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# Orthopaedic trauma surgery in low-income countries

## Follow-up, infections and HIV

Sven Young

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From the Department of Clinical Studies,
Haukeland University Hospital,
University of Bergen
Norway

# Orthopaedic trauma surgery in low-income countries

## Follow-up, infections and HIV

**Sven Young**


**Doctoral Thesis**

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## Contact address

Sven Young
Department of Orthopedic Surgery
Haukeland University Hospital
5021 Bergen
Norway
E-mail: svenyoung@gmail.com

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(Photo Sven Young)

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# Contents

ACKNOWLEDGMENTS, 2

ABBREVIATIONS, 2

LIST OF PUBLICATIONS, 2

BACKGROUND, 3
- A brief history of intra-medullary nailing of the femur, 3
- The growing burden of trauma in LMICs, 5
- The global distribution of health services, 5
- Realities of trauma care in low-income countries, 5
- Malawi and Kamuzu Central Hospital, 6
- Postoperative infection after surgery in LMICs, 7
- The HIV pandemic and trauma surgery, 7
- SIGN Fracture Care International, 8
- The SIGN Online Surgical Database, 9
- Follow-up and research in LICs, 9

STUDY AIMS, 10

METHODS, 11
- Paper I: Validation of the SOSD for research on trauma surgery in LMIC. Lack of follow-up, 11
- Paper II: Risk factors for infection in the SOSD, 11
- Paper III: Complications after IM nailing in Malawi, 11
- Ethical considerations, 12

SUMMARY OF PAPERS I–III, 13

DISCUSSION, 15
- Follow-up, 15
- Infections, 16
- HIV, 18
- Study design and limitations, 18

CONCLUSIONS, 20

FUTURE RESEARCH, 21

SUMMARY, 22

REFERENCES, 23

APPENDIX, 26
- SOSD postoperative registration form, 26
- SOSD follow-up visit registration form, 29
- Data collection form, KCH study, 30
- Follow-up registration form, KCH study, 32

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# List of Publications

This thesis is based on the following three papers. They are referred to in the text by their roman numeral.

**Paper I:** Young S, Lie SA, Hallan G, Zirkle LG, Engesæter LB, Havelin LI. Low infection rates after 34,361 intramedullary nail operations in 55 low- and middle-income countries. Validation of the Surgical Implant Generation Network (SIGN) Online Surgical Database. Acta Orthop 2011; 82 (6): 737-43.

**Paper II:** Young S, Lie SA, Hallan G, Zirkle LG, Engesæter LB, Havelin LI. Risk Factors for infection after 46,113 intramedullary nail operations in low- and middle-income countries. World Journal of Surgery 2013; 37 (2): 349-55.

**Paper III:** Young S, Banza L, Hallan G, Beniyasi F, Manda K, Munthali B, Dybvik E, Engesæter LB, Havelin LI. Complications after intramedullary nailing of femoral fractures in a low-income country. Acta Orthop 2013; 84 (5): 460-7.

# Abbreviations

| | |
|---|---|
| **AIDS** | Acquired Immunodeficiency Syndrome |
| **AO** | Arbeitsgemeinschaft für Osteosynthesefragen |
| **C-arm** | The same as II. The arm of an II x-ray machine is C-shaped |
| **CI** | 95% Confidence Interval |
| **CME** | Continuing Medical Education |
| **DALY** | Disability Adjusted Life-Years |
| **FDA** | Food and Drug Administration, USA |
| **gam** | Generalized Additive regression Model |
| **GNI** | Gross National Income |
| **HIC** | High-Income Country |
| **HIV** | Human Immunodeficiency Virus |
| **HUH** | Haukeland University Hospital |
| **II** | Image Intensifier; low-dose x-ray machine used during surgery |
| **IM** | Intramedullary, ie., inside the medullary canal of a long bone |
| **K-nail** | Küntscher nail |
| **KCH** | Kamuzu Central Hospital |
| **LIC** | Low-Income Country |
| **LMICs** | Low- and Middle-Income Countries |
| **MDGs** | Millennium Development Goals |
| **NAR** | The Norwegian Arthroplasty Register |
| **OR** | Odds Ratio |
| **ORIF** | Open Reduction and Internal Fixation |
| **PE** | Pulmonary Embolism |
| **SIGN** | SIGN Fracture Care International |
| **SOSD** | SIGN Online Surgical Database |
| **UK** | The United Kingdom of Great Britain and Northern Ireland |
| **UN** | The United Nations |
| **USA** | The United States of America |
| **VTE** | Venous Thromboembolism |
| **WHO** | The World Health Organization |

# Background

## A brief history of intramedullary nailing of the femur

*"…this method of introducing a long internal peg into the femur from the trochanter is one of some value…"*

Ernest W. Hey Groves, 1918.

Femoral fractures have been treated for many centuries by extensive periods of traction and bed rest. The outcomes were in many instances acceptable, but often terrible. Though improvements in traction (or "extension" as it was often called) techniques in the 19th and early 20th century improved outcomes a great deal, treatment still meant bed rest for months, and doctors were continually searching for better ways to treat femoral fractures. Lister's principles of antiseptic surgery and the discovery of anaesthesia in the mid 19th century opened the way for modern orthopaedic surgery.

The idea of stabilizing a fracture by inserting a peg in the medullary canal of a long bone is not a new one. In Mexico the Aztec apparently inserted wooden pegs into the medullary canal of non-united bones. This practice was described by Bernardino de Sahagún who travelled with Hernando Cortes to Mexico in the 16th century.[1,2] The Aztec seem to have used some kind of numbing anaesthesia (at least for human sacrifice…) and the use of "very resinous wood"[1] for the intramedullary peg possibly acted as an anti-infectant after the peg was inserted. A method of drilling holes in the bone near to a non-union and inserting ivory pegs to stimulate healing was attempted by several surgeons from the mid 19th century,[3,4] but this was not really IM nailing as we think of it. Bircher was probably one of the first to suggest a more systematic use of intramedullary implants when reduction could not be held by traction or plaster. He inserted short intramedullary ivory pegs into the intramedullary canal through the fracture site to hold the fracture in place while it healed and published a well illustrated paper of his technique in 1886.[5]

Hey Groves used ivory pegs similar to those described by Bircher to treat femoral fractures after gun shot injuries during the First World War, but realized that they did not give sufficient stability to allow mobilization of the joints. He experimented using a long metal "peg" introduced from the trochanter. He published a series of 60 patients treated with different methods for non-union after gun shot wounds in 1918.[6] In this article he argued that fixation of fractures and motion of the joints promoted healing, and that rigid immobilization with casts, operations with stripping of the periosteum and plating without compression or good contact across the fracture, led to non-union, essentially spelling out the problems facing the AO half a century later. Hey Groves was dealing with infected non-unions and did not have access to stainless steel or antibiotics. Consequently the results also of the four IM fixations in his series were not good. However, he concluded that "… this method of introducing a long internal peg into the femur from the trochanter is one of some value in special cases…".[6]

By the 1920s, however, stainless steel was available, and after Smith Peterson's paper popularizing nailing of neck-of-femur fractures with stainless steel nails in 1931, more people started to experiment with metal implants. Rush and Rush published a series using their rods for proximal ulna and proximal femur fractures in 1939.[7] Though the rods held the position of the fragments in subtrochanteric fractures, the technique did not give sufficient stability to allow full mobilization of the patient and this treatment did not gain much popularity. However, "Rush Rods" were widely used in the upper extremity until the introduction of AO plating techniques in the 1960s.

In Germany, Müller-Meernach used stainless steel nails with an X-shaped cross-section introduced from the fracture site from the early 1920s and reported good results with early mobilization of the patients.[8] Gerhard Küntscher was well acquainted with this work and had extensive experience with Smith Peterson Nailing of hip fractures.[9] He was impressed with how well his own first 132 patients using the Smith Peterson technique for hip fractures did. Out of the 132 patents there were 9 infections (7%), and only one he describes as deep, but they all resolved. Küntscher realized this was much less than in other open techniques used at the time and attributed this to the fact that the fractures had not been opened. He also believed that leaving the fracture haematoma, periosteal- and endosteal blood supply intact was beneficial to good healing.

Küntscher had trained briefly in an x-ray department as a young doctor and knew the method of fluoroscopy. He used a long nail that could be inserted away from the fracture site through the trochanter major of the femur. To obtain sufficient stability for the fracture to heal and to mobilize the patients quickly he wanted the nail to impinge in the bone much like a nail that is driven into wood gains purchase because of the elastic and frictional forces of the wood on the nail. Since bone is hard and brittle Küntscher used a nail with a v-shaped cross section that could be elastically compressed instead of the bone, which is why he chose the name "nail". Before he tried the method on humans he did a series of surgeries on the fractured femurs of dogs. The dogs were able to stand on their hind legs alone ("Männchen zu machen") after only 8 days. He refined the technique for use in humans and used a traction table and fluoroscopy to pass the nail into the distal fragment without opening the fracture, much as we do today.

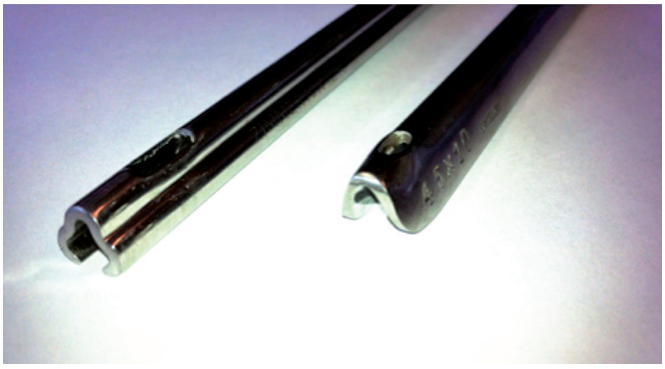

Figure 1. Küntscher's first design of intramedullary nail had a V-shaped cross section (nail on the right). Later on he advocated the use of a nail with a cloverleaf shaped cross section. The nails had a hole near the end for ease of removal. (Photo Sven Young)

He operated his first patient with the technique in 1939 and published his first results after 11 femoral IM nails in 1940,[9] including all the above information and the name of the instrument maker, Ernst Pohl of Kiel, who made and sold the nails and instruments. Though his technique at first met some resistance from his peers, the Second World War was raging and there were large numbers of young men with fractures filling the hospitals. The patients treated with the "Küntscher-nail", or "K-nail", were out of bed in a matter of days rather than months and the technique quickly spread through Germany and Austria during the war.[10] It quickly became apparent how much better the patients did compared to patients treated with traction. Hospital stays were reduced from months to a few weeks and the average number of working days lost were reduced from up to three years (!) to around three months.[11]

In the UK and America, Küntscher's technique first became known through returning allied prisoners of war who had been treated during captivity in Germany. At first there was great scepticism towards the technique, but people quickly saw how well these patients did and publications of cases treated by the Germans appeared both in the UK and the US during and just after the war.[2,12]

After the war Küntscher developed the guide wire technique for closed nailing, a Y-nail for trochanteric fractures,[11] flexible intramedullary reaming, and changed the cross-sectional profile of his nails from the V-shape to a cloverleaf shape so it could be compressed from all sides.[13] The V-shape only allows compression in one plane (Figure 1). His technique spread quickly throughout Europe and the US. However, many surgeons were, understandably, concerned about the use of the head mounted fluoroscopy used at the time. Essentially the surgeon wore a fluorescent piece of glass in front of his eyes and an x-ray beam was aimed straight at the surgeon's head through the patient's thigh. This, and the fact that penicillin was now available, led to the return to the old technique of open reduction and retrograde nailing from the fracture site that some surgeons still erroneously call the "K-nail technique". This had nothing to do with Küntscher. He was the first to systematically leave open reduction of femoral fractures behind. Not until the introduction of the C-arm image intensifier in 1955[14] (Figure 2) did the technique of closed nailing on a traction table regain acceptance. By that time, many surgeons had forgotten that this was in fact the original K-nail technique.

