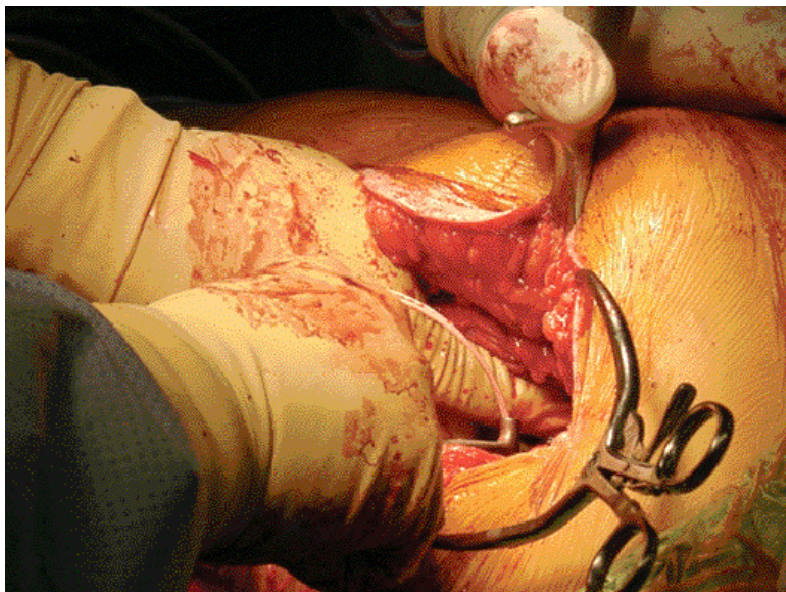


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Advances in Internal Bone Fixation

Sharps safety for orthopedic surgeonsby **Ron Stoker**

Imagine being an orthopedic surgeon and knowing that your patient's artificial hip is worn out or loose. You have made the necessary incisions and are now ready to insert your hands into the open wound so that you can palpate around the hip to see the extent of the damage. As you get ready to place your hands into the tissue, you think to yourself, "I have a pretty good chance of getting stuck on a cabling wire that is surrounding the bone. Will I get stuck? What was this patient's hepatitis or HIV status?" What would you do? This is a real concern facing surgeons and their staff every time that they perform an orthopedic surgery. Let's talk about hip joint replacement surgeries for a moment.



Surgeons often insert their hands into an area because they are relying on tactile feedback at their fingertips. This places them at risk for wirestick injuries from metal cerclage cables and wires.

One of the most essential joints in the body is the hip joint. It is called a "ball-and-socket" joint because the ball (head) of the femur rotates inside the cup-shaped, hollow socket (acetabulum) of the pelvis. The mating surfaces of the femoral head and the acetabulum are covered with a slippery tissue called articular cartilage. This articular cartilage is about one-eighth of an inch

thick and is a tough, lubricious material that allows the surfaces to slide against one another without damage.

The articular cartilage in natural hip joints can wear out. When this occurs, the result is excruciating pain and limited movement. When the hip joint wears out, it is often necessary to replace it with an implant, called a total hip replacement or total hip arthroplasty. Total hip replacement implants typically have three parts, including:

- ▶ the stem, which fits into the femur;
- ▶ the ball, which replaces the spherical head of the femur; and
- ▶ the cup, which replaces the worn out acetabular socket.

These parts come in a variety of sizes to accommodate many different body sizes. The primary objective of hip replacement surgery is to relieve pain and restore movement. For most patients, the surgery is initially successful, but many patients will eventually require further surgery due to a wearing out of the cup implant. This wear creates particulate debris, which can cause further wear ultimately resulting in a painful loosening of the implant components. This condition is often treated with revision hip surgery, in which the loose or worn implants are removed and replaced by new implants. Revision hip surgery is more complicated and more time consuming than first time (or primary) hip replacement and the outcome is often less satisfactory. Complete pain relief is less common than in primary hip replacement and complication rates are higher.

Surgeons, nurses and technicians are at risk for accidental sharps injuries each time one of these total hip replacement procedures

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is performed. These accidental sharps injuries place operating room personnel at the highest risk among healthcare professionals for occupational hepatitis B and C infections because of their frequent exposure to blood;¹ they are also at comparatively high risk for human immunodeficiency virus (HIV) infection.

