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Check for updates

Year of the Mask COVID-19 Challenges for Orthopaedic Surgery

Smith, E¹

November 2019 a novel coronavirus emerged in Wuhan, Hubei, China

As a response to the viral pneumonias and severe illnesses that were emerging in patients, an ophthalmologist Dr Li Wenliang, working at Wuhan Central Hospital, voiced his concerns only to be severely admonished by the authorities. The accelerated spread of the Severe Acute Respiratory Syndrome (SARS) in Wuhan, and then globally, as a result of the novel coronavirus was acute and pronounced. China alerted the World Health Organisation to several pneumonia cases at the end of December 2019 and the first death was recorded in early January 2020. The respiratory physician Dr Nanshan Zhong, announced human-to-human spread and a few days later on the 23 January 2020, Wuhan was placed under quarantine. The virus spread outside China and the WHO declared the outbreak a global health emergency on 30 January 2020. Tragically Dr Li Wenliang died on 7 February 2020 as a result of exposure to the virus, leaving a five-year-old son and a pregnant wife.

On 11 February 2020, WHO named the novel viral pneumonia as Coronavirus disease 2019 (COVID-19). The International Committee on Taxonomy of Viruses suggested the name 'SARS-CoV-2' as a result of their phylogenetic and taxonomic analysis of the virus.

Coronaviruses belong to the family of *Coronaviridae*, and comprise of large, single, plus-stranded RNA with a 29,903 nucleotide genome. There are 4 genera (designated α , β , γ , δ) of coronavirus and β -CoV mainly infects the respiratory, gastrointestinal, and central nervous system of humans and mammals. 2019-nCOV is the 7th member of

the family of coronaviruses. SARS-CoV and MERS-CoV also belong to β -CoV and the nucleotide sequence similarity between SARS-CoV and 2019-nCoV is about 79%.

SARS-CoV-2 possesses the typical coronavirus structure with a spike (S) protein in the membrane envelope. This S protein can bind to the receptors of the host to facilitate viral



Street Art by FAKE; Amsterdam, Netherlands. Nurse with a mask with a Superman logo.

entry into target cells and can also bind to the human angiotensin converting enzyme 2 (ACE2), but cannot bind to the human cells without ACE2. The high affinity between ACE2 and the S protein also suggests that the population with higher expression of ACE2 might be more susceptible to SARS-CoV-2. [1]

It is highly likely that the virus originated in its natural host, the horseshoe bat (*Rhinolophus affinis*) and spilled out via some wild animals such as pangolins, and from a seafood and meat market into humans. The human to human transmission of the virus is via direct transmission (cough, sneeze, droplet dispersal and droplet inhalation) and contact transmission via oral, nasal and eye mucous

Keywords: Coronavirus; COVID-19; orthopaedic; surgery *Level of Evidence*: V

membranes. Although common clinical scenarios do not include eye symptoms, it has been shown that transmission of the virus is not limited to the respiratory tract, and includes eye exposure and direct contact with blood, oral fluids and other patient materials.

The spectrum of COVID-19 ranges from a mild selflimiting respiratory tract illness, to acute respiratory distress, severe progressive pneumonia, abnormal coagulation, inflammatory heart disease, neurological deficits, multi-organ failure, and death.

The global spread of the virus produced a pandemic of respiratory illness involving 187 countries worldwide

The timeline of COVID-19 is well known to the significant majority of people, as the world closed for business.

The WHO-China Joint Mission report on Coronavirus Disease 2019 (COVID-19) was published on the 29 February 2020. [2] By late February, early March there was an

acceleration in the number of infected cases and the number of deaths due to the virus. The infection peak has now passed in Wuhan and there is a semblance of normality in the city. The first wave of COVID-19 seen in China has abated.

South Korea used extensive testing, isolation, and quarantines to keep its caseload low. Although the cap-

ital, Seoul, is less than three hours from Wuhan by air, South Korea has had fewer cases and deaths than European countries such as France, Italy, Belgium or Spain.

The first South Korean case was confirmed on 20 January 2020, the same day as the first confirmed case in the United States of America (USA).

The first genome sequence of the virus from a human became available, from China, on 10 January 2020. South Korean officials responded and test kit mass production was initiated. Incisive action was seen in New Zealand which is also protected by its geographical position, while Sweden took an alternative light touch view on the 'lockdown' approach, compared with all the other countries. The 'lockdown' process occurred at different times in the various nations.

Strategic resources and medical supplies across the world were in short supply. In a number of first world

countries, particularly the USA, there were ponderous delays without any meaningful action.

National leadership failed to comprehend the devastation that lay ahead. Sadly, policy makers wished to control the narrative. It became clear that there was a schism between senior government officials and scientists, experts in the field of virology, epidemiology and public health and statisticians, due to inaccuracies and misrepresentation of the facts.

The inadequate testing for 2019-nCoV has been a huge issue, and this has impacted on the accuracy of the data to aid in the modelling of the pandemic. Furthermore, the lack of testing facilities has impacted on the ability to manage and contain the coronavirus pandemic.

The daily reports in the world media regarding the number of infections as well as the death rate, has fuelled the fear, hysteria and irrational behaviour in response to this worldwide disaster. A broad range of misinformation has spread across traditional media and social media in what WHO has called an infodemic (i.e. excessive amounts of misinformation, disinformation, and rumours that make

> it difficult to identify reliable sources of information). Removing false claims about COVID-19 and elevating authoritative information are welcome steps to help protect public health in this extraordinary time. [3]

> Risk of death for an individual person is unknown with COVID-19. The probability that someone dies from a disease does not just depend on

the disease itself, but also on the patient's own ability to recover from it, on medical resources, and on the type and quality of the treatment they receive. The impact of obesity and age has been critical in the recovery of hospitalised patients. Immunocompromised patients, the elderly and those with comorbidities, such as cardiovascular disease, diabetes, obesity, chronic respiratory disease, hypertension and cancer, are at the greatest risk of dying. Countries with a more elderly population group will be the hardest-hit.

Black people and those from Bangladeshi, Pakistani, Indian, and mixed ethnicities have been shown to have a statistically significant increased risk of death from COV-ID-19 as compared with those of white ethnicity. The increased mortality is believed to be partly a result of socioeconomic disadvantage and other circumstances, but is yet to be fully understood. [4]



A model of a beta coronavirus, the virus linked to Covid-19. Photograph: NEXU Science Communication/Reuters from <u>https://</u> <u>www.theguardian.com/world/2020/apr/30/coronavirus-what-do-</u> <u>scientists-know-about-covid-19-so-far</u>.

It is important to know about, and to understand, the difference between the Case Fatality Rate and Infection Fatality Rate

Epidemiologists tend to use the Case Fatality Rate (CFR) or confirmed Case Fatality Rate (cCFR). CFR is the number of deaths from the disease divided by the number of *confirmed/diagnosed cases* of disease (preferably by nucleic acid testing). CFR is not constant and varies with location, country and time.

The Infection Fatality Rate (IFR) is the number of deaths from a disease divided by the *actual/total number* of cases of the disease/infection. The total number of CO-VID-19 is not known, because not everyone suspected of the disease is tested. With COVID-19 there are many undiagnosed cases worldwide.

When there are people who have the disease but are not positively diagnosed by having a specific test (as with mild and asymptomatic cases), the IFR is likely to be lower than the CFR.

Other recent pandemics such as the 2013-2016 outbreak of Ebola identified that the CFR was 40%. [5] The CFR for the MERS-CoV was 34%, whereas the CFR for SARS-CoV was 10%. [6]

The instantaneous reproduction number Rt of COV-ID-19 is analysed so that control measures can be regularly assessed and monitored during the lockdown phase. The Rt is defined as the average number of secondary cases generated by one primary case with symptom onset on day t. If Rt > 1 the epidemic is expanding at time t, whereas Rt<1 indicates that the epidemic size is shrinking at time t. At the stage where Rt < 1, control measures may be safely relaxed.