Figure 2. The introduction of the C-arm image intensifier in the 1950s and -60s made the use of closed x-ray guided nailing safer for the surgical staff. Before this you would wear a box on your head with a piece of fluorescent glass in front of your eyes. The x-ray beam would be aimed straight at your face. The picture shows the Philips BV20 C-arm introduced in 1955 and in use until the late 1960s. This one was used at Haukeland University Hospital. (Photo Sven Young)

In the 1960s, the popularity of IM nailing diminished as a result of the AO organization promoting the use of exact reduction and compression plating, but by the 1980s surgeons were again realizing the superior results of nailing, especially in femoral fractures. The problem of shortening and rotational instability was solved by using interlocking screws through the nail above and below the fracture. One of the earliest versions of an interlocking IM nail was described as early as 1953.[15] Küntscher's nailing principle with a compressible nail was used even after interlocking screws had become the gold standard of care, and his design of a slotted stainless steel nail with a cloverleaf cross section was integrated into the AO

and Grosse-Kempf nails. However, in the 1990s surgeons and designers of new nails realized the use of interlocking screws had removed the necessity for a "nail" that impinged in the medullary canal. The use of titanium, which is lighter, stronger and closer to the bone's own rigidity was introduced. Most nails used in high-income countries today are rigid titanium nails with a built in curve to match the anatomy of the femur. Though we still use the word "nail", modern "nails" are more an internal splint or rod, where the rotational and shortening forces are held by the locking screws when the fracture does not have integral stability.

Intramedullary nailing has now been used for over a century and has been the established treatment of choice for femoral fractures in Europe and the USA for over half a century. Yet in many low-income countries today traction is still the only available treatment.[16-18] History, I think, gives this fact some perspective.

## The growing burden of trauma in LMICs

Nearly six million people die annually from injuries, more people than die of HIV/AIDS, tuberculosis and malaria combined.[19,20] Over 90% of these fatal injuries occur in low- and middle income countries (LMIC). For every death from injury, between 3 to 10 more people survive an injury with a permanent disability.[21,22] If you look only at young people between the ages of 10 and 24 years, and thereby exclude expected deaths due to old age, as many as 97% of deaths occur in LMICs, over 40% of deaths are related to injuries, and road traffic injuries are the most common cause of death.[23] Injuries not only disproportionately affect the younger segment of the population in LMICs, they have a serious impact on the family of the injured as a whole. Low- and middle income countries often have no functioning social security systems and the injury of a young mother or father, often the breadwinner of the family, can be devastating to their economic situation and push them further into poverty.[24]

The global burden of injuries is growing rapidly, and almost entirely in LMICs. The main cause of this is the rapid increase in road traffic injuries.[25,26] By 2030, the World Health Organization (WHO) expects road traffic accidents (RTAs) to have risen from the 9th to the 5th leading cause of all deaths globally,[27] only surpassed by the diseases of old age such as cardiovascular, cerebrovascular and pulmonary disease. Despite these compelling facts, surgery is not mentioned at all in the Millennium Development Goals[28,29] (MDGs: http://www.un.org/millenniumgoals/). To be fair, we are currently seeing the beginnings of an increasing awareness of surgery as an integral part of the global public health effort to reach the MDGs,[28,30-33] but over 40 times as many research articles have been published on HIV in Africa than on road traffic accidents,[26] and nearly 190 times as much money was donated to LMICs for treatment of HIV than for unintentional injuries in 1990.[34]

## The global distribution of surgical health services

Africa has 24% of the global burden of disease, but has only 3% of the World's health workers and commands less than 1% of world health expenditure.[20] As a concrete illustration of the realities of these facts, the Ministry of Health in Malawi has the very modest target of 40 government employed surgeons for the whole of its 15 million inhabitants. In February 2013, only 3 of these 40 posts were filled, a vacancy rate of 92.5%.[35] The Central Region of Malawi has a population similar to that of Norway, around 5 million inhabitants. Central Region has only two orthopaedic surgeons, both funded from outside the country. In July 2013 there were 957 registered orthopaedic surgeons in Norway,[36] nearly 500 times more.

Weiser et al. reported that an estimated 234 million major surgical operations were performed in the world in 2004.[37] Of these only 3.5% were performed in the poorest 35% of the World's population. The number of performed major operations is already twice the number of annual births and seven times the number of people living with HIV.[38] However, the actual surgical workload is probably many times larger than this, as minor surgical procedures and non-operative treatment were not included in the study by Weiser and his colleagues. A cluster randomized nation-wide survey in Sierra Leone, published in The Lancet in 2012,[39] found that 25% of the population were living with a condition that could be treated by surgery, and that 25% of the reported deaths of family members in the last year could possibly have been avoided by surgical intervention. This is one of the first papers of its kind to document the huge need for surgical services in low-income countries.

## Realities of trauma care in low-income countries

The realities of trauma care in low-income countries (LICs) can be very harsh. No pre-hospital trauma care, or even a simple pick-up service ambulance, is usually available, and most patients are brought to hospital by "good Samaritans", family members or the police.[40] By that time the most severely injured are already dead. Transport is difficult and very expensive for the rural poor in LICs. This often stops people from seeking help until it is obvious they are not going to get better by themselves – or with the help of a local traditional healer. The next step is for the family to transport the patient to a local health care facility. The patient will most likely be referred to the nearest district hospital, but there will often only be the choice of plaster of Paris (POP) casting or traction. By the time the patient is seen at a central hospital often many weeks – or even months – will have passed. Even obvious emergencies such as severe open fractures often come late and are infected by the time they reach a facility that can help. Consequently, a large proportion of the fractures treated by orthopaedic surgeons in a LIC will be neglected fractures.[16]

Operating time is scarce even in referral hospitals, and prioritizing which patients to offer treatment can be hard. All this makes orthopaedic trauma surgery even more challenging in LICs than in high-income countries.

Despite half a century's experience with the good results of IM nailing, and increasing new evidence that IM nailing is more cost effective than traction,[41,42] femoral fractures are still treated in traction in most hospitals in sub-Saharan Africa, and in many other LMICs around the world. This confines the patients to bed for one and a half to three months,[17,43] and makes them dependent on walking aids for another six to twelve weeks. Contrary to some surgeons' belief, complications are common, with up to 42% pin tract infections, 22% non-union and 14% mal-union.[41,43] Pulmonary embolism[44] and serious infections[18] are also seen while on traction. People's perception of the suffering involved in being treated on traction in a Malawian hospital are well illustrated by Patrick Kaliati's wood carving, "The Patient" (see cover).

Hospitals in LICs lack many basic services that we take for granted in high-income countries (HIC). VTE prophylaxis in the form of low-molecular-weight heparin is expensive and usually not available. Simple blood tests such as haemoglobin (Hb) might not be available all the time.[18] There is often no equipment for postoperative monitoring of patients. Oxygen is often not available and even the supply of water and electricity might be erratic.

In surgery in general, but especially in orthopaedic surgery, some specialized equipment is needed. Lack of equipment forces surgeons to improvise and compromise and, though many surgeons can make this work through good knowledge of historical techniques and adherence to proper surgical and mechanical principles, this also leads to many bad results. Many people who have experienced these conditions wish to help, and under the principle that "something is better than nothing" a lot of old equipment is donated to hospitals in LICs. When these donations are well thought through they can be very helpful, but incomplete donations of implants etc can also tempt inexperienced surgeons to do surgery with inappropriate equipment.[16] The reason electro-medical equipment is decommissioned in HICs is that it is getting to an age where maintenance and repairs are becoming more necessary and more expensive. When this equipment is sent as it is, without a thorough overhaul to a LIC with no funds or systems for maintenance, it invariably breaks down quickly and becomes a new problem for the recipient.[45] They now also have a growing mountain of environmentally harmful scrap.

When we are comparing results from low-income countries with those from high-income countries we need to have in mind the setting in which the surgery was carried out. However, despite often being overwhelmed by the situation they find themselves in, short-term visitors to a LIC should not automatically conclude that it is unsafe to do surgery there. This has unfortunately probably been the case for many years, and has given rise to many myths used as arguments opposed to surgery in LICs. More research is urgently needed to confront these myths and to focus attention on the important contribution of surgery in global health.

## Malawi and Kamuzu Central Hospital

Malawi is a small land-locked country lying along the western shore of Lake Malawi bordered by Tanzania, Mozambique and Zambia in southern Africa. It has a population of around 15 million and one of the highest population densities in Africa. In 2012 Malawi was ranked number 170 out of 186 countries on the United Nations' Human Development Index. Norway was ranked as number 1. (http://hdrstats.undp.org/en/countries/profiles/MWI.html)

Because of the surgical workforce situation in LICs mentioned earlier, Haukeland University Hospital has been supporting Kamuzu Central Hospital in the capital city of Malawi, Lilongwe, to develop a postgraduate surgical training programme since 2007.[46] Through involvement in this cooperation I have had the privilege of working at KCH for several shorter and longer periods. The introduction of SIGN intramedullary nails to KCH in 2008 secured a steady supply of implants for the treatment of femoral fractures and laid the foundation for the study in Paper III.

Surgeons at KCH have done approximately 75 SIGN IM nail operations a year so far. Because of the severe lack of surgeons and theatre time at KCH, this is far below the actual number needed. At district hospitals in Malawi there are no surgeons and there is no equipment for IM nailing. Consequently all patients are still treated with traction. Even at our referral hospital in the capital city we are still forced to treat most patients with femoral fractures with traction while they wait for surgery.

For many, this becomes the definitive treatment. By the time we have available theatre time, many weeks may have gone by and some fractures are already healing (Figure 3). If this is the case, we are forced to give priority to other patients, sometimes patients with similar injuries who have waited a much shorter time. This will, of course, seem very unfair to the patients – and will no doubt also seem questionable to outside observers. However, in order to get the maximum amount of benefit for patients out of our limited resources, it is often necessary to prioritize cases that have a predictable outcome and will benefit the most people – not necessarily those who have the worst injury or have waited the longest. Many clinical decisions might, like this, be different in a low-resource setting compared to in high income countries, and it can be very difficult to adapt to this for a surgeon trained in a high income country.

Figure 3. Radiographs of a 20 year old man treated for a femoral fracture at Kamuzu Central Hospital. He was treated on traction for two and a half months. The fracture healed with shortening (left panel) and he was discharged home on crutches. He stopped using the crutches three months later or nearly half a year after the fracture but was still limping when walking. One year later his femur re-fractured while walking normally along the road. This time he was operated with a SIGN IM nail (right panel) and was up on crutches within a few days and ambulating without crutches a few weeks later. (Photos Sven Young)

## Postoperative infection after surgery in LMICs

*"Postoperative infection is the saddest of all complications..."*
Sir John Charnley, 1982.