Other reasons for hip revision surgery include fracture of the hip, the presence of infection, or dislocation of the prosthesis. In these cases the prosthesis must often be removed or replaced in order to prevent long-term damage to the hip itself. The life expectancy of implants used in first-time hip replacement surgery is usually given as 10 to 15 years, whereas revision implants may need to be removed after eight to 10 years. Periprosthetic femur fractures (i.e., fractures around a hip stem) are not rare (see sidebar story on page 36). These types of fractures are often treated in combination with revision hip replacement surgery.

The demand for hip revision procedures is projected to double by the year 2026.² As patients live longer and as the number of hip replacement and revision arthroplasty procedures increases, so does the prevalence of periprosthetic fractures. The difficulty in treating periprosthetic fractures following total hip arthroplasty is evidenced by the numerous treatment modalities and techniques available. There is no ideal treatment that is appropriate for all hip fractures.

Wires and Cables

During hip replacement and treatment of associated peri-prosthetic fractures, it is often necessary to hold the bone or fragments of bone together to create a stable environment for healing to occur. This is typically done with metal wires or cables using a technique called cerclage (ser-klahzh). A cerclage wire or cable is wound around a bone or bony fragments to hold them together to allow them to heal. Wire cerclage is one of the oldest forms of internal fixation. Cerclage has numerous applications in orthopedics as a primary method of fracture fixation and as a supplement to other forms of fixation. During hip replacement and hip revision surgeries and other times when the bone is resected or fractured, the bone fragments often require additional support. During situations like these, cerclage wires provide an opportunity for the bony pieces to unite again. For example, in a patella fracture, normal knee forces tend to pull the bony fragments apart unless they are held together by cerclage techniques.

Although wire cerclage has had numerous applications in orthopedics as a primary method of fracture fixation, it also has several disadvantages. Monofilament wires

are prone to breakage.³ Multi-filament cables are subject to fatigue and fraying, releasing metallic particulate debris into the body.^{4,5,6} Problems associated with metal cerclage wires and cables include:

- ▶ broken metal wires or cables;
- ▶ interruption of the blood supply to the bone;
- ▶ fraying and fretting.

Patient Problems from Broken Metal Cerclage Wires

Sometimes a broken fragment of a cerclage wire or cable can separate unintentionally and cause iatrogenic injury to the patient. Patients may not even be aware that this has occurred. The Center for Devices and Radiological Health (CDRH) at FDA receives nearly 1,000 adverse event reports each year related to unretrieved device fragments within the human body.

One of the problems with metal debris migration near a hip replacement is that the metallic debris can intrude into the bearing surface of the hip replacement. Exposure of metallic debris to the bearing surface can cause accelerated wear of the bearing surface and lead to premature failure of the hip replacement.

In addition, the medical literature contains several “horror-stories” that detail complications caused by broken metal cerclage wires. One notable case deals with a fragment of a broken metal cerclage wire that was found in the right ventricle of a patient who was treated 13 years previously for a patella fracture using cerclage wire. Imaging confirmed that part of the cerclage wire had broken off and had migrated into his heart.⁷

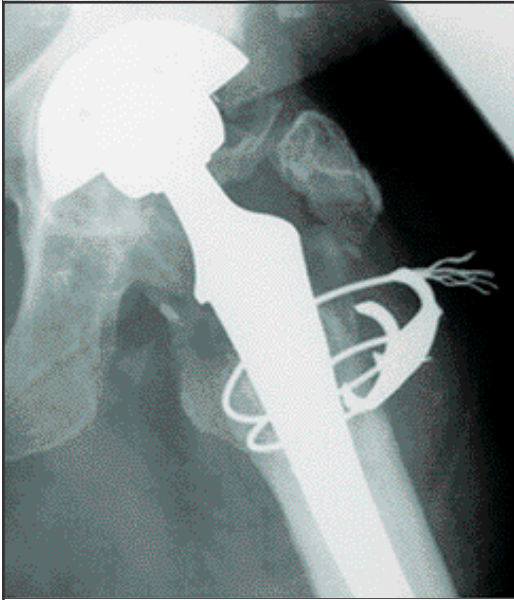
In another case, a 37-year-old man was evaluated for acute onset of sharp chest pain.⁸ His medical history indicated that he had experienced a joint dislocation of the right shoulder from a football injury that had been treated operatively with metal cerclage wire. Imaging confirmed a broken metal cerclage wire around the distal clavicle and a 1 cm segment of the broken wire in the myocardium of the right ventricle.

