative CT scan it would eliminate this time consuming step by performing intra-operative automated registration without the need of point and surface matching facilitating the use of computer-assisted MIS navigation.

The instruments with intra-operative CT navigation need to be verified and usually there is a reference frame inserted percutaneously into the posterior superior iliac spine. The image acquisition follows by performing a 3D spin. The images will be reconstructed and unlike the other common modalities used in open navigation procedures, the registration process is done automatically without the requirement of calibration as the CT or 3D images are directly downloaded to the machine. The surgical procedure will be initiated by determining the trajectory of the pedicle after verifying the trajectory in the surgeon monitor and making a small skin incision that is appropriate for the size of the utilized navigated instruments. The navigated instrument will be inserted using life navigation. The navigated awl, tap, screw insertion can be performed using real time navigation.[8]

Navigation in spine surgery requires special training and it has a learning curve but helps reduce radiation exposure especially in cases where visualization is an issue, making the utilization of this technology helpful in many procedures especially in obese patients, revision cases and cases with complex spinal anatomy. A survey based study was conducted to evalu-

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-104

ate the attitude of spine surgeons towards using computer-assisted navigation.[9] This study showed that only 11% would use it routinely. Those surgeons are the high volume surgeon at busy medical centers. The most common cited reasons by surgeons for not using navigation were inadequate training, lack of equipment and high costs. This would be expected when introducing any new technology or surgical techniques.

In conclusion, with the newer available systems it can be safely stated that computer-assisted MIS navigation can aid the surgeons to safely navigate complex spinal anatomy, and more accurately completing the procedure of pedicle screw fixation with complete avoidance of radiation exposure to surgeons while increasing accuracy.[4,5]

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-105

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Volume 1 : Issue 1
Article Ref. #: 1000ORTOJ1105

Article History
Received: May 14th, 2016
Accepted: May 25th, 2016
Published: May 25th, 2016

Citation
Erickson BJ, Campbell K, Jain A, et al. Are post-operative drains beneficial in total and reverse total shoulder arthroplasty?. *Orthop Res Traumatol Open J*. 2016; 1(1): 22-27. doi: 10.17140/ORTOJ-1-105

Are Post-Operative Drains Beneficial in Total and Reverse Total Shoulder Arthroplasty?

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ABSTRACT

Background: Total shoulder arthroplasty (TSA) and reverse total shoulder arthroplasty (RTSA) are effective treatments for glenohumeral arthritis and rotator cuff arthropathy
Purpose: To determine if the use of a post operative closed-suction drain following TSA and RTSA affects hemoglobin levels, clinical outcomes, and complications
Hypothesis: Patients who did not receive a drain will have less hemoglobin loss, better clinical outcome scores, and lower complication rates following TSA/RTSA
Methods: All patients who underwent TSA or RTSA by one of two surgeons between January 1, 2011 and May 15, 2013 were recorded. Patient demographic information was recorded. Patients were grouped based on use of a post-operative deep drain. Pre and post-operative hemoglobin, length of hospital stay, clinical outcome scores, and complications were recorded and analyzed.
Results: Sixty-four patients (average age 58.9±9.9 years, 55% male) underwent RTSA (13) or TSA (51) without the use of a post-operative closed-suction drain; 304 patients (average age 66.7±9.6 years, 55% female) underwent RTSA (179) or TSA (125) with the use of a post-operative closed-suction drain. Average follow up was similar in both groups: 14.95±7.22 months in the drain group and 14.55±6.74 months in the no drain group (p=.723). Using multivariate analysis to control for confounding variables and differences between the two groups, drain usage was correlated with significantly lower postoperative hemoglobin (p=0.0002), longer length of stay ($p\leq$0.0001), and lower postoperative SST (p=0.003).
Conclusion: Closed-suction drain usage following RTSA and TSA leads to greater loss of hemoglobin and longer length of stay. No clinically significant differences in transfusion rate and clinical outcome scores were seen with or without drain usage.

LEVEL OF EVIDENCE: III: case-control study.

KEYWORDS: Total Shoulder Arthroplasty (TSA); Reverse Total Shoulder Arthroplasty (RTSA); drain; Hemoglobin (Hgb); Complications; Shoulder.