'Lockdown' measures have flattened the epidemic curve but flattening the curve does not mean that infected cases disappear, merely that the number of COVID-19 cases are spread over a longer time period allowing healthcare systems to cope. It is unknown whether deferring infected cases will prove advantageous. However, close monitoring of *Rt* and cCFR is necessary to inform strategies against a potential second wave, to achieve an optimal balance between health and economic protection.

As the COVID-19 response gathers momentum across sub-Saharan Africa, additional research will be needed to fully understand the susceptibility, transmission dynamics, pathogenesis and clinical outcomes of COVID-19 among people living with HIV compared to the general population.

On 23 March 2020, the 'lockdown' phase (Level 4 National Incident) started in the United Kingdom (UK). Social distancing and symptom positive self-quarantine was effected. Only essential services remained operative, online shopping and delivery services were permitted. Once daily outdoor exercising within one's locality, travel to/ from work, if unable to work from home, and travel to buy basic necessities like food or medicines were allowed. Social visits, gatherings and all sport was cancelled, Schools (except for vulnerable pupils and children of key workers). Universities were closed. Final year medical school exams were suspended. Social distancing was enforced everywhere.

Measures altering population behaviour and social distancing substantially reduced virus transmission. However, it was necessary to adopt a functional working framework in key labour markets during 'lockdown' to enable working from home, physical interface for essential travel, and to accommodate those working away from home.

The National Health Service (NHS), at risk of being overwhelmed, geared up and prepared for the increased burden of admissions and severely ill patients, many of whom would require intensive care support as a result of COVID-19.

The regular NHS service was suspended, resources and staff were redeployed to cope with the influx of daily patients into hospitals all over the country. Visitors to hospital were restricted and detailed coronavirus supporting information was provided to staff, patients and the few permitted visitors.

Elective orthopaedic surgery was halted and many consultant orthopaedic surgeons' roles were sublimated to provide support on wards and to undertake work in minor fracture clinics. Orthopaedic consultants acted as the third wave of support behind the orthopaedic residents and junior doctors. Personal protective equipment (PPE) training was provided, resuscitation skills refreshed, and up skilling to provide care on intensive care units (e.g. proning patients, use of ventilators) was widespread. Retired doctors were requested to return for duty. Heads of departments and senior consultants in managerial roles as 'directors', were involved in strategic organisation of the major hospitals and organisation of acute response programs to deal with the predicted tsunami of patients at the peak of coronavirus pandemic transmission.

Frontline healthcare workers are at high risk of infection, in particular Anesthesiologists, Ear Nose and Throat Surgeons, and Intensive Care Specialists and nurses. Tragically, there were a number of deaths of healthcare workers in many world countries.

Alarms were raised concerning PPE shortages in the UK and this is assessed and addressed on a frequent basis. Up to date guidance during the pandemic is regularly circulated by the Royal College of Surgeons of England. [7,8]

Trauma and emergency admissions have reduced by some 40% in the UK. However, surgical activity and front line orthopaedic care continued with acute trauma, orthopaedic cancer and desperate cases during 'lockdown'. Conservative treatment of fractures was adopted wherever feasible and imaging reduced, except where vital.

Use of masks by patients is not mandatory, but hospital facilities have adjusted for social distancing, hand hygiene facilities and protective screens are used where feasible.

Nasopharyngeal swab tests for SARS-CoV-2 and low dose CT scans which accurately evaluate the lung fields, are performed to assess the presence of COVID-19 infection prior to surgery.

Algorithms for treatment for asymptomatic versus symptomatic patients have been produced

There are unresolved issues regarding risk disclosure and consent for orthopaedic operations during the pandemic. It is possible that the USA and UK, who experience the highest and similar negligence claims, may be most affected. Informed consent for orthopaedic operations is crucial in the surgeon-patient relationship and it would be helpful for a unified approach to this potential problem during, and beyond, the pandemic.

Protocols have been individualised for the different institutions regarding the flow of traffic in the operating room (OR) complex, OR staffing levels, equipment volume, patient transport to and from the OR and post-operative care facilities.

Patients are anaesthetised, intubated and extubated in the OR.

All OR staff involved in patient care wear full PPE. An N95 respirator mask (or equivalent), full-face shield or safety goggles, fluid resistant gown, double gloves, and a hat or surgical balaclava is standard practice.

Power tools used in drilling, reaming, cutting and impaction of bone and electrocautery in the OR, facilitate the spread of droplets from mechanical disruption, and this supports the spread of SARS-CoV-2 virus. While difficult in modern orthopaedic surgery, minimisation of aerosol generating activity is important.

The high airborne virus load places the operating orthopaedic surgeon, and all surgical staff in the OR at high risk. This risk is far greater than in the community, where the viral load would be lower.

Enhanced pre-operative and post-operative preparations and cleaning, delays to allow for clean air exchange in the OR post extubation and between surgeries, has extended the average duration for all procedures undertaken. Necessary radiographs are performed in the OR wherever possible. Wound closure is performed in the standard fashion and the wound sealed with occlusive dressing.

The doffing of PPE gear is critical. It is performed with care and attention to detail, in designated areas and is followed by thorough hand washing, prior to leaving the theatre complex. The OR is cleaned with chlorine based or similar disinfectant to eliminate the virus on surfaces.

During my specialist orthopaedic training in South Africa, orthopaedic patients requiring surgery were assumed to be HIV positive. A standard approach to surgical procedures was always adopted, with the maximum vigilance and protection available. The same strategy is mandatory in orthopaedic surgery during the pandemic, and beyond.

Post-operative care regimes have already adapted and altered to allow for early discharge with post-operative follow-up and rehabilitation by remote consultation if possible. Venous thromboprophylaxis is essential except for those with a known aberrant response to such treatment. Specific arrangements are made with regard to operative complications.

Prior to the pandemic, the Internet had fundamentally changed the way individuals were managing healthcare. Numerous Apps for healthcare professionals already exist. Telemedicine, social media and online technology utilised in the retrieval of meaningful information now become more essential than ever. Virtual medicine and working in 'bubbles' as in New Zealand, has been harnessed in the care of patients.

Population demographics, the needs of orthopaedic patients and medical resources differ throughout the world. The review for resuming elective orthopaedic surgery during the COVID-19 pandemic provides extensive and detailed guidance, but at the same time a utopian consensus on this subject. [9] Orthopaedic surgeons have already adapted their approach and response to the pandemic in daily trauma operating based on their national and local predicament.

In all probability, the trauma burden in the UK will increase as relaxation of 'lockdown' takes place

Furthermore, as the UK overcomes the peak of the first wave of the pandemic, the NHS will prepare for the resumption of elective cases in hospitals across the country, in light of the potential second wave of COVID-19, predicted by many international virologists. Increases in demand and changes to supply will not only affect patients with COVID-19 but will have massive knock-on effects on care provided to the wider population. This challenge will reverberate throughout the majority of the 187 countries affected by the pandemic. It is also likely that the changes will impact most on the poorest socio-economic groups. Inevitably NHS waiting times for elective care will rise.

From an ethical perspective, there is little doubt that patients thought to be infected, or at high risk from COV-ID-19, should have elective surgery deferred and also receive Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) testing. Parvis et al. identify no evidence to support routine serum antibody testing for all patients, but following the development of a vaccine, antibody testing will be crucial to differentiate at risk populations.

RT-PCR testing of saliva and sputum should ultimately be part of mandatory screening for patients undergoing elective surgery

High Efficiency Particulate Air filtration (HEPA) systems should be utilised in the OR as well as in more crowded areas in hospitals. [9] Periodic surveillance in hospitals should become part of an institutions' protocol to halt the unknowing spread of this, or any future devastating virus.