Broken Metal Cerclage Wires are a Serious Threat to Clinicians

Metal wires and cables used for cerclage can also pose a serious risk of injury and the subsequent transmission of bloodborne pathogens to hospital personnel. Mono-filament wires are prone to breakage. Multi-filament cables tend to undergo fatigue failure and fray, often releasing metallic particulate debris into the body.

When a multi-filament metal cable is trimmed to length by the clinician, it has many sharp ends that can tear gloves resulting in the loss of valuable operating room time to change gloves. It also can injure the clinician. Metal cables also experience fatigue failure resulting in frayed and sharp ends jutting out into the tissue. Sharp metal cable ends can cause “wirestick” type injuries that pose a risk of disease transmission to surgeons and surgical staff. When a clinician is stuck by one of these wires it can tear the glove breaking the sterile barrier thereby placing the patient at risk of infection and exposing the clinician to bloodborne pathogens.

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X-ray of broken, frayed metallic cerclage cable leading to loss of fixation. Sharp metallic ends can irritate patient tissue and pose sharps hazard to the surgical team at the time of revision surgery.

Photo courtesy of Robert L. Barrack, MD, and R. Allen Butler, MD. "Current Status of Trochanteric Reattachment in Complex Total Hip Arthroplasty"; Clinical Orthopaedics and Related Research; Number 441, pp. 237-242.



Trimmed or broken ends of wire cerclage cables fray and can irritate patient tissue. These sharp ends also pose a safety hazard to surgical teams.

The procedure must be stopped in order to allow the clinician to re-glove. This process soaks up valuable OR time.

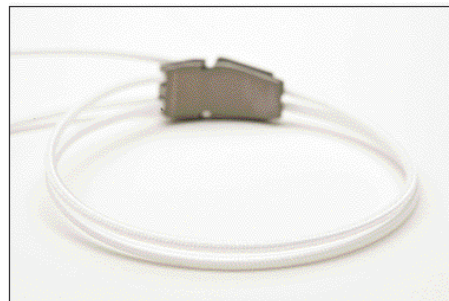
Orthopedic surgeons often rely on tactile feedback, making them very prone to wire stick injuries from metal cerclage cables and wires. As evidence of this again refer to the first picture in this article where surgeons often insert their hands into an area because they are relying on tactile feedback at their fingertips. This places them at risk for wirestick injuries from metal cerclage cables and wires.

During revision surgery, clinicians are often exposed to the sharp metallic ends of cerclage cables that have broken or frayed. This creates a significant hazard to the surgical team.

All of this data indicates that a clinical need exists for a cable that can maintain compression across a fracture without the inherent mechanical problems associated with metallic wires or cables.

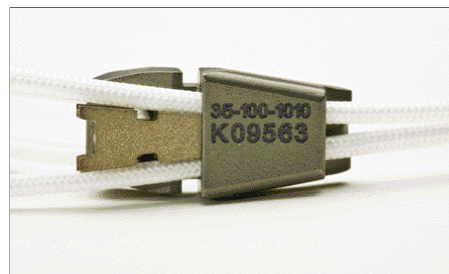
New Product Replaces Old-fashioned Cerclage Cables

I recently had the opportunity to examine a relatively new type of cerclage cable. The cable, called SuperCable Iso-Elastic Cerclage, is manufactured by Kinamed Inc. (Camarillo, Calif.) and has been used in several thousand procedures worldwide since being introduced in 2003. This elastomeric polymer cable consists of a nylon core encased in a jacket of ultra-high-molecular-weight polyethylene (UHMWPE) braided fibers. This combination of materials results in a flexible, soft cable that exhibits extremely high fatigue strength. Fatigue failure is primary mode of failure of metallic cerclage wires and cables.