INTRODUCTION

Total Shoulder Arthroplasty (TSA) and Reverse Total Shoulder Arthroplasty (RTSA) have become common procedures performed by sports medicine, shoulder and elbow, as well as trauma orthopaedic surgeons.[1,2] In 2011 there were an estimated 66,485 shoulder arthroplasty procedures performed in the United States.[3] Indications for TSA and RTSA include glenohumeral arthritis, rotator cuff arthropathy, three and four part proximal humerus fractures, and others.[4] While some surgeons routinely place a drain post-operatively following TSA and RTSA, others do not. Currently there are no studies in the literature that have compared outcomes, complications, and change in hemoglobin levels in patients undergoing TSA or RTSA who have either

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY
ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-105

had a closed-suction drain placed *versus* those who did not have a drain placed.

There have been several studies following total and unicompartmental knee arthroplasty as well as total hip arthroplasty that have evaluated the use of post-operative closed-suction drains.[5-7] While many surgeons still routinely use post-operative drains following total knee arthroplasty (TKA), the data suggests this is unnecessary. Bjerke-Kroll et al reviewed the use of post-operative drains in patients following 598 TKA and 536 total hip arthroplasties (THA).[6] The authors found that not only was the use of a post-operative drain associated with an increase in cost of $538 for a THA and $455 for a TKA, but THA and TKA patients who had a post-operative drain placed had an increase in the number of allogeneic blood transfusion, estimated blood loss, and the THA patients had an increased length of hospital stay.[6] Similarly, Al-Zahid et al found no benefit with the use of post-operative closed-suction or re-infusion drains following primary, elective TKA.[5] These results seem to suggest drains may not be warranted following lower extremity arthroplasty, and as such, it is necessary to determine if these drains are necessary following shoulder arthroplasty.

The purpose of this study was to determine if the use of a post operative closed-suction drain following TSA and RTSA affects hemoglobin levels, clinical outcomes, and complication rates. The authors hypothesize that patients who did not receive a closed-suction drain will have less hemoglobin loss, better clinical outcome scores, and lower complication rates compared to those who did receive a post-operative drain.

METHODS

All consecutive patients who underwent primary TSA or primary RTSA between January 1, 2011 and May 15, 2013 were identified. An Institutional Review Board exemption was granted for this study (exemption number ***). All surgeries were performed by one of the two senior authors (*** or ***) who are both Shoulder and Elbow Fellowship trained surgeons. Both TSA and RTSA patients with at least one year follow up data were eligible for inclusion. Exclusion criteria were: less than one-year follow-up, absence of post-operative hemoglobin levels. Patients were divided into two groups: group one had a post-operative closed-suction drain placed while group two did not have a post-operative drain placed. Charts were retrospectively reviewed to obtain the desired information. Patient demographics (age, body mass index (BMI), sex, ASA class, and diabetes) were recorded and compared between drain and no drain groups. Pre and post operative hemoglobin, length of hospital stay, and clinical outcome scores, including American Shoulder and Elbow Surgeons Shoulder Score (ASES), visual analog scale (VAS); and simple shoulder test score (SST) were recorded. Post-operative hemoglobin was checked on every patient in the morning on post-operative day (POD) 1, and this value was used in the analysis. Complications, including superficial and deep infections, as well as number of revision surgeries were recorded. The number of patients who required an allogeneic transfusion, and the overall number of transfusions were recorded.

The two surgeons whose patients were included were both fellowship trained shoulder and elbow surgeons who perform the RTSA and TSA through the standard deltopectoral approach in a modified beach chair position. One surgeon (***) placed a drain in all TSA and RTSA patients during the entire study period. This surgeon removed all drains on POD 1. The second surgeon (***) used a drain in all TSA and RTSA patients at the start of the study period but switched to not using a drain in all TSA and RTSA patients during the study period. In patients who did receive a drain, this surgeon pulled all drains on POD 1. Hence, there were more patients who received a post-operative drain than those who did not. Both surgeons placed the closed-suction drain into the deep layer of closure. All drains were removed on POD 1, prior to discharge from the hospital. No patient was sent home with a drain. Post-operatively, both surgeons followed to a strict transfusion protocol with a threshold of Hgb<8 g/dl, unless the patient had symptoms due to anemia or hypovolemia (tachycardia that did not respond to pain medication and fluids, or hypotension). As transfusions have associated harms and costs, the surgeons balanced the benefit of treating anemia with the desire to avoid unnecessary transfusions.