Deep infection after orthopaedic implant surgery can be disastrous. It invariably leads to prolonged hospitalization, more operations, increased suffering for the patient and increased costs to society. To address this, orthopaedic surgeons have continuously tried to increase the sterility of the operating field, even through reducing the number of microscopic particles in the air in the theatre with special types of ventilation. It might be understandable, then, that when surgeons from high income countries meet the realities of surgery in hospitals in LICs they assume results will be bad. Visiting surgeons to LICs will see many cases of acute and chronic osteomyelitis, septic joints, neglected open fractures and many amputations done on septic indications. Naturally there will be more surgical site infections in this setting.[47] They will also, most likely, see badly performed ORIF done with inappropriate implants by undertrained visiting and local surgeons.[16] All this, unfortunately, seems to have led to a widespread belief among many surgeons and policy makers in high income countries that postoperative infection rates are very high in LICs and that orthopaedic implant surgery is best avoided there. Several reports of high infection rates after abdominal and gynaecological surgery in LICs have added to this perception.[48-51] There is, however, no scientific basis for the assumption that modern orthopaedic trauma surgery, when done in a well-organized manner by well-trained surgeons, will have the same high infection rates. In fact several papers have reported similar outcomes in LMICs and HICs.[52,53] Most hospitals, even in LICs, have the basic requirements for sterile surgery such as autoclaves, antiseptic wash and prophylactic antibiotics. If the surgeon receives the correct implants and good training, such as through a SIGN programme, is there really any reason why results should not be good? This is one of the questions I have attempted to address in this thesis.

## The HIV pandemic and trauma surgery

Since the first reports of Acquired Immune Deficiency Syndrome (AIDS) in California in 1981 and the discovery of the Human Immuno-deficiency Virus (HIV) in 1983,[54] HIV/AIDS has been high on the global public health agenda, and for good reason. Currently an estimated 34 million people are living with HIV; 23 million of these, more than two thirds, live in sub-Saharan Africa.[55] In Malawi, where we conducted the study in Paper III, the HIV prevalence in the adult population between 15 and 49 years is 10%. Internal audits in the medical department at Kamuzu Central Hospital (KCH) have revealed an HIV prevalence among the patients of up to 30%.

In the 1980s HIV/AIDS was a semi-acute lethal infection. With the development of anti-retroviral therapy (ART) from the 1990s, HIV infection can now be supressed so efficiently that the virus is undetectable in the blood and CD4 T-lymphocyte levels are in the normal range. Consequently, HIV positive patients no longer need to develop AIDS and die of opportunistic infections after only a few years. HIV infection has become more of a chronic disease, with the possibility of a normal lifespan, in countries where affordable ART and good follow-up is available.

Unfortunately, the stigma of the 1980s HIV scare still hangs over the disease. The logical assumption has been that HIV positive trauma patients will have more postoperative infections and worse outcomes than HIV negative patients. The fear of patient to surgeon transmission of HIV has also probably contributed to some surgeons being sceptical of the use of internal fixation in HIV positive patients. This has even led to recommendations that ORIF should be avoided in the treatment of closed fractures in HIV positive patients.[56] However, there is very little documentation to support this policy. In Paper III we sought to shed more light on this issue.

Another aspect of the HIV pandemic in sub-Saharan Africa, is its direct and indirect impact on the health workforce. In

Figure 4. The SIGN intramedullary nail has a proximal bend like a traditional tibia nail. However, it is used without problems both antegrade and retrograde in the femur and antegrade in the humerus. The fact that it is a solid stainless steel nail makes it stiffer, so the target arm is more likely to indicate the correct position of the distal screw slots in the nail. (Image © SIGN Fracture Care International. Used with permission.)

parts of southern Africa where prevalence rates of HIV in many places are above 10% there is, of course, a similar HIV prevalence among the health care workers themselves. This and other factors has lead to a high mortality rate also among health workers,[57] and is devastating to an already minimal and overworked health workforce. In addition, the fear of patient to surgeon transmission during surgery can be an extra "push factor" leading to "brain drain" of health workers from sub-Saharan LMICs.

## SIGN Fracture Care International

SIGN Fracture Care International (SIGN) is a non-profit organization based in Washington State, USA, that provides orthopaedic surgical implants and instruments to hospitals in low-income countries free of charge (www.signfracturecare.org). Dr Lewis G. Zirkle was drafted as a young resident orthopaedic surgeon in the Vietnam War. He was appalled by the difference in care given to civilians and soldiers and insisted on treating the local civilian population the same as the American soldiers. After the war he returned to Asia many times and helped train orthopaedic surgeons in Vietnam and Indonesia

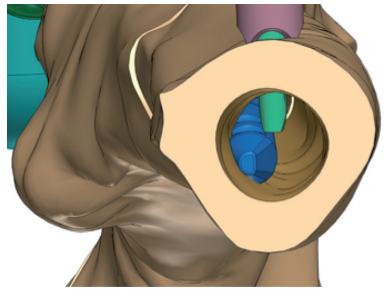

Figure 5. The SIGN nail (blue) is solid, i.e. has no cannulation. "Slot finder" instruments (green) are used with the SIGN IM nail to find the screw slots in the nail. When the nail does not lie centrally these instruments allow the surgeon to feel for the slot by twisting the nail and changing the angle of the slot finder. Once the "slot finder" is placed in the slot, the opposite cortex can be drilled through the instrument. (Image © SIGN Fracture Care International. Used with permission.)

over many years. One day he came across a patient in Indonesia that had been treated in traction for three years because he could not afford to buy the implants needed to treat his fracture. It then became clear to Dr Zirkle that it was useless to train surgeons to treat fractures unless they also had access to the equipment needed.[58]

Since then SIGN has developed an FDA approved intramedullary nail that can be used without expensive equipment such as an orthopaedic traction table, C-arm image intensifier (II) or surgical power tools.[44,59-61] The SIGN nail instruments include an external target arm (Figure 4) used to drill the holes for the distal interlocking screws, and specially designed instruments ("slot-finders") are used to ensure the screws are placed through the slots in the IM nail (Figures 4 and 5).

The SIGN nail itself is a solid stainless steel nail with a bend proximally like a traditional tibial IM nail (Figure 4). This allows its use for tibia fractures as well as in antegrade and retrograde femoral nailing and humerus nailing. The fact that the nail is solid makes it stiffer so the target arm is more likely to indicate the correct position of the distal slots in the nail. Also it reduces the surface area of the nail and dead space in the IM canal, possibly reducing the risk of infection. The design of the holes in the nail as oval slots, not round holes, makes the use of the "slot-finder" instruments possible and allows some dynamic compression of the fracture on weight bearing. The top hole in the nail is, however, round so that a screw placed here will statically lock the nail in place. This, amongst other things, prevents the nail backing out into the joint when used retrograde in the femur or antegrade in the humerus.

In LMICs traction tables and C-arm IIs are rare. In addition, one is often dealing with neglected or late-presented fractures. Therefore open reduction is usually necessary and reaming of the distal fragment is done from the fracture site. Since 1999, SIGN has supplied over 80,000 IM nails and provided training to surgeons in the correct use of the nail in over 200 hospitals in low- and middle-income countries.[62]

## The SIGN Online Surgical Database

The SIGN Online Surgical Database (SOSD) was established in 2003 to ease communication between SIGN and the surgeons using SIGN IM nails. Since then, when a SIGN nail is used the operation is reported to SIGN via the SIGN Online Surgical Database (SOSD) so SIGN can send a replacement nail and locking screws of the right size to the hospital.

In addition to being a fast and effective way to report what nails have been used and need to be replaced, SIGN has realized that the SOSD is an important tool for communicating with surgeons that use the system. The fact that broken instruments or nails are also replaced motivates surgeons to report difficulties with the system so SIGN can constantly evaluate and improve the system. The surgeon also uploads pre- and postoperative radiographs, and all radiographs are reviewed by an orthopaedic surgeon at SIGN in the USA. When the surgical technique does not seem to have been up to scratch or there have been technical problems with the operation SIGN discusses this with the surgeons at that specific hospital. In effect SIGN is also probably the largest single provider of continuing medical education (CME) to surgeons in many of the countries using their nails. Not all problems and complications are apparent immediately postoperatively, though, and SIGN also realizes the need for research on longer term outcomes. Surgeons are therefore strongly encouraged to register follow-up visits in the SOSD, including a few basic clinical parameters and radiographs. A copy of both the SIGN Postoperative Data Collection Form and the SIGN Follow-up Form have been included in the Appendix to show what data is included in the SOSD.

The SOSD in October 2010 contained over 36,000 IM nail operations in 55 LMICs.[63] By November 2011 another 10,000 operations had been added to the SOSD,[62] making it one of the largest and fastest growing databases of orthopaedic trauma surgery in the world. SIGN kindly allowed us to use this data in the first two studies included in this thesis.[62,63] The SOSD has one problem, however; a very low rate of registered follow-up. In 2009 it was reported to be only 12.6%.[64] This is why we wished, in Paper I, to validate the data in the SOSD to see if it could be used for further scientific research.

## Follow-up and research in LICs

The achievement of high enough follow-up rates is a concern in clinical research all over the world, but is especially difficult in low-income countries. Surgeons in LICs often tell you that their patients do not return unless they feel they have a problem. The reason usually given for this is the availability and cost of transport. In Malawi over 80% of the population still live in rural villages and depend on subsistence farming. People have very little cash income and transport is expensive. When someone needs to go to hospital in town this can lead to the family having to borrow money or sell off some of their property.[24] For someone who has very little this is a considerable investment, and it would be understandable if people did not want to use money on this if they had no complaints.

Lack of follow-up after surgery in low income countries is problematic in many ways. Most importantly, it may result in inferior results for patients where early postoperative complications are not addressed in a timely or proper manner. But also, studies with low follow-up rates are less likely to be published, contributing to the exclusion of studies from LICs from the literature.

In research we cannot trust our results fully unless we actually confirm progress of the people in the study. In reality, we always lose some patients to follow-up. This is often addressed by excluding all patients in a study who did not return for follow-up. However, if the proportion of people who do not return for follow-up is large, and it is true that patients in LMICs do not return if they are feeling well, this will give the results a strong negative bias; you will be looking at a group of patients with an over representation of those that came back because they had a problem. This negative "selection bias" may also have contributed to the perception that surgery results in bad outcomes in LMICs.

In papers I and III we wished to see if we could get a clearer picture of the pattern of follow-up and its effect on results after IM nailing in LMICs.

# Study aims

The overall aim of this thesis was to contribute to the current knowledge on follow-up patterns and infection rates after intra-medullary nailing in low- and middle-income countries.

The specific aims of each paper were:

*Paper I:* To describe the pattern of follow-up in the SIGN Online Surgical Database (SOSD) and discuss whether the registered data, in light of the low reported follow-up rates, could be used in future in-depth research into infection rates and risk factors.

*Paper II:* To use the data in the SOSD to investigate whether the follow-up and infection rates were changing over time and to identify risk factors for infection after IM nail operations in LMICs.