Ultimately a proportion of general population will acquire immunity against SARS-CoV-2, which mutates at a lower frequency as compared with seasonal influenza virus. There is intense worldwide research for an effective treatment to counter COVID-19 and many institutions and pharmaceutical companies are performing research to develop a vaccine. It is hoped that a vaccine may be available in early 2021. It is equally possible, however, that it will be many years before global collaboration brings fruition and delivers the Holy Grail.

The burden of the pandemic is unquantifiable, both to the world economy, where choices are already being made regarding survival versus sickness, as well as the impact on world healthcare. The 'lockdown' has resulted in mental health deterioration, reduced exercise, domestic and child abuse, increased alcohol use, distress, fear and in some cases death. The future healthcare challenges will be immense.

As in all times of threat, there has been churlish, inappropriate and despicable behaviour, but this is contrasted by great human kindness, endeavour and support, especially for the vulnerable and elderly, as well as the virtual sharing seen on a daily basis throughout our interactive world.

As a result of the COVID-19 pandemic there has been a seismic paradigm shift in life as we know it, and this will resonate for decades to come. It has impinged upon all our lives and it is a challenge for all orthopaedic surgeons worldwide.

A happy irony however is that it has brought about the healing of the planet.

The Great Wall of China is no longer a fortress, Mecca is empty, Disneyland has no more magic and Paris is no longer romantic!

The safety of the patient remains paramount, but the safety of all healthcare workers is also vital. There is colossal appreciation for all front line and key workers in every sphere of life in 2020 - *the year of the mask*.

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The Author declares that there is no conflict of interest.

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ORIGINAL ARTICLE

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Impact of Anterior Cruciate Ligament Status on Early Satisfaction and Clinical Outcomes Following Total Knee Arthroplasty

Etemad-Rezaie, A¹; Edmiston, T²; Kearns, S²; Locker, P²; Bohl, D²; Sexton, A²; Frank, R³; Levine, B²

Abstact

Background: While total knee arthroplasty (TKA) is a successful treatment for debilitating arthritis, up to 20% of patients may be dissatisfied with their outcome. One hypothesis for dissatisfaction is the distortion of native knee kinematics following sacrifice of the anterior cruciate ligament (ACL) during TKA. The purpose of this study was to determine the impact of ACL status at the time of surgery in patients undergoing Posterior Stabilized (PS) TKA for osteoarthritis (OA).

Methods: A consecutive prospective series of patients undergoing TKA by a single surgeon underwent prospective intraoperative assessment of their ACL status divided into three different groups:1) intact, 2) attenuated, or 3) deficient. Demographic, preoperative, intraoperative, and postoperative data were collected for each patient by two blinded, independent observers. Outcomes included patient satisfaction and Knee Society Score for Pain (KSS) and Function (KSF), Kellgren and Lawrence (K&L), UCLA Activity Score (UCLA), Short Form-12 (SF12), EuroQol (EQ5D) and patient satisfaction.

Results: Of 116 patients, 33 (28.4%) patients had an ACL deficient knee, 40 (34.5%) patients had an attenuated ACL, and 43 (37.1%) patients had an intact ACL. Those with absent ACL were significantly more likely to have a higher BMI (p=.007) and be male (p=.003). Patient with a deficient ACL had significantly lower preoperative KSF and higher K&L scores (p=.009, p=1.26 x 10-7). Attenuated and deficient groups had the greatest change in SF-

12PCS scores at their one-year follow-up with increases of 9.9 (\pm 10.0) and 10.8 (\pm 8.0), respectively (p=.037). No significant differences in overall postoperative KSS, KSF and satisfaction scores based on ACL status (p=.574 and p=.529, respectively) were found.

Conclusion: In a relatively large series, patient with ACL deficiency were more likely to have worse pre-operative outcome scores and similar or better post-operative outcome scores. This suggests that those with ACL insufficiency may experience more subjective improvement from TKA. ACL status can be used as an additional surgical marker to help orthopaedic surgeons identify which patients would most benefit from TKA.

Background

Total knee arthroplasty (TKA) is considered a successful treatment for severe osteoarthritis (OA) of the knee, often eliminating an affected patient's pain and discomfort [13]. However, as many as 20% of patients feel neutral, dissatisfied, or very dissatisfied about their TKA post-operatively [4]. This is evident with previously reported average post-operative Knee Society Function (KSF) scores ranging from 66.7-75.7 [1,2,10].

It is theorized that native knee structures such as the

Keywords: anterior cruciate ligament; ACL; total knee arthroplasty; TKA; clinical outcomes; satisfaction; impact *Level of Evidence*: III ACL may play an important role in patients achieving normal knee kinematics and satisfaction following their TKA. Patients undergoing TKA often exhibit variable histopathological changes in their ACL prior to surgery, which is thought to result in impaired knee joint stability and kinematics [11]. Multiple authors have reported degenerative changes being more severe with typically multiple compartment involvement of the knee with ACL deficiency [6,7]. As a result, it has been suggested that pre-operative ACL deficiency may precipitate degenerative patterns due to altered knee kinematics [16], and that lack of an ACL may lead to impaired knee kinematics for patients with end stage degenerative joint disease. Therefore, knowing the status of the ACL in the degenerative knee can be an important indication for TKA [11].

To the author's knowledge, no previous study has directly assessed ACL status and its impact on clinical outcome scores and patient satisfaction following TKA. Therefore, the purpose of this study is to determine the impact of a patient's pre-operative ACL status on post-operative outcomes following TKA. The hypothesis of this study is that a patient's prior ACL status has a significant impact in the pre-operative outcome measures. Specifically, the authors hypothesize that patients with absent or deficient ACLs will have worse pre-operative clinical scores, consistent with more advanced degenerative changes, and postoperatively, will have same or greater increase in their outcome measure scores. The results of this study will prove useful in understanding the role of natural knee kinematics in TKA and help to identify the role of ACL in degenerative joint disease of the knee. In addition, determining the prevalence of an intact ACL shed light on the possible utility of ACL-preserving knee arthroplasties for patients.

Methods

Following Institutional Review Board (15092303-IRB01) approval, a consecutive series of 466 patients undergoing TKA by the senior investigator between September 1, 2013 and August 1, 2016 were queried using CPT code (27447). Patients under this code were considered for our prospective study. Inclusion criteria included patients over the age of 18 years who underwent Posterior Stabilized (PS) TKA and had their ACL status determined by the senior author intra- operatively. Exclusion criteria included patients that underwent a revision TKA, patients with a previous ACL reconstruction surgery, any patient with a prior open surgical procedure on the affected knee and any patient with missing or incomplete outcome scores at their one-year follow-up. A total of 116 patients out of 466 were deemed eligible. All patients undergoing TKA had their ACL status determined using a standard physical exam, as well as direct intra- operative visualization by a single surgeon. ACL statuses were categorized as: 1) intact, 2) present and weak in the case of fraying, partial tear or mild/moderate degenerative changes, or 3) deficient in the case of full thickness tear or severe degenerative changes. Preoperative, intraoperative, and postoperative data was collected from medical charts by blinded, independent observers. Data gathered included: ACL status, physical exam findings, age at the time of surgery, BMI, sex, medical comorbidities, surgical history, surgery laterality, and patient reported outcomes (PROs). PROs included Knee Society Score for Pain (KSS) and Function (KSF), UCLA Activity Score (UCLA), Short Form-12 (SF12), and EuroQol (EQ5D). Patient reported satisfaction was documented as: very satisfied (1), satisfied (2), satisfied with complaints (3), and unsatisfied (4).

Statistics

Statistical analyses were conducted using Stata version 13.1 (StataCorp, CollegeStation, TX). First, baseline and operative characteristics were compared between patients in the absent, attenuated, and intact ACL groups using Pearson's chi-squared test (for categorical outcomes) or ANOVA (for continuous outcomes). Second, clinical outcomes were compared between patients in the absent, attenuated, and intact ACL groups using ANOVA. These clinical comparisons were conducted for findings at the preoperative time point, for findings at the 1-year postoperative time point, and for the change between the preoperative and 1-year postoperative time point. All clinical comparisons were adjusted for age, sex, and BMI. The level of significance was set at p<0.05.