Statistical Analysis

Descriptive statistics were calculated for drain and no drain groups with mean±standard deviation for continuous variables and frequency with percentage for categorical data. Univariate analysis was performed to compare the drain to no drain group using Student t test for continuous variables and Fisher's exact test for categorical variables. Multiple preoperative variables differed between drain and no drain groups on univariate analysis. Therefore, to account for this difference, multivariate analyses were performed to determine if drain use or other patient variables served as the main determinant of outcomes. In addition to drain use, patient-related independent variables in the model were: type of TSA (reverse or anatomic), sex (male or female), age, ASA class, presence of diabetes (yes or no), and BMI. Dependent variables were postop ASES score, postop VAS score, postop SST score, postop hemoglobin, and transfusion (yes or no). Baseline preoperative outcome scores (ASES, VAS, SST, and preoperative hemoglobin) were also included in the respective multivariate models. Surgical site infection and reoperation were not analyzed with multivariate regression as these events did not occur in the drain group. $p<0.05$ was considered statistically significant.

RESULTS

Sixty-four patientswith an average age of 58.9±9.9 years, 55% male, underwent either RTSA (13 patients) or TSA (51 patients) without the use of a post-operative closed-suction drain during the study period. Conversely, 304 patients with an average age 66.7±9.6 years, 55% female, underwent either RTSA (179 pa-

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ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-105

tients) or TSA (125 patients) with the use of a post-operative closed-suction drain. Average follow up was similar in both groups: 14.95±7.22 months in the drain group and 14.55±6.74 months in the no drain group (p=.723). Table 1 shows the pre-operative demographics of each group; it was found that the drain group had a higher percentage of RTSA performed, was older age, had lower pre-op hemoglobin, and had lower SST outcome scores. To account for these differences, multivariate analysis was performed.

The average change in hemoglobin from pre to post surgery was significantly less in the no drain group (2.6±1.1 *vs.* 3.1±1.1 (p=.001)) (Table 2). Average postoperative hemoglobin was significantly higher in the no drain group compared to the drain group (11.5±1.5 *vs.* 10.5±1.5 (p<.001). Average length of hospital stay was significantly less in the no drain group (34.0±13.3 hours *vs.* 54.9±23.5 hours p<.001).Also, the postoperative ASES and SST, and change in SST were significantly better in the no drain group. No differences in superficial or deep infections, reoperations, or transfusions existed seen between groups

Because of the multiple differences between drain and no drain groups on univariate analysis (% RTSA, age, preop-

	Drain	No Drain	*p* value
Number of Patients	304	64	
% Males	45.40%	55.70%	0.224
ASA Class	2.41±0.55	2.27±0.63	0.072
BMI	30.6±6.3	29.4±6.3	0.168
% Diabetics	11.20%	15.60%	0.434
% RTSA	58.90%	20.30%	<0.001
Age (years)	66.72±9.6	58.91±9.9	<0.001
Length f/u (months)	14.95±7.22	14.55±6.74	0.723
Pre-Op Hgb	13.6±1.5	14.1±1.5	0.016
Pre-Op ASES	37.6±16.6	40.7±16.3	0.442
Pre-Op VAS	5.7±2.4	5±2.4	0.234
Pre-Op SST	3.1±2.3	5±2.7	0.002

Table 1: Demographic characteristics of patients who underwent RTSA/TSA and either had a post-operative closed-suction drain placed or did not have a post-operative drain placed. There were significantly more patients in the drain group who underwent RTSA and these patients were also significantly older and had lower pre-op hemoglobin levels. Additionally, these patients in the drain group were noted to have significantly lower pre-op SST. BMI: Body mass index; ASA: American Society of Anesthesiologists; Hgb: hemoglobin; RTSA: reverse total shoulder arthroplasty.

Outcome scores	Drain	No Drain	*p* value
Post-Op ASES	75.8±20.2	93±16.3	<0.001
Change in ASES	38.2±22.3	48.8±23.9	0.058
Post-Op VAS	1.5±2.1	0.7±1.0	0.081
Change in VAS	3.9±2.7	4.1±2.6	0.759
Post-Op SST	6.6±3.2	10.6±1.3	<0.001
Change in SST	3.7±3.3	5.3±2.5	0.037
Complications:			
% Patient Requiring Transfusion	3%	4.70%	0.445
% Patients with Superficial Wound Infections	0.66%	0%	0.999
% Patients with Deep Wound Infections	0.33%	0%	0.999
% Patients Requiring Revisions	3.30%	0.00%	0.221
Other			
Post-Op Hgb	10.5±1.5	11.5±1.5	<0.001
Change in Hgb	3.1±1.1	2.6±1.1	0.001
Length of Hospital Stay (hours)	54.9±23.5	34±13.3	<0.001

Table 2: Univariate analysis of outcomes and complications comparing drain and no drain groups. This analysis showed that the post-op ASES and SST score, as well as the change in SST were significantly higher in the no drain group. Additionally, it was found that the post-op hemoglobin was higher in the no drain group and the change in hemoglobin was also less in this group. Furthermore, patients who did not have a drain had a significantly shorter length of stay in the hospital after shoulder arthroplasty. Significance is P<0.5 Hgb: hemoglobin; ASES: American Shoulder and Elbow Surgeons Shoulder Score; VAS: visual analog scale; SST: simple shoulder test score.