*Paper III:* To examine the possibility of approaching 100% follow-up in a low-resource setting in Malawi, and to clarify whether patients who did not return for follow-up after femoral nailing really did have fewer complications than those that returned as scheduled. Considering the regional impact of HIV, we also wished to compare outcomes in HIV-positive and HIV-negative patients.

# Methods

Below I wish to explain briefly the basic methods used in this thesis and in our three papers. I do not wish merely to repeat the method sections from the papers, but rather to rephrase these descriptions and the thoughts behind the methods in simpler language. Papers I-III are all published under the Creative Commons Attribution licence as open access and can be downloaded for free from the respective journal's Internet site. I refer the reader to the original articles for a more detailed description of the methods used in each paper.

## Paper I. Validation of the SOSD for research on trauma surgery in LMIC. Lack of follow-up

SIGN kindly supplied our research group with a data file containing an anonymous export of all surgeries registered in the SOSD from the start of the registry in 2003 to October 8th 2010. The SOSD then contained surgeries using 36,454 SIGN IM nails. After exclusion of humerus and hip fractures and cases with missing data, there were 34,361 IM nail operations of the tibia or femur remaining for analysis. These operations were performed in 55 different low- and middle-income countries with widely differing follow-up rates. With the belief mentioned in the chapter on "Follow-up and research in LICs" in mind (page 9), that patients in LICs do not return for follow up if they have no complaints, this offered the possibility to study if there is a relationship between the amount of follow-up and the infection rate in different countries. In other words: Do most people with postoperative infections in LMICs actually come back for follow-up, or do countries with higher follow-up rates find more infections and therefore get higher infection rates?

To visualize the relation between the follow-up rates and the risk of infection, Professor Stein Atle Lie used a generalized additive regression model (gam), with spline smoothing of the follow-up rates compared to the risk of infection to generate a graph (Figure 8). He calculated follow-up rates over time based on fixed effects in a mixed effects Poisson regression model (Paper I, Figures 1 & 2). The analyses were done using the lme4 and the mgcv libraries in the statistical computer program R, version 2.12.2 (R Development Core Team 2010).

## Paper II. Risk factors for postoperative infection in LMIC. Data from the SOSD

Having to some extent established in our first paper that the SOSD could be used for research into risk factors for infection after IM nailing in LMICs, in our second study we wished to do just that. One year after our first study validating the data in the SOSD, it contained data on 46,722 IM nail operations, 10,000 more than the year before. SIGN provided us with a new anonymous export of all surgeries registered in the database from the start of the registry up to November 29th 2011. This time we also included humerus fractures and only excluded the relatively few hip fractures and the very few operations done in high income countries, leaving 46,113 IM nail operations of the humerus, femur or tibia for analysis. In this paper, simpler (logistic regression) statistics were employed to calculate both crude and adjusted risk, odds ratio (OR), of postoperative infection after IM nailing for different risk factors.

## Paper III. Postoperative complications after IM nailing in Malawi. Lack of follow-up and impact of HIV

The introduction of SIGN intramedullary nails for the treatment of long bone fractures in 2008 at last allowed Kamuzu Central Hospital to step into the modern era of orthopaedic trauma surgery. It gave us the opportunity to prospectively follow up in more detail a local series of SIGN nail patients to determine the infection rate after surgery in our specific setting in Malawi. Also, if we could trace the patients that did not return for follow-up of their own accord, we might find out if these patients really did have fewer complications than those who returned for scheduled follow-up.

In addition to the data recorded for the SOSD, a separate Study Data Collection Form was used for all patients to record additional information. A copy of this form is included in the Appendix. Information about patients who returned for follow-up was recorded on the SIGN follow-up form and uploaded to the SOSD. For the patients who needed to be contacted as they did not have a registered follow-up visit we used a separate follow-up form that contained some more information than the SOSD allows. A copy of this form has also been included in the Appendix.

Patients who did not return for follow-up were, if possible, contacted by phone and given a follow-up appointment. If patients refused to come for follow-up when contacted by phone, we interviewed them by phone only. Some patients could not be reached by phone. Though mobile phones are rapidly becoming very common even in low-income countries, in Malawi many patients do not own a phone or even know someone who does. Also phone numbers are often

Figure 6. In our study from Malawi (Paper III) we drove 2006 km over 8 days on very rough, some times hardly passable roads to follow up 11 patients; 182km per patient contacted. The difficulties facing people in the districts in Malawi to return for follow up at a hospital became quite apparent to us during these outreach visits. (Photo Sven Young.)

Figure 7. Patient confidentiality is difficult to uphold both in the hospital and on rural outreach visits in Malawi. Here Mr Fletcher Beniyasi is interviewing a patient. The extended family and neighbors have all joined in to greet the visitors. The patient gave consent to the use of the image. (Photo Sven Young)

discontinued if people lose or sell their phone or cannot pay for phone credits over a long period. In cases where people could not be reached by phone, but had an accurate address recorded, we tried to examine them at home on outreach visits. Where we found the right village and family but the patient was not at home, we obtained a phone number to reach the patient if possible. Where the patient was not reachable for some reason (e.g. had died), we interviewed the family to get as much information as possible. We drove a total of 2006 km on very rough, sometimes scarcely passable, roads over 8 days to find these 11 patients; 182 km per patient found (Figure 6).

Of the 137 patients included in this study 79 (58%) returned for follow-up as scheduled, in itself not a bad number in our setting. Of the remaining 58 patients who did not return for follow-up we managed to contact or obtain information about exactly half, i.e. 29. Of these, 11 returned for an outpatient visit after being contacted by phone, an additional 7 were only available for interview by phone, 7 more patients were found on outreach visits and examined at home, while 4 were contacted through relatives or friends found on these visits.

## Ethical considerations

Papers I and II were both register studies carried out on anonymous data provided by SIGN from the SIGN Online Surgical Database. The study proposal was reviewed and approved by the Norwegian Regional Committee for Medical and Health Research Ethics (20.09.10, 2010/2040).

Paper III is based on a prospective registration of SIGN nail operations at Kamuzu Central Hospital in Lilongwe, Malawi. The research proposal for this study was reviewed and approved by the National Health Sciences Research Committee in Malawi (approval # 753). All patients were counselled and asked for their consent to be included in the study. All patients were also asked to take an HIV test. They received the same treatment regardless of their answers to these requests.

Research on femoral fractures in a low resource setting had its ethical challenges. At KCH the patients lie in large open wards with up to 18 patients listening in on the conversation with the patient. This makes patient confidentiality next to non-existent. There are no treatment rooms for more discrete counselling, and even if the room and time were available the patients are confined to bed in traction, and most beds have no wheels. On outreach visits too, it was difficult to talk to the patient alone. Driving into some of the most remote villages brought the whole extended family and many neighbours to the scene (Figure 7). However, patients seem to be used to this lack of privacy in Malawi and they all accepted that we talked to them in front of other people.

# Summary of Papers I–III

## Paper I

*Young S, Lie S A, Hallan G, Zirkle L G, Engesæter L B, Havelin L I. Low infection rates after 34,361 intramedullary nail operations in 55 low- and middle-income countries. Acta Orthop 2011; 82 (6): 737-43.*

### *Background*

The Surgical Implant Generation Network (SIGN) supplies intra-medullary (IM) nails for the treatment of long bone fractures free of charge to hospitals in low and middle-income countries (LMIC). Most operations are reported to the SIGN Online Surgical Database (SOSD). Follow-up, however, has been reported to be low. We wished to examine the pattern of follow-up and assess if infection rates could be trusted.

### *Patients and methods*

The SOSD contained 36,454 IM nail surgeries in 55 LMIC. Humerus and hip fractures, and fractures without a registered surgical approach were excluded. This left 34,361 IM nails operations of the femur and tibia for analysis. A generalized additive regression model (gam) was used to explore the association between follow-up rates and infection rates.

### *Results*

The overall follow-up rate in the SOSD was 18.1% (CI: 17.7–18.5) and national follow-up rates ranged from 0% to 74.2%. The overall infection rate was 0.7% (CI: 0.6–0.8) for femoral and 1.2% (CI: 1.0–1.4) for tibial fractures. If only nails with a registered follow-up visit (n=6,224) were included, infection rates were 3.5% (CI: 3.0–4.1) for femoral and 7.3% (CI: 6.2–8.4) for tibial fractures. We found an increase in infection rates with increasing follow-up rates up to a level of 5%. Follow-up above 5% in a country did not result in increased infection rates.

### *Interpretation*

Reported infection rates after IM nailing in the SOSD seem to be reliable and could be used for further research. The low infection rates suggest that IM nailing is a safe procedure also in low and middle-income countries.

## Paper II

*Young S, Lie S A, Hallan G, Zirkle L G, Engesæter L B, Havelin L I. Risk factors for infection after 46,113 intramedullary nail operations in low- and middle-income countries. World J Surg 2013; 37 (2): 349-55.*

### *Background*

The fields of surgery and trauma care have largely been neglected in the global health discussion. As a result the idea that surgery is not safe or cost effective in resource-limited settings has gone unchallenged. The SIGN Online Surgical Database (SOSD) is now one of the largest databases on trauma surgery in low- and middle-income countries (LMICs). We wished to examine infection rates and risk factors for infection after IM nail operations in LMICs using this data.

### *Methods*

The SOSD contained 46,722 IM nail surgeries in 58 different LMICs. 46 113 IM nail operations of the humerus, femur and tibia were included for analysis.

### *Results*

The overall follow-up rate was 23.1%. The overall infection rate was 1.0%; 0.7% for humerus, 0.8% for femoral and 1.5% for tibial fractures. If only nails with registered follow-up (n=10 684) were included in analyses, infection rates were 2.9% for humerus, 3.2% for femoral and 6.9% for tibial fractures. Prophylactic antibiotics reduced the risk of infection by 29%. Operations for non-union had a doubled risk of infection. Risk of infection was reduced with increasing income level of the country.

### *Conclusions*

The overall infection rates were low, and well within acceptable levels, suggesting IM nailing is safe also in low-income countries. The fact that operations for non-union have twice the risk of infection compared to primary fracture surgery, further supports the use of IM nailing as the primary treatment for femoral fractures in low- and middle-income countries.

## Paper III

*Young S, Banza L, Hallan G, Beniyasi F, Manda K, Munthali B, Dybvik E, Engesæter L B, Havelin L I. Complications after intramedullary nailing of femoral fractures in a low-income country. Acta Orthop 2013; 84 (5): 460-7.*

### *Background*

Some surgeons believe that internal fixation of fractures carries too high a risk of infection in low-income countries (LIC) to merit its use there. However, too few studies from LIC with sufficient follow-up to answer this are available. We wished 1) to explore whether complete follow up could be achieved in a LIC, and 2) to find the true infection rate at Kamuzu Central Hospital in Malawi, and 3) to examine the influence of HIV and lack of follow-up on patient outcomes.

### *Patients and methods*

137 patients with 141 femoral fractures that were treated with intra-medullary (IM) nails were included. We compared outcomes in patients who returned for scheduled follow-up and patients who did not return and therefore needed to be contacted by phone or visited on outreach visits to their home villages.