Results

A total of 466 patients were enrolled, of which 116 met the inclusion criteria and had complete pre-operative and one-year follow-up data and represented the study population. Of these, 33 (28.4%) had an ACL deficient knee, 40 (34.5%) had an attenuated ACL, and 43 (37.1%) had an intact ACL. ACL status was associated with male sex and higher BMI (p=0.003 and p=0.007, respectively; Table 1).

Subsequent results are adjusted for age, sex, and BMI (Table 2). Patients with an absent or attenuated ACL were more likely to have a lower pre-operative KSF score than other patients (p=0.009). In addition, ACL absent group had a higher Kellgren and Lawrence (K&L) score (P=1.26 x 10-7). ACL absent and attenuated groups expe-

Table 1. Baseline and operative characteristics.*

	Absent (33 patients)	Attenuated (40 patients)	Intact (43 patients)	P-value
Age (years)	67.6 ± 10.1	69.4 ± 8.0	65.5 ± 8.5	0.140
Male sex	11 (33.3%)	6 (15.0%)	15 (37.7%)	0.003
Body mass index (kg/m2)	38.8 ± 10.6	35.6 ± 9.7	32.0 ± 7.1	0.007

*Bolding indicates statistical significance.

Table 2. Clinical outcomes

	Absent	Attenuated	Intact	P-value
KSS (mean points)				
Preoperative	48.1±13.2	52.5±12.9	54.0±14.4	0.248
1 year postoperative	86.3±14.1	85.4±15.7	84.2±14.2	0.574
Pre- to 1-year postoperative change	+34.0±18.1	+34.2±17.3	+28.6±19.9	0.226
KSF (mean points)				
Preoperative	35.3±18.3	44.51±11.9	50.3±15.3	0.009
1 year postoperative	60.4±27.3	64.7±21.5	71.5±23.4	0.529
Pre- to 1-year postoperative change	+6.7±15.9	+15.5±21.7	+15.2±19.6	0.199
UCLA (mean points)				
Preoperative	3.7±1.2	3.7±1.5	4.0±1.9	0.916
1 year postoperative	3.9±1.8	4.5±1.7	5.4±1.9	0.198
Pre- to 1-year postoperative change	+0.7±1.2	+1.2±1.6	+0.6±2.0	0.719
SF12PCS (mean points)				
Preoperative	28.0±7.6	29.8±7.7	32.4±8.6	0.219
1 year postoperative	36.9±11.5	36.8±10.3	40.4±10.4	0.571
Pre- to 1-year postoperative change	+9.9±10.0	+10.8±8.0	+3.7±10.5	0.037
SF12MCS (mean points)				
Preoperative	53.5±11.6	53.2±11.4	51.8±10.4	0.900
1 year postoperative	54.5±11.2	55.1±9.5	55.0±8.0	0.715
Pre- to 1-year postoperative change	-1.1±8.3	+0.6±14.3	+0.8±11.6	0.578
ED5D (mean points)				
Preoperative	0.64±0.20	0.62±0.19	0.67±0.20	0.707
1 year postoperative	0.71±0.23	0.80±0.16	0.78±0.23	0.617
Pre- to 1-year postoperative change	+0.14±0.20	+0.18±0.22	+0.08±0.17	0.404
Extension (mean degrees)				
Preoperative	4.0±8.2	2.5±4.7	3.0±4.5	0.620
1 year postoperative	0.2±0.9	0.3±1.6	0.8±2.8	0.169
Pre- to 1-year postoperative change	-2.5±5.0	-2.3±4.9	-2.4±4.5	0.890
Flexion (mean degrees)				
Preoperative	108.0±13.5	113.0±9.8	111.0±11.9	0.290
1 year postoperative	109.3±10.8	116.5±10.9	115.2±11.1	0.027
Pre- to 1-year postoperative change	+1.4±13.4	+1.6±11.8	+3.0±12.9	0.985
Kellgren and Lawrence				
Pre-opeative score	3.56±0.32	3.02±0.33	3.02±0.30	1.26x10 -7
Overall satisfaction (mean score)		-	1	
1 year postoperative	2.64±0.81	2.51±1.04	2.51±0.90	0.660

* Adjusted for age, sex, and body mass index.

rienced greater improvement in SF12PCS from pre-operative to 1-year postoperative than patients with intact ACLs (p=0.037). ACL- deficient patients had a decreased postoperative flexion at 1-year than other patients (p=0.027). However, the pre- to post-operative change in flexion did not show any difference across the three groups (p>0.05). All other clinical outcome assessments did not differ between the three groups. The mean satisfaction for all groups corresponded to satisfied, with no observed difference in patient satisfaction based on ACL status (P=0.660).

Discussion

Despite the success of TKA as a means for alleviating severe arthritis, a large number of patients remain dissatisfied with their outcomes. The role of patients' pre-operative ACL status has been hypothesized to affect both the post-operative outcome and satisfaction of patients. This study aimed to investigate whether patients with deficient ACLs had different post-operative outcomes compared to those with intact ACLs. We hypothesized that ACL pathology is associated with degenerative knee arthritis and patients with deficient ACLs experience similar or better outcomes at their 1-year follow-up.

The majority of the patients in this study (62.9%) had an attenuated or deficient ACL, which is consistent with previously reported histologic studies. Cushner et al. and Mont et al. both demonstrated histologically that the ACL is part of the degeneration process that occurs in arthritic knees with abnormalities being present in 47% and 85% of knees undergoing TKA respectively [5,11].

Our study results indicated that ACL-deficient knees had worse pre-operative KSF scores and a higher K&L score, suggesting further clinical and radiological significance to the observed histological and radiographic findings in degenerative joint disease. Berend et al. demonstrated increased chondral and meniscal damage with more extensive osteophyte formation in ACL deficient knees [3]. In addition, Berend et al. discovered that ACL deficient knees were found to require more deformity correction and had lower pre-operative ROM [3]. These combined findings suggest that ACL deficiency is closely correlated with worsened degenerative joint disease both in terms of the patient's perspective as well as radiographic and clinical exam findings.

This study is one of the first studies that examined the role of ACL status in post-operative outcome measures of patients undergoing TKA. It was discovered that those with deficient ACL status exhibited similar or greater improvement across all their post-operative outcome measures up

to one year. This can possibly be attributed to the abnormal knee kinematics that patients with deficient ACLs experience prior to their TKA, allowing for more subjective improvement post- operatively. Overall, ACL derangement can be used as one of the surgical markers of degenerative joint disease of the knee and can help orthopaedic surgeons identify potential candidates whom will benefit from a TKA.

Strengths of this study include 1) Visual inspection of ACL. The ACL of each patient was assessed intra-operatively by a single surgeon, 2) Blinded data collection. Observers collecting post-operative outcomes were blinded to the intra-operative ACL status of subjects, 3) Prospective nature of the study which allowed enough time for 1-year follow-up and inclusion of all the relevant outcome scores, and 4) Inclusion of multiple outcome scores. Nine total outcome scores were included in the study for a comprehensive assessment.

Limitations to this study include a relatively short, 1 year, follow-up period. Longer term follow- up may have revealed further changes in functional status following TKA between the three groups. However, 1 year is generally adequate to allow for a subsidence of residual pain and swelling caused by the surgery. Postoperatively, a 0-10 scale satisfaction survey may have yielded better estimation of patients' satisfaction compared to 1-4 scale that was used in this study. Lastly, having administrative measures placed to track patients and reduce the number of patients lost to follow-up would have minimized the possibility of attrition bias. However, 116 patients is still an adequate number in terms of sample size and overall power of the study.