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ORTHOPEDICS RESEARCH AND TRAUMATOLOGY

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-105

Outcome	Drain	RTSA	Age	ASA	Diabetic	BMI	Preop Hgb	Preop ASES	Preop VAS	Preop SST
Postop Hgb	0.0002	0.0007	0.9321	0.7812	0.0808	<.0001	<.0001	-	-	-
Length of stay	<.0001	0.0146	<.0001	0.6439	0.4426	0.086	-	-	-	-
Postop ASES	0.0946	0.2577	0.0656	0.4314	0.9733	0.2719	-	0.034	-	-
Postop VAS	0.1193	0.8367	0.0688	0.7119	0.9877	0.4253	-	-	0.0394	-
Postop SST	0.0031	0.413	0.5414	0.7265	0.4032	0.4169	-	-	-	0.0897
Transfusion	0.5355	0.3274	0.6468	0.7299	0.629	0.109	0.0109	-	-	-

Table 3: Multivariate analysis results including the relevant preoperative score in each regression (or preoperative Hgb for transfusion and postoperative Hgb). Drain usage was correlated with lower postoperative hemoglobin (p=0.0002), longer length of stay (p=<0.0001), and lower postoperative SST (p=0.003). Hgb: hemoglobin; ASES: American Shoulder and Elbow Surgeons Shoulder Score; VAS: visual analog scale; SST: simple shoulder test score; RTSA: reverse total shoulder arthroplasty; ASA: American Society of Anesthesiologists; BMI: Body mass index.

erative Hgb, and preoperative SST, as well as a trend for ASA class), multivariate regression was performed to determine if drain use was the main determinant of outcomes, or if other patient variables had an effect on these outcomes (Table 3). The multivariate analysis which controlled for the differences between groups demonstrated that drain usage was independently correlated with lower postoperative hemoglobin (p=0.0002), longer length of stay (p≤0.0001), and lower postoperative SST (p=0.003), but not with postoperative ASES (p=0.0946), postoperative VAS (p=0.1193), and number or rate of transfusions (p=0.5355). RTSA led to longer length of hospital stay and lower postoperative hemoglobin with no difference in transfusion rate or outcome scores.

DISCUSSION

There is a paucity of literature regarding the use of post-operative closed-suction drains after shoulder arthroplasty, as well as the effect these drains have on change in hemoglobin, clinical outcomes, and complication rates following TSA and RTSA. The authors' hypotheses were partly confirmed in that patients who did not receive a closed-suction drain following surgery had less hemoglobin loss, shorter length of hospital stay and higher postoperative SST scores on multivariate analyses than those who did receive a post-operative drain. However, complication rates did not differ between patients who received a drain and those who did not.

There are no current American Academy of Orthopaedic Surgeon (AAOS) clinical practice guidelines (CPG) which comment on the use of a post-operative drain following TSA or RTSA. While very limited literature is currently available regarding post-operative drain use in TSA or RTSA, there are several studies that have evaluated blood loss, change in hemoglobin, clinical outcomes, and complication rates in TKA and THA between patients who received a post-operative drain and those who did not.[5-10] Zhang et al performed a meta-analysis of 15 studies including 1,361 TKA and found that patients with a post-operative drain had less ecchymosis and a decreased need for dressing reinforcement but higher rates of allogeneic blood transfusions than patients without a post-operative drain. The authors also found no differences in post-operative range of motion (ROM) or complication rates including deep venous thrombosis (DVT) or infection between the drain and no drain groups. Similarly, Confalonieri et al evaluated the effectiveness of post-operative drains following unicompartmental knee arthroplasties and found a lower analgesic requirement in patients without a drain and no difference in ROM or length of hospital stay between patients with and without a drain.[11] Finally, Niskanen performed a prospective randomized study of 58 patients who underwent a THA and 39 patients who underwent a TKA with or without use of a post-operative drain and found no difference wound healing, postoperative blood transfusions, complications, or ROM.[12] These results were similar to our study as complication rates did not differ between groups, but there was a lower post-operative Hgb seen in the drain group, independent of other variables.