### *Results*

79 patients returned for follow-up as scheduled, 29 of the remaining patients were reached by phone or outreach visits giving a total follow-up rate of 79%. 7 nails (5.0%) were complicated by a deep postoperative infection, all of whom returned for scheduled follow-up. There were no infections among patients who did not return for follow-up, compared to 9.6% in the group that did return as scheduled (p=0.11). Two deaths occurred among HIV positive patients (8.7%), while no HIV negative patients died < 30 days postoperatively (p=0.031).

### *Interpretation*

There was an acceptable infection rate in this study. The risk of infection should not be used as an argument against IM nailing of femoral fractures in LIC. Many patients in Malawi did not return for follow-up because they had no complaints about the fracture. There was an increased postoperative mortality rate in HIV positive patients.

# Discussion

The main findings from the three papers on which this thesis is based were:

1. People in LMIC did, mostly, seem to return for follow-up if they had complaints after an IM nail operation, but often chose not to return if they had no complaints.
2. Postoperative infection rates after IM nailing in LMIC were not alarmingly high.
3. HIV positive trauma patients did not have a greatly increased risk of infection, but might have an increased early postoperative mortality rate in resource limited settings with long preoperative traction times and no available VTE prophylaxis.

## Follow-up

In our analysis of the follow-up and infection rates in the 55 LMICs in the SOSD in Paper I, we found that registered infection rates in a country increased with increasing follow-up rates up to a level of 5%. However, countries with follow-up rates higher than this did not show correspondingly increased infection rates (Figure 8). This, of course, does not mean that a follow-up rate of 5% in any given country is enough to register all infections. There could be many factors influencing this finding. In Paper II we found that infection rates fell the higher the income level of a country (Paper II, Table 2). One might be tempted to think that more prosperous countries will have both higher follow-up and lower infection rates and that this might explain the plateau of the curve in Figure 8. However, this does not seem to be the case as low-income countries actually had higher follow-up rates than middle-income countries in our first study (Paper I, Table 2). The plateau in Figure 8 might in fact reflect the possibility that a large proportion of infections were being registered in the SOSD at the time. In that case it would seem to support the notion that people in LMICs return for follow-up if they have complications after an IM nail operation and choose not to if they have no complaints. Another finding that might support this is the fact that the follow-up rate in the SOSD went up by 28% from 18% to 23% between 2010 and 2011. This however had very little effect on the recorded infection rates in the SOSD.

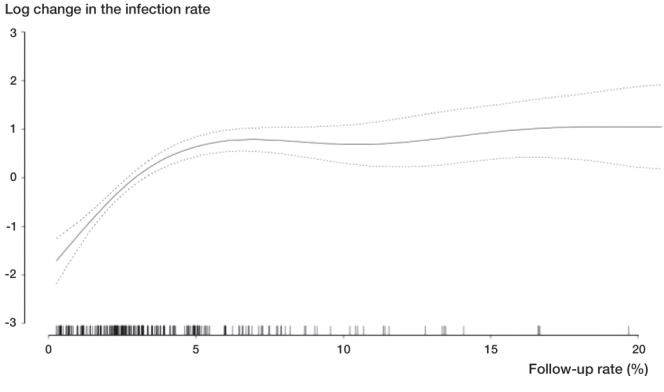


Figure 8. Follow-up rate plotted against log change in the infection rate. The curve is based on a generalized additive regression model (gam). Dotted lines represent 95% CI. With follow-up over 5%, there is very little increase in infection rate and the curve is consequently nearly horizontal. Short vertical lines on x-axis represent observations in different countries. (Figure from: Young S et al. Low infection rates after 34,361 intramedullary nail operations in 55 low- and middle-income countries. Acta Orthop 2011; 82 (6): 737-43.)

It seems that the cost and availability of transport can be an important factor stopping people in Malawi from coming for follow-up.[65,66] However, to our knowledge, no studies have been done specifically asking trauma patients why they did not return for review after surgery. In Paper III we attempted to look more closely at this when we followed up our own patients in Malawi. We found that the main reasons given by our patients were that the cost of transport was high and that they did not have any complaints. Considering the challenges we had, even in a 4-wheel-drive vehicle, of getting to the few patients we were able to locate on outreach visits (see page 11 and Figure 6), and the fact that people in rural Malawi have very little cash income, it is hardly surprising that people do not prioritize returning for review after surgery (see page 9).

Nearly one third (9/29) of the patients who did not have registered follow-up actually claimed to have returned once. Some of them said that they had been seen by a clinical officer and told not to come back. In these cases it is, of course, a lack of registration that is the problem. At KCH, this can result from several factors, even at times as basic as the lack of writing paper. Others said they were sent away because the doctor was not there, or the x-ray department was closed because of lack of film or water, both plausible explanations in our setting. If someone has made a considerable effort at great expense to come for review and experienced this kind of problem, it is even more understandable that they, or even others they tell about this, would not be motivated to come back.

In this last study (Paper III) we managed to contact half of the 58 patients who did not return for follow-up. None of these (0/29) had a postoperative infection, compared to 8 infections in the 83 patients who did return (9.6%). Despite this finding not reaching statistical significance (p=0.11) with this study's size, I believe this finding supports the idea that people often do not return for follow-up in low-income countries unless they have a complaint. As a consequence, research from LICs

should be interpreted with this in mind. Complication rates based only on the number of patients that returned for follow up are likely to be negatively biased, i.e. too high.

## Infections

### *Femoral fractures*

Contrary to traditional perceptions of the risk of infection after surgery in low-income countries (see page 7), our studies from the SOSD and first-hand in Malawi have shown acceptable infection rates. In Paper II the overall postoperative infection rate after IM nailing of femoral fractures across all the 55 low and middle-income countries in the SOSD was 0.8%. If only patients with follow-up were used in the analysis the rate was 3.2%.

The postoperative deep infection rate after femoral nailing at Kamuzu Central Hospital was 5% (Paper III). This is considerably higher than the average infection rates in the SOSD. This, however, has to be seen in the context of the limited resource setting at KCH and the severity of the trauma being treated. In this study 87% of the fractures were the result of high-energy trauma, 25% of patients were polytrauma victims, and 7% of fractures were open. In the SOSD, the risk of infection increased with decreasing resources in a country (Paper II, Table 2). Malawi was ranked number 170 of 186 countries on the United Nations' Human Development Index (http://hdrstats.undp.org/en/countries/profiles/MWI.html) in 2012, making it one of the poorest countries in the world. Limited resources lead to many risks for postoperative infection. In Malawi wards are overcrowded and under-staffed. Stock-outs are frequent, even of antibiotics, anaesthetic drugs, painkillers and antiseptic preparation wash. Surgical drapes and gowns frequently have holes in them and the supply of water and electricity is erratic. In such a situation infections are bound to be more frequent than in high-income countries. However, an infection rate of 5% is not alarmingly high and should not be used as an argument to avoid IM nailing of femoral fractures in LICs. Similar infection rates have been reported after IM nailing in high-income countries. In the UK, Malik et al. found a deep infection rate of 4.1% after 122 femoral nailings.[67] In the USA, Bone and Johnson reported 6.3% infections after nailing of 112 tibial fractures.[68] In Oslo, Norway, a recent study by Westberg et al. found an infection rate of 9% after hemiarthroplasty for femoral neck fractures in elderly patients.[69] Deep postoperative infection of an IM nail is a serious, potentially life-threatening, complication. Even when successfully treated, an infected nail often leads to knee stiffness. This was also seen in our last study (Paper III, Table 3) from Lilongwe. However, in most cases the infection can be controlled with early debridement and suppressive antibiotics until the fracture has healed.[70] The nail can then be removed and the IM canal reamed to remove any dead or poorly vascularized infected tissue.[71]

Though an infection rate of 5% might not be an argument against the use of IM nailing of femoral fractures in LIC, there is definitely room for improvement. Winquist et al.[72] reported an infection rate of 0.9% in a series of 520 IM nails with 17% open fractures nearly 30 years ago, and in a prospective series of 172 IM nail operations in Boston,[73] no infections were seen at all. Efforts should be made to reduce the infection rate where possible through the training of surgeons and specialist theatre nurses, increased hospital ward staffing, and the improvement of infrastructure and supply chains in hospitals in LICs.

### *Tibia and humerus fractures*

In Paper II we found that the infection rate for tibial fractures in the SOSD was 1.5% overall and 6.9% if only patients with registered follow-up were included in analyses. The equivalent rates for humerus fractures were 0.7% and 2.9%. The true infection rates probably lie somewhere between these two extremes, but most likely closer to the lower figure. The doubled crude risk of infection after nailing of tibial fractures compared to antegrade nailing of the femur can partially be explained by the higher number of open tibial fractures, but even after adjusting for this in the analyses tibial fractures had a 71% increased risk of infection, compared to antegrade femoral nailing. Whereas the femur and the humerus are entirely surrounded by well circulated muscle, the tibia has much less muscle cover with the whole medial surface of the bone lying subcutaneously.

The increased risk of postoperative infection after tibial nailing should be considered when selecting treatment for tibial fractures in resource-limited settings. Whereas the benefit to patients with femoral fractures from IM nailing is obvious and large, good results can be achieved with functional bracing of closed tibia and humerus fractures.[74] The patients can be treated as outpatients and need not be admitted for long periods as with femoral fractures. In a setting of severe resource limitations it is probably best to reserve IM nailing of the tibia and humerus for cases of mal- and non-union. In Gustilo grade 2–3 open fractures of the tibia, external fixation and early soft tissue cover is probably the best option. However, if external fixation is not available, good results have been reported with IM nailing of open tibial fractures.[59]

### *Open fractures*

As discussed earlier, the spectrum of trauma is severe in LMICs, largely due to the increasing number of road traffic accidents involving vulnerable road users (i.e. pedestrians, bicyclists, motorcyclists, passengers on the back of lorries etc.). This leads to a large number of open fractures. In the SOSD 17% of the registered fractures were open fractures at the end of 2011 (Paper II), and at Kamuzu Central Hospital in Malawi we found that 7% of femoral fractures were open (Paper III). Other authors have shown a clear correlation between increasing severity of the open fracture (Gustilo grade) and the rates of infection.[71,75] We found this to be the

case also in the SOSD. Previous research from high income countries has shown very little increased risk of infection in Gustilo grade 1 injuries and some authors even group these fractures with closed fractures.[71] However, our results in Paper II suggest that also grade 1 injuries have a clinically significant increase in infection risk of 86% compared to closed fractures after IM nailing (OR 1.86, 95% CI 1.32–2.62; p<0.001). Proper treatment protocols for open fractures including intravenous antibiotics, debridement and irrigation should also be followed in grade 1 open fractures.