Conclusion

In a relatively large series, over 60% of patients had a deficient or attenuated ACL at the time of TKA for OA. Compared to patients with an intact ACL, patients with ACL deficiency are more likely to have worse preoperative KSF and radiological K&L scores, indicative of a more severe degenerative disease. However, those with ACL deficiency experience similar or possibly more relief from arthroplasty as demonstrated in SF12PCS outcome scores suggesting that abnormal knee kinematics prior to TKA may lead to more subjective improvement from arthroplasty compared to patients with intact ACLs prior to surgery. This indicates that natural knee kinematics and its alteration during surgery may play a role in clinical outcomes following TKA. As a result, ACL status can be used as an additional surgical marker to help orthopaedic surgeons

identify which patients would most benefit from TKA.

List of abbreviations

TKA - Total Knee Arthroplasty ACL - Anterior Cruciate Ligament KSS – Knee Society Score KSF – Knee Society Function SF-12- Short Form 12 EQ5D - EuroQol

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ORIGINAL ARTICLE

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Early Post-operative Rises in Serum Metal Ion Levels in Total Hip Arthroplasty – A Prospective Cohort Study

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Abstact

Background: Serum Cobalt (Co) and Chromium (Cr) forms part of the diagnostic process for metallosis following Total Hip Arthroplasty (THA). While knowledge exists on longer term metal ion levels, expected early post-operative rises in serum Co and Cr in Metal-on-Polyethylene (MoP) THAs are currently unknown. This study aims to describe early rises in serum Co and Cr at 6 months post-operatively.

Methods: A prospective cohort study of 84 consecutive patients with an uncemented titanium stem from a single THA manufacturer was performed. Patients had either a metal (n=43) or ceramic (n=41) head articulating with a highly cross-linked polyethylene. Serum Co and Cr levels were measured six months post-operatively. Analysis compared mean values between groups and to determined baseline levels. Subgroup analysis investigated the effect of femoral head size and offset on metal ion levels.

Results: A mean difference of 0.002259 ppb (95% CI 0.000449-0.004069 ppb; p=0.015) was found when comparing 6-month serum Co in the metal head group compared to baseline. No significant differences were found in serum Cr (p=0.943) at six months post-surgery compared to baseline. Mean serum Co levels were higher in the MoP group compared to the CoP (Ceramic-on-Polyeth-ylene) and auxiliary control group (p=0.012). There were no differences in serum Cr (p=0.976) between the MoP and CoP groups at 6 months post-surgery. Variations in femoral head size and offset did not impact metal ion levels.

Conclusion: At six months post-surgery, a higher magnitude of serum Co exists in metal heads when compared to baseline (p=0.015) and to ceramic heads (p=0.012). Further study is required to determine whether serum concentrations of metal ions will continue to increase over time which might leads to implant failure and revision.

Background

Trunnionosis in Total Hip Arthroplasty (THA) is the mechanical wear or corrosion occurring at femoral modular head-neck interfaces [1]. Trunnionosis has been attributed to elevated serum levels of cobalt and chromium in THAs [1,2]. The release of metal ions has the potential to lead to adverse local tissue reaction, persistent pain, increased wear, physiological dysfunction requiring revision surgery [3–5]. Its prevalence ranges between 0.023% to 2% accounting for 1.8% to 3.3% of the total THA revision burden [6–8].

The exact predisposing factors for trunnionosis are currently unclear. However, several aetiologies have been postulated. Shorter, narrower taper designs, longer neck, head size and femoral offset are factors suggested to increase edge loading at the bases causing local stress, micro-motion and subsequent damage [9–11]. Taper material

Keywords: Trunnionosis; Arthroplasty; Cobalt; Chromium; Femoral offset; Femoral head size *Level of Evidence*: II and bearing surfaces have also been considered as factors affecting trunnionosis [12]. The impact of larger femoral head sizes is inconclusive although some studies associate it with higher metal ion levels in Metal-on-Polyethylene (MoP) THAs [13–15]. Ceramic-on Polyethylene (CoP) THAs have been a suggested solution. However, recent studies have suggested that taper corrosion still remains an issue [16,17].

There is currently no recommended single diagnostic tool to detect trunnionosis [18]. Serum cobalt (Co) and chromium (Cr) forms part of the diagnostic process; but consensus regarding its value in routine follow-up is lacking. The mean time from surgery to presentation with clinically significant trunnionosis is between 3.7 and 4.3 years [7]. In the absence of symptoms, many patients are not identified until revision surgery. It is not known whether metal ion levels alone should precipitate revision, however patients late to be diagnosed experience higher rates of complications [19,20].

Expected early post-operative rises in serum cobalt and chromium are currently unknown [21]. To date no studies in our search of the literature have evaluated the metal ion levels at intervals of less than 12 months in modern bearing couples. The best available evidence for levels of cobalt and chromium in well-functioning MoP bearing surfaces was demonstrated in a 10-year prospective follow-up study by Levine et al [22]. Their study measured metal ion levels at 12, 36, 60, 84 and 120 months post THA.

This study aims to determine whether there are early rises in serum cobalt and chromium at 6 months post MoP THA using pre-operative baseline and a CoP THA comparator groups. Additionally, we aimed to determine whether there was a difference in metal ion release based on variations in femoral head size and offset in MoP and CoP THAs.

Materials and Methods

A prospective study was performed to evaluate serum cobalt and chromium levels in patients undergoing primary elective THA for osteoarthritis in 2016 and 2017. Following institutional approval (HREC Approval Reference Number: 017105S), 100 consecutive patients aged 18 years or older were enrolled. All patients received an uncemented titanium femoral stem and acetabular component (MicroPort Orthopaedics Inc., Arlington, TN, USA; Dynasty Acetabular component, Profemur L Classic Monoblock Femoral component) using the Supracapsular Percutaneously Assisted Total Hip (SuperPATH) technique with in situ reduction of femoral head on trunnion under direct vision without impaction to avoid taper/trunnion damage as per the standard of care of a single surgeon (SQ) [23]. The PROFEMUR L Classic stem taper is made of Titanium Alloy (Ti6AI4V) with a 12/14 morse taper at the head-neck junction, Patients either had a metal (CoCr) (n=50) or ceramic (Biolox Delta, CeramTec North America Corp. Laurens, SC 29360, USA) (n=50) femoral head coupled with a High Cross-Linked Polyethylene (HCPE) liner. Choice of bearing surface was sequentially allocated with the first 50 consecutive patients receiving metal heads and the next 50 consecutive patients receiving ceramic heads.

Patients were deemed ineligible if they hand undergone bilateral THAs, previous joint arthroplasty or underwent another arthroplasty procedure prior to follow-up (n=16).

Following exclusion criteria, of the 100 consecutive cases, eighty-four patients remained. These eighty-four cases with either a metal-on-polyethylene (n=43) or ceramic-on-polyethylene (n=41) were deemed eligible for inclusion.

Demographic data for each patient was collected including age, gender, BMI and previous joint arthroplasty. Implant specific information incorporating femoral head type, size, neck length, offset, trunnion taper design; and acetabular cup type and design were recorded.

The primary outcome was the serum level of cobalt and chromium levels at a single time point (6 months post-operatively). Baseline pre-operative serum Cobalt and Chromium values were determined from a separate group of pre-operative patients (n=50) (Auxiliary control group). Additionally, the CoP group served as a second comparator as its prothesis (femoral head) does not contain cobalt or chromium. Patients were consented at their final preoperative appointment and underwent pre-operative blood assessment of serum Cobalt and Chromium. Bloods samples were collected from patients into EDTA vacutainers test tubes using a stainless steel needle at the pathology collection centre. Blood samples were transported to the laboratory at ambient temperature for analysis. All blood samples were analysed for Serum Cobalt and Serum Chromium levels by Sullivan Nicolaides Pathology (Sullivan Nicolaides Pathology Pty Ltd, Queensland, Australia). At the standard six-month follow-up, enrolled patients were sent to the same centre for blood collection by trained phlebotomists. All specimens were prepared and transported to one laboratory for analyses.