Gartsman et al performed the only prospective randomized study to date that evaluated the use of post-operative drains in shoulder arthroplasty in 1997.[12] The study looked at wound hematomas/dehiscence, infection, reoperation rates, and length of hospital stay in patients following multiple surgeries including rotator cuff repair, anterior stabilization for instability, and TSA (63 patients) and hemiarthroplasty (37 patients). The results for each indication were reported separately. The authors found no difference between the 49 patients who received a drain and the 51 patients who did not receive a closed suction drain following TSA/ hemiarthroplasty in any of the outcome parameters. The number of patients was much higher in the current study, and multivariate analysis was used to control for the difference in patient numbers for the drain and no drain group. Furthermore, the results of this study differ slightly, as patients who did not have a drain placed had less hemoglobin loss and a shorter hospital stay. While the authors of the previous study, similar to this study, concluded that the use of a post-operative drain following shoulder arthroplasty is not necessary, the differing results may have come from the inclusion of RTSA and exclusion of hemiarthroplasty in the current study or improvements in surgical techniques for shoulder arthroplasty.

With the multitude of studies regarding drain usage following THA and TKA, as well as the randomized trial mentioned above, it seems that the results of this study agree with the current literature.[12] There does not appear to be a benefit for

ISSN 2473-0963 Open Journal http://dx.doi.org/10.17140/ORTOJ-1-105

shoulder arthroplasty patients in post-operative outcomes and complication rates with use of a drain, while not using a drain may lead to decreased length of stay and reduced cost.[6] With the evolving healthcare field and an increased focus on patient centered outcomes and cost consciousness, studies looking at both outcomes and cost are imperative. While cost was not analyzed in this study, prior studies have evaluated the cost of placing a drain in patients following a THA or TKA and have found that placing a drain, on average, costs an extra $538 for a THA and $455 for a TKA.[6] Hence, avoiding the use of a post-operative drain seems to have the benefit of less blood loss (as evidenced by a higher post-operative hemoglobin) as well as cost savings. Similarly, as surgeons continue to move certain procedures to the outpatient setting, it is vital to understand how to achieve the best outcomes, especially in the immediate post-operative period. Given the shorter length of stay and lower loss in hemoglobin in patients who did not receive a drain, it seems logical that if and when TSA/RTSA moves to the outpatient setting in select patients, those patients would benefit from not having a post-operative drain placed.

The clinical significance of the hemoglobin change is unclear as the transfusion rate did not differ between groups in this study, likely related to the low number of transfusions needed in postoperative shoulder arthroplasty patients in general.[13,14] This consecutive series of patients who underwent TSA/RTSA by one of two highly experience shoulder arthroplasty surgeons yielding clinical outcome data is a significant addition to the current literature. Given the results of this study, it appears unnecessary to use a post-operative drain following TSA and RTSA. However, further prospective randomized studies are necessary to validate the results seen in this study.

LIMITATIONS

While this is the first study the authors know of that compares clinical outcomes and change in hemoglobin between patients who received a closed-suction drain and those who did not following RTSA/TSA, there are several limitations.[15] The study is a retrospective comparison of patients from only two surgeons, and although hemoglobin levels, complications, etc. were available for all patients, clinical outcome scores were only available for some patients, which could have introduced bias. Range of motion data was not able to be included nor was patient satisfaction. Both surgeons were fellowship trained shoulder and elbow surgeons, but there is the possibility of small differences in their technique that may potentially affect patient outcomes. The study analyzed both TSA and RTSA patients, so there is a possibility that having a separate, larger, multi-center study that analyzed each set of patients separately would have found different results given some of the differences between procedures (more potential for dead space following RTSA, etc.) There were more patients in this study who had a drain placed than who did not as one author changed his practice part way through the study period, so there were fewer patients without a drain to analyze. Multivariate analysis was used to account for this difference in numbers, but it is still possible that bias was introduced because of this. Preoperative demographic data differed between the two groups, and although a multivariate analysis was performed to control for potential confounding factors, there may be factors that were not controlled for. Finally, surgical indications and rehabilitation protocols were not evaluated which could have introduced bias into the results.

CONCLUSION

Closed-suction drain usage following RTSA and TSA leads to greater loss of hemoglobin and longer length of stay. No clinically significant differences in transfusion rate and clinical outcome scores were seen with or without drain usage.

CONFLICTS OF INTEREST: None.

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