### Open reduction

Küntscher realised over 70 years ago, before penicillin was available in normal clinical practice, that closed reduction reduced the risk of infection and non-union after IM nailing (see page 3). However, the fear of harmful irradiation from early versions of x-ray fluoroscopy in the operating theatre made many surgeons revert to open reduction when doing IM nailing. The technique was widely used until the 1980s with good results and few reported infections.[76] There is a conspicuous absence of good quality studies actually showing an increase in infections after open reduction. Though it is logical and probable that there would be at least some more infections after opening the fracture site, this risk is probably small due to the widespread use of prophylactic antibiotics. A few studies have compared infection rates after open and closed reduction in IM nailing of the tibia, but the studies were too small and underpowered to prove differences in outcomes.[77,78] Large studies are needed to show any small differences in outcomes, and the SOSD therefore offers a rare opportunity to study this. In Paper II we found an increase in the crude risk of infection (OR 1.34, 95% CI 1.07–1.66; p = 0.010) after open reduction. However, after adjusting for other risk factors such as open fractures, surgical approach, prophylactic antibiotics etc., the difference marginally lost its statistical significance (OR 1.23, 95% CI 0.97–1.55; p = 0.083). Also, the actual increase in the infection rate was only from 0.8% to 1.1% and as such is probably of little clinical significance. The need for open reduction because of the lack of expensive equipment such as orthopaedic traction tables, C-arm II etc. is no contraindication to the use of IM nailing in LMICs.

### Non-union

In literature from high-income countries a non-union, a fracture that has not united, is usually seen as a complication of surgery. In low-income countries, however, non-union is a separate and common indication for surgery as non-operative management is still widely used. Any orthopaedic surgeon will tell you that operating a delayed- or non-union is more difficult and takes longer than operating a fresh fracture, but actual evidence of this is difficult to find in the literature. In Paper III we confirmed that this seems to be the case at Kamuzu Central Hospital in Malawi. Fractures defined by the surgeon preoperatively as a delayed or non-union had a mean operating time of 130 (SD 36) minutes and estimated blood loss of 400 (SD 309) mL. Fractures that were defined as primary fracture treatment had a mean operating time of 112 (SD 43) minutes, mean difference 18 minutes (95% CI 0.6–35, p=0.04) and an estimated blood loss of 279 (SD 202) mL, mean difference 121 mL (95% CI 10–252, p=0.07). The fact that differences were not larger can probably be explained by the fact that even the patients with "acute" fractures had waited on average 17 days for surgery in this study. Muscles soon start contracting when a bone is left with shortening and many of these fractures were therefore already difficult to reduce at the time of surgery. Despite these differences we found no difference in infection rates in these two groups in Paper III with this study's relatively small size (OR 0.47, 95% CI 0.1–4.0, p=0.68). In Paper II, however, we looked at this in the SOSD and found that patients undergoing IM nailing for a non-union had a more than doubled risk of postoperative infection (OR 2.31, 95 % CI 1.83–2.91; p<0.001). The operating time and blood loss are not recorded in the SOSD, but other authors have shown a correlation between increased operating time and infection rates in total hip replacement surgery.[79] The increased infection rate in operations of non-unions in the SOSD may be an indirect measure of this, or there might be biological factors with the non-union itself affecting the outcomes. Either way, in my opinion, this further supports that, at least femoral fractures, should be treated early with IM nailing. It also shows that the large proportion of neglected fracture patients treated in LICs (see page 5) can lead to inferior results. This must be considered when interpreting results from such countries.

### Prophylactic antibiotics

After the Second World War, antibiotics became readily available and the use of prophylactic antibiotics quickly became the standard before bone surgery. In a large multicentre study from the 1980s of over 8,000 hip and knee replacements a reduction in the risk of infection of 75% was seen when prophylactic antibiotics were given before surgery.[80] Though, few people will advocate not using antibiotic prophylaxis before IM nailing these days, the consequences of not providing this is at least of interest. Data from the SOSD (Paper II, Table 2) showed a reduction in the risk of infection of nearly one third for those that received prophylactic antibiotics (OR 0.71, 95 % CI 0.55–0.91; p = 0.008).

### Income level

The World Bank classifies a country into one of four income groups based on its gross national income (GNI) per capita (http://data.worldbank.org/about/country-classifications). The groups are: low-income, lower middle-income, higher middle-income and high-income countries. Low-income countries have a GNI per capita of below US$ 1,000, whereas high-income countries have a GNI per capita over US$ 12,000 (2012 figures). The fewer resources a country has, the more

unfavourable one would expect the condition of its hospitals to be, as described earlier for KCH in Malawi (see page 6). As a consequence, one might expect results to be poorer in low-income countries than in high-income countries. The data in the SOSD does seem to support this to some degree, as we did find a lower adjusted risk of infection the higher the income level of a country in Paper II (Table 2). The risk of infection in higher middle-income countries was half that of low-income countries in that study. This does show that there is clear room for improvement of infection control in low-income countries, but the rates of infection are still low and should not be used as an argument against the use of surgical treatment in LIC.

## HIV

In our study of patients at Kamuzu Central Hospital in Lilongwe, Malawi, 17% of the patients were HIV positive and 6.6% had an unknown HIV status (Paper III). The HIV positive patients had an infection rate of 8.7% (2/23) and the HIV negative patients 4.8% (5/105). This seemingly doubled risk of infection was not statistically significant with our study's size, however (OR 1.9, 95% CI 0.3–10, p=0.61). Bates et al. followed 609 patients after internal fixation of different fractures in Blantyre, Malawi.[81] 132 of these patients were HIV-positive. They found no difference in infection rates in HIV-positive and HIV-negative trauma patients. In a paper from Rwanda in 1991, Hoekman et al. found an increased risk of postoperative infection after fracture surgery in HIV seropositive patients with "symptomatic disease".[82] However, they did not use systemic prophylactic antibiotics before surgery, and if all HIV positive patients were combined in one group no significant difference in infection rate was seen. A recent meta-analysis did suggest that there might be more postoperative infections in HIV positive patients,[83] but the findings were based on many old and small studies and were not conclusive. Infection does seem to be more common in HIV-positive patients after open fractures,[84] but the increased risk is probably more influenced by the severity of the injury[85] and contamination of the wound,[86] or with the life style of the patients.[87] There is increasing evidence both from high-income countries and LMICs that clean implant surgery in HIV-positive patients is safe and that the long-term outcomes after surgery in general are no worse for HIV-positive patients than for other patients.[88-91] However, there is still a lack of good studies of the results of surgery in HIV-positive trauma victims and this has unfortunately even led to poorly founded general recommendations that closed fractures in HIV patients should be treated non-operatively in low-income settings.[56]

HIV positive trauma patients at KCH had an increased over all risk of death (OR 16, CI 1.5–158, p=0.018) in the study period (Paper III, Table 4). The 30 day postoperative mortality was 8.7% (2/23) in HIV-positive patients compared to 0% (0/105) in HIV-negative patients (p=0.03). Numbers were small and care must be taken in concluding from these. However, there is available literature that may support this finding. HIV-positive patients are reported to have an up to tenfold increased risk of venous thromboembolism (VTE).[92] Immobilization in traction can also lead to VTE, including pulmonary embolism (PE). In a study of the use of SIGN nails in Uganda, Sekimpi at al. diagnosed and treated two patients for pulmonary embolism (PE) while they were waiting for surgery for femoral fracture.[44] In their study patients waited an average 13 days for surgery. A prospective randomized study by Bone et al. from 1989 found that delayed stabilization of femoral fractures over 24 hours increased the incidence of pulmonary complications.[93] At KCH patients waited on average 17 days (nearly two and a half weeks) for surgery of acute fractures. Due to economic constraints we did not have available VTE prophylaxis with low-molecular-weight heparin. All three postoperative deaths were suspected to be pulmonary embolisms with sudden onset hypotension and respiratory distress, though definitive diagnosis or post-mortem examination were not available. The lack of VTE prophylaxis could, together with the seriousness of the trauma in our patients and the long period of immobilization, explain the increased postoperative mortality recorded in Paper III. As HIV-positive patients have an increased risk of VTE, this might disproportionately affect this group. HIV-positive patients did not have increased time to ambulation or length of stay postoperatively in this study and therefore seem to have the same potential for rehabilitation postoperatively as other patients with femoral fractures. In my opinion, these findings further strengthen the argument for early IM fixation of femoral fractures in HIV positive patients. Surgeons should also try to provide VTE prophylaxis in some other form (e.g. compressive stockings or Aspirin) to these patients if low molecular weight heparin is not available.

## Study design and limitations

Papers I and II are based on the SOSD and are in essence register studies, or prospective observational studies, using a large database of intra medullary nail surgery registering data on the use of one specific implant. The SOSD gathers systematic prospective data on trauma surgery on a large scale and is probably the largest and fastest growing database of its kind in the world. It is also unique because all operations recorded are carried out in LMICs giving us the opportunity to study outcomes in countries with fewer resources and higher burdens of disease than in high-income countries.

Randomised controlled trials (RCTs) are generally considered to generate the highest level of evidence for differences between treatment modalities. However, this trial design is not always practical or even sensible. Large RCTs are difficult and expensive to implement, even in high-income countries. Register studies are likely to include much larger numbers of patients and are therefore better suited to study rare outcomes,

such as infection and death. An RCT comparing outcomes of skeletal traction and IM nailing in a high-income country would be considered completely outrageous by most surgeons and would not be likely to pass ethical review. The benefits of IM nailing over traction are obvious and well proven over the last 70 years, and there is absolutely no reason why a study of this kind should be ethically acceptable in a low-income country either.

Despite this being the focus of our interest in our first paper, the most obvious limitation in our two register studies was the lack of follow-up in the SOSD. This was discussed in more detail at the beginning of this chapter. Infection is registered as superficial or deep in the SOSD. However, the definition of this is at the discretion of the surgeon reporting, and in a register study from 55 countries we had no way of auditing the reporting practice. We assumed that infections reported in an environment of resource and time constraints would be clinically significant, e.g. not just a stitch abscess or passing inflammation of the wound that cleared with a few days of oral antibiotics. We therefore grouped superficial and deep infections together. In calculating infection rates, we assumed that people who had infections returned for follow-up. This, of course, is not correct in all cases, but the statistical model used in Paper I, and our findings in Paper III, seem to support that this assumption holds to some degree. We also assumed that if patients returned they would be registered in the SOSD. This also is not always the case, as we found in Paper III where a third of patients who were not registered as having come for follow-up actually claimed to have returned as requested (Paper III, Table 3). Assumptions like these introduce uncertainty into the analyses and conclusions. However, in light of our findings in Papers I and III that a large proportion of patients with complaints did return, the large size of the register studies (Papers I and II) and the fact that we have done all calculations of infection rates both including and excluding patients without follow-up, I believe that the reported figures give a good indication of the true infection rates in low- and middle-income countries.

Our prospective study of femoral fractures at KCH (Paper III) also had its own clear limitations, including the relatively small number of included patients limiting that study's power to prove small differences in relatively rare complications. Despite considerable effort we did not achieve our goal of 100% follow-up in this study either. However, in the light of the setting in which this study was conducted, and the fact that we managed to get close to 80% follow-up despite huge resource challenges, I do believe this study has brought some new information to the field of orthopaedic trauma care in low-income countries.

# Conclusions

Returning for follow-up in LICs can be difficult and very expensive for many patients. The motivation for returning for follow-up is therefore very low if a patient does not have any complaints. Insisting on very high follow-up rates in clinical research from low-income countries is unrealistic and can exclude important information from the literature. It does, however, seem as if people in low income countries mostly do return for follow-up if they have a complaint after surgery, even if total follow up rates are low. This implies that results based only on the patients who returned for follow-up in LICs will be negatively biased. This should be kept in mind when interpreting results in research from LICs.