Statistical Analysis

A priori, we hypothesized there would be no difference in serum cobalt or chromium at 6 months post-operatively between MoP and CoP THAs from a single manufacturer. Additionally, we hypothesized that variations in femoral head size and offset would have no significant impact on metal ion levels at 6 months. With an alpha level of significance set to 0.05, a sample size of 32 patients in each group were required to detect a significant difference at a power level of 0.8. Differences in clinical characteristics between the two groups were evaluated using two-tailed sample T tests for statistical significance of continuous variables. All analyses were completed using Epitools Epidemiological Calculators (Ausvet, Australia).

Results

Patient Demographics

There were no significant differences were observed between the metal and ceramic groups with respect to gender, mean age at time of surgery or BMI. Table 1 outlines the demographic data.

Serum Ion Comparisons with Baseline

A primary analysis was performed in which patients were grouped based on whether they had metal (MoP) or ceramic (CoP) heads. Significant difference was found in serum Co levels at 6 months post-surgery compared to baseline (auxiliary control group) in the MoP group (mean difference: 0.00226 ppb, SD 0.00438 ppb, 95%CI 0.000449 ppb – 0.00407 ppb; p=0.015). No significant difference was found in serum Cr levels (p=0.943) compared to baseline (auxiliary control group). In the CoP group, no significant difference was found in serum Co or serum Cr levels at 6 months compared to baseline (p=0.833 and p=0.932). Tables 2 and 3 outlines this data.

Metal-on-Polyethylene vs Ceramic-On-Polyethylene

A secondary analysis was performed comparing serum Co and Cr levels between MoP and CoP groups. Significant higher serum Co was found in the MoP group compared to CoP group (mean difference: 0.00211 ppb, SD 0.003774 ppb, 95% CI 0.000471-0.003749 ppb; p=0.012). However no significant difference was found in serum Cr levels between the two groups (p=0.98) at 6 months as well as baseline (auxiliary control group). Table 4 outlines this data.

Femoral Offset Comparison

The MoP cohort was further divided into standard (n = 10)_and extended offset groups (n = 31). There were no significant differences found in serum Co (p=0.473) or serum Cr (p=0.398) levels between these two groups. Table 5 outlines this data.

Table 1: Population demographic characteristics

	CoP THA group	MoP THA group	P value
Number of patients	41	43	
Males (%)	57%	56%	
Females (%)	43%	44%	
Age (mean)	62.5 ±12.8	66.2 ±9.46	0.13
BMI (mean)	28.3±4.6	30.3 ±5.4	0.07

Table 2: Baseline vs 6 1	nonths post MoP THA
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	Baseline (n=43)	6/12 post MoP THA (n=43)	P value
Mean Cobalt (ppb)	0.00468	0.00694	0.015
Mean Chromium (ppb)	0.00981	0.00978	0.943

Table 3: Baseline vs 6 months post CoP THA

	Baseline (n=41)	6/12 post CoP THA (n=41)	P value
Mean Cobalt (ppb)	0.00468	0.00483	0.833
Mean Chromium (ppb)	0.00981	0.00976	0.932

Table 4: MoP vs CoP 6 months post surgery –serum chromium and cobalt comparison

	MoP THA group	CoP THA	
	(n=43)	group (n=41)	P value
Mean Cobalt (ppb)	0.00694	0.00483	0.012
Mean Chromium (ppb)	0.00978	0.00976	0.976

Table 5: All	standard	vs all	extended	offset
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	All Standard Offset	All Extended offset	P-Value
Mean serum cobalt (ppb)	0.00726	0.00550	0.473
Mean serum chromium (ppb)	0.00995	0.00916	0.398

Significant difference was found only when comparing serum Co between MoP (n = 9) and CoP (n = 10)in those with extended offset (p=0.016). Table 6 outlines this data.

In further subgroup analyses, no other significant differences were found when comparing serum Co and Cr levels between MoP standard, MoP extended offset, CoP standard and CoP extended offset groups. Tables 6, 7, 8 and 9 outlines this data.

Femoral Head Size Comparison

Each cohort (MoP and CoP0 were further divided by head size into small (<36mm) and large (\geq 36mm). There

Table 6: Extended Offset CoP vs MoP-serum chromium and cobalt comparison

	CoP group (n=10)	MoP group (n=9)	P value
Mean serum cobalt (ppb)	0.00420	0.00848	0.016
Mean serum chromium (ppb)	0.00940	0.0138	0.399

Table 7: Standard Offset CoP vs MoP-serum chromium and cobalt comparison

	CoP group (n=31)	MoP group (n=34)	P value
Mean serum cobalt (ppb)	0.00547	0.00653	0.360
Mean serum chromium (ppb)	0.00984	0.01040	0.650

Table 8: Extended vs Standard Offset in MoP-serum chromium and cobalt comparison

	MoP group Extended Offset (n=10)	MoP group Standard Offset (n=31)	P value
Mean serum cobalt (ppb)	0.00849	0.00653	0.280
Mean serum chromium (ppb)	0.00940	0.00984	0.774

Table 9: Femoral head size <36mm, MoP vs CoP

	MoP group femoral head <36mm (n=7)	CoP group femoral head <36mm (n=10)	P value
Mean serum cobalt (ppb)	0.0091	0.0058	0.07
Mean serum chromium (ppb)	0.0096	0.009	0.24

were no significant differences when comparing head sizes between MoP groups nor the CoP groups. Tables 9, 10, 11 and 12 outlines this data.

Discussion

In recent times there has been a growing clinic concern for metal ion release from trunnionosis in THAs [10]. Whilst not routinely measured, serum ion levels are important in the work-up of poorly performing THAs [18,24,25]. Currently, there exists minimal information on expected metal ion levels in patients with modern bearing coupled

Table 10: Femoral head size \geq 36mm – MoP vs CoP metal ion levels

	MoP group (n=37)	CoP group (n=32)	P value
Mean serum cobalt (ppb)	0.008	0.005	0.11
Mean serum chromium (ppb)	0.0105	0.001	0.63

Table 11: CoP – femoral head size of <36mm vs \geq 36mm metal ion levels

	CoP femoral head <36mm (n=10)	CoP femoral head 36mm (n=32)	P value
Mean serum cobalt (ppb)	0.0058	0.005	0.47
Mean serum chromium (ppb)	0.009	0.010	0.53

Table 12: MoP - femoral head size of <36mm vs $\geq 36mm$ metal ion levels

	MoP femoral head <36mm (n=7)	MoP femoral head ≥36mm (n=37)	P value
Mean serum cobalt (ppb)	0.0091	0.0079	0.75
Mean serum chromium (ppb)	0.0096	0.0105	0.63

THAs [<u>26,27</u>].

Results from this study showed a significant elevations in mean serum cobalt six months post-operatively in the MoP group but not in the CoP comparator group. Despite this, the mean short-term serum Co levels were within normal laboratory limits. No significant differences were found in serum Cr in either the MoP or CoP group compared to baseline levels. A differential elevation in cobalt has been attributed to greater solubility properties and localised head-neck modular precipitation of chromium orthophosphate [6,28]. This is consistent with literature suggesting that cobalt rises in a ratio of 1-5:1 in modular neck THAs [28–30]. Despite a lack of demographic difference between MoP and CoP groups, it is also important to consider ceramic heads more often being used in younger patients due to reports of improved wear rates [28,31].