Infection rates after IM nailing in LMICs are acceptable and infections, when they occur, are usually manageable. The risk of infection should not be used as an argument against well-proven surgical treatment of fractures by properly trained surgeons in LMICs. Patients with femoral fractures in particular have a great deal to gain from IM nailing as opposed to spending months in hospital on skeletal traction. Patients with tibia and humerus shaft fractures can in most cases be treated effectively by functional bracing. In a setting of severe resource constraints with limited operating time it is probably best to reserve IM nailing of the tibia and humerus for cases of mal- and non-union.

Patients undergoing IM nailing for a non-union had a more than doubled risk of postoperative infection in the SOSD. This further supports that, at least femoral fractures, should be treated early with IM nailing also in LMIC. The large proportion of neglected fractures treated can also explain inferior results in research from LICs. This must be considered when interpreting results from these countries.

Data from the SOSD suggests that there is a statistically increased risk of postoperative infection with the decreasing income level of a country. However, infection rates are still low and should not be used as an argument against the practice of orthopaedic trauma surgery in low-income countries.

We found no statistically significant increase in infection rates when open reduction was used compared to closed reduction. The need for open reduction because of the lack of expensive equipment such as orthopaedic traction tables, C-arm image intensifiers etc. is no contraindication to the use of IM nailing in LMICs.

There is a large potential for decreasing the length of hospital stay both pre- and postoperatively for femoral fracture patients in Malawi. Increased surgical capacity and better availability of affordable crutches could realistically reduce the length of stay at Kamuzu Central Hospital from the current average of 30 days to around 10 days. At hospitals where IM nailing has not yet been introduced this reduction in length of hospital stay would be even larger.

People living with HIV do not seem to have a much increased risk of postoperative infection. This certainly is no argument against the surgical treatment of fractures in HIV-positive trauma patients. They might, however, have an increased postoperative mortality risk due to venous thromboembolism (VTE) after prolonged preoperative traction when low-molecular-weight heparin VTE prophylaxis is not available. This needs to be confirmed in larger studies, but in my opinion further strengthens the argument for the earliest possible IM nailing of femoral fractures in HIV-positive trauma patients. Surgeons should also try to provide VTE prophylaxis in some other form (e.g. compressive stockings or acetylsalicylic acid) to these patients if low-molecular-weight heparin is not available.

# Future research

### *The SOSD*

The SOSD is already probably the largest database on orthopaedic trauma surgery in the world. The increasing numbers and follow-up rates in the SOSD offer exciting prospects for future research. However, the SOSD was set up for ease of reporting and feedback on surgery and was not primarily designed for research. As a consequence some data that would be of interest is not recorded in the database. This includes epidemiological data such as mechanism of injury, risk factors for surgery such as other medical conditions and smoking, operation time, blood loss, surgical positioning, use of C-arm, draping material etc. Also a clear way of registering a reoperation and connecting it to the primary surgery is missing. Minor changes and additions to the SOSD could greatly increase its importance in orthopaedic trauma research.

The information registered at follow-up also limits the use of the SOSD for research. With slight changes to the follow-up form, such as automatically adapting the form to the bone operated, more reliable and interesting end points could be registered. For the femur, differentiating between knee, trochanter and fracture pain would be interesting in looking at results after retrograde and antegrade nailing. For tibias, it would be interesting to record anterior knee pain, ankle pain and peroneal nerve / anterior compartment function. For humerus fractures, abductor power, shoulder pain and radial nerve function could easily be recorded. One must of course realize that increasing or complicating the reporting process can affect surgeons' motivation to report follow-up, but improving the follow-up form does not necessarily mean it would take longer to fill in.

Even without changes to the SOSD, there are still many areas of interest to be studied with the current data set. As the database grows and follow-up hopefully increases, results will be more reliable and the SOSD promises to continue to be an important source of information on trauma surgery in LMIC.

### *Documenting the need for and cost effectiveness of surgery in LIC*

Despite the large burden of trauma and surgical disease in LMICs, surgery has not been a priority in global health. Though several reports have documented the need for surgery in LICs (see page 5) there is an urgent need for more documentation to bring surgery into the mainstream of the global health discussion. Unless a larger body of research is produced in this field from LICs, surgery is bound to continue to lose in the competition for funds with communicable diseases like HIV, TB and malaria. There is a pressing need for more documentation of the negative consequences of the absence of surgical services in LIC, as well as demonstrating that surgery in LICs is cost effective.

### *Stimulating clinical research on surgery in LIC*

Though surgical techniques introduced to a low-income country usually are well proven in high-income countries, documenting outcomes after the introduction of the same techniques to a LIC can be important for several reasons. First, it can identify problems that need to be addressed for the safe introduction of specific techniques in low-resource settings. Secondly, documenting outcomes of surgery in LICs similar to those in HICs is important in advocating inclusion of surgery as an essential part of national and global health planning. Thirdly, stimulating research in LICs is a way of empowering local clinicians and academic institutions to take charge and search for information important in their own setting. On-going clinical research is necessary to check the quality of services being provided and the consequences of a service not being provided in a country. Lastly, orthopaedic surgery in high-income countries is heavily influenced by the surgical implant industry. This affects both indications for surgery and the choice of implants. In LMICs one is forced to pay much more attention to the cost of the surgery, and one is more likely to end up with older technology, and perhaps inferior quality implants. The research being done now in HICs, on implants that are usually not available in LICs, might therefore not be as relevant to surgeons in LICs. On the other hand, results from LMICs might in the future show equally good results with much cheaper technology.

### *Documenting results in HIV positive patients*

Our knowledge on the outcomes of surgery in HIV-positive patients is largely based on a few small studies with inconclusive results (see page 7). Many of these studies are old and based on cohorts of haemophilia patients further making the validity of the results uncertain. Larger prospective studies, including data on CD4/CD8 and viral load values and duration and type of ART medication, are needed to document the real risks of complications for HIV patients undergoing surgery, so that we can address risk factors and improve the outcomes for these patients. With sufficient funding a prospective international multicentre study using the SOSD in Southern Africa, possibly under the umbrella of the College of Surgeons of East, Central and Southern Africa (COSECSA), could give reliable results in a relatively short timeframe.

# Summary

This thesis is based on three published papers about complications after intramedullary (IM) nailing of fractures of the long bones in low- and middle-income countries (LMICs). The first two studies were register studies using data from the SIGN online surgical database (SOSD). The third study was a prospective study of patients treated for femoral fractures at Kamuzu Central Hospital in Malawi. The SOSD is, to my knowledge, currently the largest database in the world containing data on orthopaedic trauma surgery in LMICs. It was established to ease communication between SIGN Fracture Care International (SIGN) and surgeons using their IM nail. SIGN provides hospitals in LMICs with IM nails free of charge for the treatment of fractures in poor people. Being operated with an IM nail for a fracture of the thigh bone (femur) will have a patient out of bed in a few days, and this has been the obvious treatment of choice in high-income countries for more than half a century now. In many LMICs, however, femoral fractures are still treated with the patient in bed on traction for one and a half to three months. There are still many myths about the risks of doing surgery in LMICs. We wished to document the results and complications of IM nailing in LMICs so that better informed decisions can be made when planning surgical services in these countries. Lack of sufficient follow-up is a challenge in research in LMICs. We also wished to see how this influences results.

We found that returning for follow-up in LIC can be difficult and very expensive for many patients. The motivation for returning for follow-up is therefore very low if a patient does not have any complaints. Insisting on very high follow-up rates in clinical research from low-income countries is unrealistic and can exclude important information from the literature. It does, however, seem as if people in low income countries mostly do return for follow-up if they have a complaint after surgery even if total follow up rates are low. This implies that results based only on the patients that returned for follow-up in LIC will be negatively biased. This should be kept in mind when interpreting results in research from LIC.

Infection rates after IM nailing in LMIC are acceptable and infections, when they occur, usually manageable. The risk of infection should not be used as an argument against well-proven surgical treatment of fractures by properly trained surgeons in LMICs. Patients with femoral fractures in particular have a great deal to gain from IM nailing as opposed to spending months in hospital on skeletal traction.

Patients registered in the SOSD undergoing IM nailing for a non-union had a more than doubled risk of postoperative infection. This further supports that, at least femoral fractures, should be treated early with IM nailing also in LMIC. Data from the SOSD suggests that there is a statistically increased risk of postoperative infection with decreasing income level of a country. However, infection rates are still low and this should not be used as an argument against the practice of orthopaedic trauma surgery in low-income countries.

We found no statistically significant increase in infection rates when open reduction was used compared to closed reduction. The need for open reduction because of the lack of expensive equipment such as orthopaedic traction tables, C-arm image intensifiers etc. is no contraindication to the use of IM nailing in LMICs.

People living with HIV do not seem to have a much increased risk of postoperative infection. This certainly is no argument against surgical treatment of fractures in HIV positive trauma patients. They might, however, have an increased postoperative mortality risk due to venous thromboembolism (VTE) after prolonged preoperative traction when low molecular weight heparin VTE prophylaxis is not available. This needs to be confirmed in larger studies, but in my opinion further strengthens the argument for the earliest possible IM nailing of femoral fractures in HIV positive trauma patients.

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# Appendix

## SOSD postoperative registration form

SIGN SURGICAL DATABASE
Data Collection Sheets
For Data Entry In The SIGN Surgical Database
www.signsurgery.org

| **PATIENT CASE INFORMATION:** (All fields are required unless otherwise noted.) | | | |
|---|---|---|---|
| **Patient Name:** | **Age:** | **Gender:** | **Injury Date:** |
| **Hospital Name:** | | **Case Number:** (optional) | |
| ***Optional Patient Contact Information:*** *(This information will be available only to the applicable hospital).* | | | |
| **Address:** | | | |
| **Phone Number:** | **Email Address:** | | |



| **SURGERY INFORMATION:** Copy this page for each additional surgery for this patient. |
|---|
| **Date (month/day/year):** |
| **Surgeon Name(s):** |

**1. Antibiotics Used?** ☐ **Yes** ☐ **No**
**If yes:**
**How long from time of injury? _____ hours _____ days**

**Name of Antibiotic: _____**

**Duration of Antibiotic Coverage: _____ hours _____ days**

**2. Surgery Comments:**

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

| **FRACTURE INFORMATION:** (Copy pages 3 - 4 for each additional fracture.) |
|---|
| **Patient Name:** |
| **Case Number:** |

**1. Fracture Side:** ☐ **Left** ☐ **Right**

**2. Surgical Approach:** ☐ **Tibia** ☐ **Retrograde Femur** ☐ **Antegrade Femur** ☐ **Antegrade Humerus**
**Other:** _____

**3. Location of Fracture:** (check all that apply) ☐ **Proximal** ☐ **Middle** ☐ **Distal** ☐ **Segmental** ☐ **Femoral Neck** ☐ **Intertrochanteric**

**4. Type of Fracture:** ☐ **Closed** ☐ **Gustilo I** ☐ **Gustilo II** ☐ **Gustilo IIIa** ☐ **Gustilo IIIb** ☐ **Gustilo IIIc**

**5. Time from injury to Debridement: ____hours ____days**

**6. Time from injury to Skin Closure: ____days**

**7. Method of Wound Closure:**
(check all that apply) ☐ **Primary** ☐ **Skin Graft** ☐ **Muscle Flap** ☐ **Secondary** **Other:** _____

**8. Previous Implant Used:** ☐ **Yes** ☐ **No**
If Yes, check all that apply: ☐ **External Fixation** ☐ **Plate** ☐ **IM Nail** ☐ **Wire**
If External Fixation: **1. How long was external fixation in place? ____days**
**2. Time between removal of ext. fixation and SIGN? ____days**

**9. Method of Reaming:** ☐ **None** ☐ **Power** ☐ **Hand**

**10. Fracture Reduction:** ☐ **Open** ☐ **Closed**

**11. Comments:**
_____
_____
_____
_____
_____
_____
_____
_____

| **FRACTURE INFORMATION** (continued from page 3) |
|---|
| **Patient Name:** |
| **Case Number:** |

**13. Nail Type Used:** (Please mark the type of nail used to treat this fracture.)

| Standard Nails | 200 mm | 220 mm | 240 mm | 260 mm | 280 mm | 300 mm | 320 mm | 340 mm | 360 mm | 380 mm | 400 mm | 420 mm |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 8 mm | | | | | | | | | | | | |
| 9 mm | | | | | | | | | | | | |
| 10 mm | | | | | | | | | | | | |
| 11 mm | | | | | | | | | | | | |
| 12 mm | | | | | | | | | | | | |

| Fin Nails | 160 mm | 190 mm | 240 mm | 280 mm |
|---|---|---|---|---|
| 7 mm | | | | |
| 8 mm | | | | |
| 9 mm | | | | |
| 10 mm | | | | |
| 11 mm | | | | |
| 12 mm | | | | |

**14. Screw Quantities Used:** (Please enter the quantity of each type of screw used with this nail.)

| Length in mm | 25 | 30 | 35 | 40 | 45 | 50 | 55 | 60 | 65 | 70 | 75 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| #Proximal | | | | | | | | | | | |
| #Distal | | | | | | | | | | | |


**15. X-Rays Taken:** (Please list the names of the digital image files for all x-rays of this fracture.)

| Digital Image X-Ray File Name(s) | Pre-Op | Post-Op | Date Taken |
|---|---|---|---|
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |
| | ☐ | ☐ | |

**Notes on uploading digital image x-ray files:**

1. This table is provided for you to keep track of digital x-ray images so that the process of uploading these images to the online database goes smoothly.
2. The time required to upload image files is determined by the size of your digital image files and your internet connection speed.
3. VERY IMPORTANT: You can reduce the size of your digital image files by converting them to grayscale (remove all color) and by reducing the dimensions of your pictures to approximately 640 x 480 pixels. Many digital cameras come with software programs capable of these tasks.

## SOSD follow-up visit registration form



| **FOLLOW-UP INFORMATION:** (Copy this sheet for each additional follow-up.) | |
|---|---|
| **Patient Name:** | |
| **Case Number:** | **Date (month/day/year):** |
| **If multiple fractures, which fracture is this a follow-up for?** | |

**1. Infection:** ☐ Yes ☐ No
If yes:
Incision of the wound: ☐ Yes ☐ No
Infection depth: ☐ Superficial ☐ Deep (patient returns to surgery)
Duration of infection: _____ weeks
☐ Osteomyelitis ☐ Amputation

**3. Partial weight bearing:** ☐ Yes ☐ No
**4. Painless full weight bearing:** ☐ Yes ☐ No
**5. Healing by x-ray:** ☐ Yes ☐ No
**6. Knee flexion greater than 90 degrees:** ☐ Yes ☐ No
**7. Screw breakage:** ☐ Yes ☐ No
**8. Screw loosening:** ☐ Yes ☐ No
**9. Nail breakage:** ☐ Yes ☐ No
**10. Nail loosening:** ☐ Yes ☐ No

**11. Deformity:** ☐ Yes ☐ No (under 10 degrees)
If yes:
Alignment: ☐ Over 10 degrees varus ☐ Over 10 degrees valgus
☐ Over 20 degrees varus ☐ Over 20 degrees valgus

Rotation: ☐ Over 30 degrees

**12. Repeat Surgery:** ☐ Yes ☐ No
If Yes, check all that apply: ☐ For Infection ☐ For Deformity ☐ For Non-union

If For Non-Union, check all that apply: ☐ Dynamize ☐ Exchange Nail
☐ Iliac Crest Bone Graft
Other:_____

**13. Comments:**
_____
_____
_____

**14. X-Rays Taken:** (Please list the names of the digital image files for all x-rays during this follow-up.)

| Digital Image X-Ray File Name(s) | Date Taken |
|---|---|
| | |
| | |
| | |

## Data collection form, KCH study (Paper III)

# Prospective registration of SIGN intramedullary nails at Kamuzu Central Hospital 2010-2011

**Data collection sheet.**

**Please fill in ALL fields** at latest on discharge of patient. Circle all appropriate choices.

Patient must sign consent form on reverse.

| | | |
|---|---|---|
| **Name**: | **Gender**: F / M | |
| **SIGN database case no.:** | **Age**: | |
| **Current address / Contact details:** | **Phone no of pt. or guardian**: | |
| **Date of injury (D/M/Y):** | **Date of surgery (D/M/Y):** | |
| **Mechanism of injury:**<br>Pedestrian run down by motor vehicle<br>Bicyclist run down by motor vehicle<br>Driver or passenger in private car<br>Driver or passenger in Minibus<br>Passenger on back of pick up or lorry | Wall or roof of house fell down<br>assault by thugs / robbers<br>domestic violence<br>pathological fracture<br>other (please state below): | |
| **Fracture site:**<br>subtrochanteric / midshaft / distal shaft / supracondylar | **Fracture config.:**<br>transverse / oblique / spiral / segmental / comminuted | **Side of injury:**<br>Right / Left |
| **Fracture type:**<br>Closed<br>Open, grade 1 / 2 / 3a / 3b / 3c | **Treatment before surgery:**<br>Skin traction / skeletal traction / ExFix / No treatment | |
| **Indication for surgery:**<br>Primary fracture treatment<br>Delayed union<br>Non-union<br>Malunion: valgus / varus / rotation / shortening (circle all that apply)<br>Palliative care / pathological fracture | **Symptoms preop.** (circle all that apply):<br>Pain on manipulation /<br>Pain on weight bearing /<br><br># completely loose /<br># stiff but some movement on manipulation /<br>no movement at # site on manipulation | |
| **Other diseases / risk factors** (circle all that apply):<br>Diabetes: Yes / No<br>Heart disease: Yes / No<br>Hypertension: Yes / No<br>Asthma / chronic lung disease: Yes / No | Malnutrition (pt under weight): Yes / No<br>Obesity: Yes / No<br>Smoker: Yes / No<br>Cancer (state type): Yes / No<br>HIV (see next page): Yes / No | |

| | |
|---|---|
| **HIV:**<br>Non-reactive / reactive / unknown | **ART:**<br>Yes / No<br>If yes how long: |
| **CD4 count / date:** | **Preoperative Hb / date:** |
| **Antibiotic(s):**<br>Yes / No | **Type and dose of antibiotics:** |
| **Date antibiotic(s) started (D/M/Y):** | **Date of last antibiotic dose (D/M/Y):** |
| **Operating time (skin to skin):** | **Estimated peroperative blood loss (ml):** |
| **Date up on crutches (D/M/Y):** | **Date of discharge (D/M/Y):** |
| **Knee range of motion (ROM) at discharge (degrees ext. and flex., eg.: 0° – 30° ):** | **Wounds clean and dry on date of discharge?**<br>Yes / No |
| **Planned follow up / review date (D/M/Y):** | **Form filled out by (name):** |

Consent form:

I have been informed of the current study on the use of SIGN nails at Kamuzu Central Hospital by Mr / Mrs : _____ and give my consent to the above information being used for research purposes in an anonymous form.

Nda dziwitsidwa za maphunziro a kagwiritsidwe ka SIGN nail ku Kamuzu Central Hospital ndi Mr / Mrs: _____ ndi kubvomereza ndondomeko yogwiritsidwa mu kafukufuku mosatchulidwa dzina langa.

Name: Signature:

Date:

## Follow-up registration form used for patients that had not returned for follow-up in KCH study (Paper III)

# FOLLOW-UP FORM

# SIGN intra-medullary nails at Kamuzu Central Hospital

**Please fill in ALL fields**. Circle all appropriate choices. One form for each IM nail if >1.

<table>
<tr><td colspan="3">Circle one: Follow-up visit / telephone interview</td><td colspan="3">Follow-up date (D/M/Y):</td></tr>
<tr><td colspan="3">Name:</td><td colspan="2">Gender: F / M</td><td>Age:</td></tr>
<tr><td colspan="3">SIGN case no.:</td><td colspan="3">Date of surgery (D/M/Y):</td></tr>
<tr><td colspan="3">Reason for this follow-up:<br>Study / Problem / routine postop. visit<br>Other (specify):</td><td colspan="3">Returned for follow-up before?<br>Yes / No</td></tr>
<tr><td colspan="6">Reason if not returned for follow-up before (circle all that apply):<br>Had no problem / could not afford / did not think it necessary / was not told to come back /<br>Other reason (specify):</td></tr>
<tr><td colspan="3">Place of stay:<br>Urban / rural</td><td colspan="3">Cost of transport to KCH, one way:</td></tr>
<tr><td colspan="3">Fractured bone:<br>humerus / femur / tibia</td><td colspan="2">Fracture type:<br>Closed / Open</td><td>Side of injury:<br>Right / Left</td></tr>
<tr><td colspan="3">HIV:<br>Non-reactive / reactive / unknown</td><td colspan="2">ART: Yes / No<br>If yes, no. months:</td><td>CD4 count / date:</td></tr>
<tr><td>Infection at this follow-up?<br>Yes / No</td><td>Deep?<br>Yes / No</td><td>Infection at earlier follow-up?<br>Yes / No</td><td colspan="3">Treatment for infection:</td></tr>
<tr><td colspan="3">Partial weight bearing?<br>Yes / No</td><td colspan="3">Painless full weight bearing?<br>Yes / No</td></tr>
<tr><td colspan="3">Healing on x-ray?<br>Yes / No</td><td colspan="2">Broken / loose screws? Yes / No</td><td>Broken / loose nail?<br>Yes / No</td></tr>
<tr><td colspan="3">Deformity? No / Yes<br>If yes specify degrees or cm and circle direction<br>___ degrees: varus / valgus / external / internal<br>___ cm shortening</td><td colspan="3">Knee pain? Yes / No<br>Crepitation in knee? Yes / No<br>Trochanter pain? Yes / No<br>Tenderness over screws? Yes / No</td></tr>
<tr><td colspan="3">Knee range of motion (ROM) at follow-up (degr. ext. and flex., eg.: 10°- 0° – 150° ):</td><td colspan="3">Happy with result? Yes / No<br>Other complaints / problems: Yes / No<br>If yes, specify:</td></tr>
<tr><td>Pictures of x-rays taken?</td><td colspan="2">Follow-up reported to SIGN?<br>Date:</td><td colspan="3">Form filled out by (name):</td></tr>
</table>