The current evidence on femoral head size and offset variation in relation to serum metal ion levels remains inconclusive [19]. It has been speculated that increasing femoral head size would lead to increased tribocorrosion secondary to increased torque at the trunnion [11,32]. However, results from this study failed to identify any significant association with increased ion levels when stratifying based on head size regardless of bearing type. This might be a type 2 error as the subgroups used for head size analysis were relatively small (<10). Hence the result is inconsistent with prior studies [14, 17]. White et al in their analysis of metal heads found a significant difference between serum cobalt levels in the 36mm group compared to the 32mm group. Similarly, Craig et al found a significant increase in serum cobalt levels in the 36mm group compared to the 28mm group. Interestingly there no significant differences between the 40mm group compared to 28mm group; although this lack of difference may be attributed to increased offset in the 28mm group. Bolland et al conducted a longer term study (mean follow up of 62 mths), they showed high rate of failure and high wear at the trunnion-head interface and passive corrosion of the stem, rising concern with using larger head on a conventional 12 taper [33]. The FEA simulation study by Laverniaet al. highlighted the potential influence of head size on trunnionosis. They showed that regardless of head material used, stress levels (underneath the junction between head and trunnion) had a direct correlation to head diameter. Therefore a larger head size could lead to high rate of trunnionsis [<u>32</u>].

There was a significant difference in serum Co levels only when comparing the MoP to CoP groups with extended femoral offset. There were no other significant differences in serum Co or Cr levels between MoP or CoP groups regardless of offset type. This result is in contrast to recent findings and laboratory-based studies demonstrating increased movement at the head-neck junction for higher offsets [11,19]. Martin et al found a significant increase in serum cobalt in those with increased offset. Significant differences in increased serum chromium were found only when comparing very high femoral offset (+7 to 9mm) to low offset (-2 to 1mm). However, it should also be noted that the average time to follow-up in this study was 28.7 (24.4-58.9) months. The differences in our study may not yet be apparent at six months.

There are a number of limitations to this study. Firstly, the baseline serum metal levels were taken from 50 preoperative patients unrelated to our study cohort. Ideally pre-operative serum levels in our study cohort should have been used. Hence, a second comparator was found in the CoP group as the prosthesis was without any sources of Cobalt or Chromium. Secondly, this study did not account for potential confounders such as medical comorbidly such as renal insufficiency and level of daily activity level. Renal insufficiency is known to affect metal ion levels [34] although there were no patients with major renal disease in our cohort. Differences in occupational exposure, diet and nutritional supplementation are also known to affect ion levels [6,35].

To our knowledge, this is the largest prospective study of metal ion levels concerning trunnionosis in a consecutive cohort based on sample size calculations and power analysis. However, subgroup comparisons concerning variations in implant components only included small numbers in each. The subgroup analyses were likely underpowered, leading to a type 2 error. A study with a larger sample size with adequate power would better reflect the impact of implant specific variations. It is unclear whether a "running-in" period exists as with older metal-on-metal implants where Co and Cr levels gradually stabilise [<u>36</u>]. Long term prospective cohort studies suggest that metal ion levels continue to increase with time and did not plateau [22,37]. Jacobs et al in a prospective longitudinal study found that at 36 months they were 5-8 times pre-operative levels [<u>37</u>]. Therefore, continued surveillance is necessary to determine if serum concentrations of metal ions will increase overtime in our cohort. Future research could focus on identifying those at risk of trunnionosis through detection of early post-operative serum metal ion rises.

Conclusions

This study allows a number of conclusions to be made. Rises in serum cobalt exist in the early stages post THA. At six months, increases were apparent in Metal-on-Polyethylene THAs when compared to baseline (p=0.015) and Ceramic-on-Polyethylene THAs (p=0.012). Serum metal ion levels were not affected by implant specific variations.

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AUTHOR DISCLOSURES

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REVIEW

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An Overview of Trauma Center Levels and **Disparities in Rural Trauma Care**

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Abstact

Trauma centers in the United States focus on providing care to patients who have suffered injuries and may require critical care. These trauma centers are classified into five different levels: Level I to Level V. Level V trauma centers are the least comprehensive, providing minimal 24hour care and resuscitation, and Level I trauma centers are the most comprehensive, accepting the most severely injured patients and always delivering care through the use of an attending surgeon. However, there is a major inequity in access to trauma centers across the United States, especially amongst rural residents. Level III to Level V trauma centers tend to be dominantly situated in rural and underserved areas. Furthermore, trauma centers tend to be widely dispersed with respect to rural areas. Therefore, these areas tend to have a greater mortality rate in relation to traumatic injuries. Improvements in access to hightier traumatic care must occur in order to reduce mortality due to traumatic injuries in underserved rural areas. Possible improvements to rural trauma care include bolstering the quality of care in Level III trauma centers, increasing Level II center efficiency through the involvement of orthopedic traumatologists, placing medical helicopter bases in more strategic locations that enable transport teams to reach other trauma centers faster, building more Level I and Level II trauma centers, and converting Level III centers into either Level I or Level II centers.

Keywords: trauma centers, rural access, disparities, orthopedics, traumatologists, surgeons



Publication Note: While the subject matter of this article is not typical to Reconstructive Review, we feel the topic is extremely important given the current COVID-19 health crisis.

Defining Trauma Center Levels

Trauma centers around the United States are established to provide care to individuals who have been injured and may possibly be in critical condition [1]. Trauma centers are divided into five levels, Levels I-V, with Level I centers fulfilling the most stringent standards and Level V centers adhering to the least stringent standards. Level IV and V centers are located primarily in rural and underserved areas and are tasked with providing 24-hour emergency care and providing resuscitation. These less comprehensive centers are seen as supplementary care facilities that transfer most patients to a trauma center with a higher designation [1].

Level III centers are capable of providing continuous surgical coverage with surgeons responding to patient arrival within 30 minutes at most. Level III trauma centers are able to manage most injuries, but they also have to

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transfer many patients to a Level II or Level I center [1].

Level II trauma centers place a significant emphasis on the delivery of care by an attending surgeon, and they have around-the-clock availability of an attending surgeon. Although residents are permitted to resuscitate patients when an attending surgeon is not immediately present, they cannot deliver care as an equivalent substitute for an attending surgeon. Level II trauma centers receive severely injured patients whose care cannot be comprehensively managed at a trauma center at any of the lower levels. In areas with low population densities, Level II centers are geographically distant from these areas. Conversely, in areas with high population densities, Level II centers supplement Level I centers to help provide further resources to care for all severely injured individuals [1].

Level I trauma centers have the exact same standards for quality of clinical care delivery as Level II centers. The two designations are distinguished from one another by additional requirements placed on Level I centers. The criteria for a Level I center includes admitting 1,200 trauma patients annually or admitting 240 patients who have an Injury Severity Score greater than 15, actively conducting trauma research, leading resident training and community outreach programs, and running a critical care service that is surgically directed [1].

Disparities in Trauma Care Among Rural Residents

Access to trauma centers is a major inequity across the United States. Compared to trauma patients living in states with more clustered centers, trauma patients living in areas where centers are more sparsely distributed experience significantly higher mortality rates [2]. Given that the leading cause of death among individuals under the age of 46 is traumatic injury, addressing the geographic disparity in access to trauma centers is a public health issue of paramount importance [3].

As of the most recent 2010 United States Census, approximately 29.7 million Americans lack adequate trauma care, living more than one hour away from a Level I or Level II trauma center by car or helicopter [4]. Living in large cities, suburbs, or high-income areas is associated with better access to trauma care whereas living in rural areas, areas with high uninsurance rates, and areas with high rates of Medicare and Medicaid beneficiaries are associated with poorer access to trauma care [4]. Furthermore, individuals from rural areas are 14% more likely to die following traumatic injury than non-rural residents, and this

disparity is especially prominent at Level I, Level II, and Level IV trauma centers [5]. Increased mortality in rural residents is likely due to a high time to treatment caused by living far away from trauma centers [5]. Rural residents also face disparities in pre-hospital deaths. In particular, subpar prehospital care, injury prevention initiatives, and trauma center access are implicated in prehospital deaths among rural residents, especially with regard to motor vehicular traffic (MVT) injuries and penetrating injuries [6].

Potential Improvements to Rural Trauma Care

A major issue facing rural communities is access to exceptional trauma care for particularly severe injuries. In rural regions where Level I and Level II trauma centers are especially inaccessible, it is common for patients to be taken to Level III trauma centers for stabilization before being transferred to the closest Level I or Level II center [7]. However, if Level III trauma centers were better developed as part of an organized, regionalized system, the number of transfers made to Level I or Level II trauma centers could potentially be reduced [7]. A reduction in transfers is associated with better allocative efficiency of resources from a holistic standpoint and further benefits to a patient and their family [7]. In fact, patients who are not transferred from a Level III trauma center to a Level I or Level II trauma center do not experience a significant difference in mortality, further suggesting a reduction in transfers would be beneficial to the trauma system [7].

Given that Level II trauma centers serve as main hospital facilities in rural areas located far away from Level I trauma centers, rural health outcomes could be improved by incorporating orthopedic traumatologists into patient care teams at Level II trauma centers [8]. Compared to general orthopedic surgeons, orthopedic traumatologists perform 16 of 18 procedures more efficiently, which is defined by completing surgeries in less time and subsequently with fewer labor, supply, and implant costs $[\underline{8}]$. By integrating orthopedic traumatologists more broadly into surgical teams, Level II trauma centers can better allocate limited resources by reducing costs $[\underline{8}]$. By becoming more efficient, Level II trauma centers can better fulfill their roles as the main deliverer of comprehensive trauma care in sparsely populated areas and as effective complementary care providers in densely populated areas with Level I trauma centers in the vicinity.

Additionally, trauma systems in rural areas would benefit from formally agreeing to share resources, which would improve allocative efficiency and access to trauma care for patients, especially those from rural areas [9]. By better placing medical helicopter bases to be able to comprehensively cover a greater area of land, geographic inequities in access to Level II and Level I trauma centers can be better addressed. These inequities can be more directly addressed by building more Level I and Level II trauma centers in rural areas or better staffing and funding Level III trauma centers already located in rural areas so that they can be upgraded to Level II or Level I designations. On a smaller scale, orthopedic surgeons can also opt to utilize more cost-effective implants and devices to make trauma care more affordable and subsequently more accessible, which is especially relevant in making trauma care available to the underinsured and the uninsured [10]. Furthermore, as of 2010, the National Institutes of Health allocated just 0.02% of its research budget for traumatic injury research [11]. By advocating for the building of new trauma centers the upgrading of existing trauma centers, striving to secure a larger research budget dedicated to trauma research, and making more fiscally conservative decisions regarding patient treatment and transfers without detracting from the quality of patient care, healthcare professionals, especially orthopedic surgeons, can strive to improve the rural trauma care system.

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In Memorium Richard D. "Nik" Nikolaev August 24, 1938 – December 19, 2019

Cipolletti, G¹

The worldwide orthopaedic industry lost one of our true giants, as Nik Nikolaev passed away in December of last year. Nik is survived by Sandy, his wife of nearly 60 years, daughter Kimberly and son Cort, of whom he was immensely proud. He is also survived by all of us who had the privilege of knowing and working with him, and by the millions of patients who received the gift of a new prosthesis that Nik was responsible for commercializing.

Nik was born in Moscow at the advent of the second world war and was shipped to the Ural Mountains with millions of civilians fleeing the German invasion. Nik's dad was exiled to Siberia and was never heard from again. Nik would recall his arduous journey out of Russia with his mother after the war, travelling on a cargo ship across the Black Sea, through the Suez Canal, and eventually finding their way to New York. The family relocated to Denver, where he spent most of his childhood. Nik had a strong desire to make his own way, joining the Marines at age 17. The strong, focused mind and self-discipline that were Nik's trademarks were almost certainly planted in these formative years.

Nik's legendary orthopaedic career got started with DePuy in 1966. At that time, DePuy's product line consisted mostly of plaster casting products, and his territory was the entire southwestern United States! He was very successful in the field, and was asked to take over as the product manager for a new product line – the Mueller Total Hip System, which in 1969 was the first commercially available total hip replacement system in the U.S. The suc-

cess of this new technology in the market place led to positions over the next 5 years National Sales as Manager and Vice President of Sales and Marketing, creating training programs and recruiting what was to become one of the strongest international sales and marketing teams our industry has ever seen.

Nik was an excellent salesman and sales leader, but it



Richard D. Nikolaev

was his vision of the future that will be his legacy. He took over as Executive Vice President for DePuy in 1975, overseeing all commercial and R&D activities for the company. He saw the future in cementless total hips, purchasing the company that developed the technology to sinter spherical beads onto an implant, then recruited Dr.'s Austin Moore and Emmett Lunceford to design what would become the AML stem. This was the first device to go through the new "PMA" process, and of course was the gold standard for cementless fixation for many years. Similarly, Nik recruited Dr.'s Beuchel and Pappas, introducing the first mobile bearing total knee system, the LCS. Again opting for the PMA route, this technology (since bought by J & J) remains the only mobile bearing knee available in the U.S.

In 1984, Nik was recruited by the Swiss company Protek, A.G., to become the President and CEO of their struggling US operation. Over the next 6 years, he presided over an average growth rate of 25% per year with excellent profitability, helping to create enough value that the parent was acquired in 1990.

This began the first in a series of the one area where Nik consistently "failed" – retirement. He joined the Board of Orthomet, Inc. after doing some consulting with them, only to be called on to take over as CEO when the company logged another dismal quarter of no growth and no profitability. Of course, Nik was able to turn things around, turning a profit in just his second quarter and growing at an average rate of 35%/year. The company's stock nearly tripled in value over 4 years, and was acquired by Wright Medical technology.

After a brief stint as CEO of Osteobiologics, Inc., Wright asked Nik to step in and lead the company as President and CEO, hoping to reduce their losses and revamp the product lines. He was able to bring costs under control, and brought the new Advanced Medial Pivot Knee to market with Mr. Michael Freeman and Dr. Kent Samuelson. He began the development of new extremity and biologics platforms, which eventually enabled WMT to divest its large joint products and focus on extremities.

Nik served on many Boards after leaving Wright and accepted the job as Chairman of the Board for a small startup, OMNI life science, Inc., serving from 2006 through 2013. He was a very active Chairman, instrumental in several key acquisitions and financings. On his watch, the company grew from a little over \$5mm in sales to nearly \$50mm. Nik seemed to know everyone in our business. It was impossible to walk more than 50 feet with him at a AAOS meeting without someone stopping him to say hello. Those who worked for Nik remember him as "tough but fair", and he never asked anyone to work harder than he did. He would be on the Academy floor 30 minutes before opening through closing, and wouldn't tolerate anyone sitting in the booth. He developed a unique way of letting you know when you were in trouble with him- he would leave a stuffed Gorilla on your chair. It was bad enough to get a Gorilla, but Heaven help you if you didn't know why you got it!

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AUTHOR DISCLOSURES

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Reconstructive Review has adopted the American Academy of Orthopaedic Surgeons (AAOS) Levels of Evidence for Primary Research Question. These guidelines will now be part of the review process for manuscript submission.

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	 High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic Review2 of Level I RCTs (and study results were homogenous3) 	 High quality prospective study4 (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) Systematic review2 of Level I studies 	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review2 of Level I studies	 Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review2 of Level I studies
Level II	 Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) Prospective4 comparative study5 • Systematic review2 of Level II studies or Level 1 studies with inconsistent results 	• Retrospective6 study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review2 of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review2 of Level II studies	 Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review2 of Level II studies
Level III	• Case control study7 • Retrospective6 comparative study5 • Systematic review2 of Level III studies	Case control study7	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review2 of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review2 of Level III studies
Level IV	Case Series8	Case series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

- 2. A combination of results from two or more prior studies.
- 3. Studies provided consistent results.
- 4. Study was started before the first patient enrolled.
- 5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
- 6. The study was started after the first patient enrolled.
- 7. Patients identified for the study based on their outcome, called "cases"; e.g. failed total arthroplasty, are compared to those who did not have outcome, called "controls"; e.g. successful total hip arthroplasty.
- 8. Patients treated one way with no comparison group of patients treated in another way.

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Article 2, page 15.

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