SuperCable Polymer Cerclage Cable with locking clasp.

The unique design of the SuperCable provides a combination of strength, elasticity and resistance to fatigue failure—which is the primary cause of broken metal wires and cables. I believe that the system offers important benefits and safety features for patient, staff and



Locking clasp holds flexible, soft cable tight.

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surgeon because it is the only cerclage cable that is not made of metal. It does not produce sharp, frayed wire ends when cut. It greatly reduces the incidence of glove tears thereby reducing the risk of patient infection or pathogen transmission to the clinician when the sterile

glove barrier is torn. It also saves time in the operating room because the surgeon does not have to stop to re-glove.

The fretting and fraying of traditional metallic cerclage cables are a cause of premature total joint failure. Metallic debris from these devices can migrate into the joint, causing massive wear and

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The Real Number of Procedures Requiring Cerclage

As indicated in the main article, there are a number of peri-prosthetic femoral fractures (i.e., fractures around a hip stem) that require cerclage cabling for fixation and treatment. Periprosthetic fractures are not rare. In a series of more than 30,000 hip arthroplasties from the prestigious Mayo Clinic, the prevalence of postoperative femoral fractures was 1.1 percent after primary hip arthroplasty and 4.0 percent after revision hip arthroplasty.⁹

Applying these percentages to the number of primary and revision hip arthroplasty procedures performed in the United States each year, there are literally thousands of procedures (and growing) per year where cerclage cables will be used. These numbers, of course, do not even include all the other procedures where cables are used including humerus fractures, patella fractures, olecranon fractures, and so on. **Each usage of a metal cable is an opportunity for a sharps related injury to surgeon and staff, and each metal cable is a hazard to the patient after surgery.**

Let's look at the following tables which estimate the number of peri-prosthetic hip fractures that will occur in the United States next year and 20 years from now.

Table 1

Number of Hip Arthroplasties ²	Year 2010	Year 2030	% Increase
Primary	300,000	572,000	91 percent
Revision	50,000	100,000	100 percent

Table 1 shows that the number of hip arthroplasties, both primary and revision, will be dramatically increased over the next 20 years.

Table 2 estimates the number of fractures that can be anticipated from these hip replacement surgeries in the United States. Remember that each one of these surgeries will likely involve the use of at least one cerclage wire or cable.

	Year 2010	Year 2030
Bone fractures from primary hip surgery ⁹ (1.1% fracture rate)	3,300	6,292
Bone fractures from revision hip surgery (4% fracture rate)	2,000	4,000
Annual number of peri-prosthetic femur fractures following hip replacement surgery	5,300	10,292

These data suggest that in the year 2010, more than 5,000 femur fractures will occur around a hip replacement in the United States. Many of these fractures will be treated with internal fixation utilizing multiple cerclage cables. In the year 2030, this number will increase to over 10,000! This data establishes the prevalence of fractures after hip replacement and demonstrates that problems and complications related to the treatment of peri-prosthetic fractures are expected to grow over time. It would appear that fractures requiring cerclage may only be the tip of the iceberg of what is coming. Applying these percentages to the procedure volumes reported by Kurtz and colleagues for primary and revision hip replacement, there are thousands of procedures (and growing) per year where cables will be used. These numbers, of course, do not even include all the other procedures where cables are used (peri-prosthetic humerus fractures, patella fractures, olecranon fractures, etc.) Each usage of a metal cable is an opportunity for a sharps related injury to surgeon and staff, and each cable is a hazard to the patient after surgery.

In addition to hip fractures, there are many other fractures that require internal fixation involving cerclage techniques. These fractures include periprosthetic humerus fractures, olecranon (elbow) fractures; patella (kneecap) fractures, and so on. These fractures number up to 600,000 per year.¹⁰ Table 3 provides a breakdown of fractures for the year 2006 in the United States.

Type of fracture	Number of fractures
Femur	268,495
Tibia/fibula	166,434
Radius/ulna	70,053
Humerus	49,935

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Metal wires and cables used for cerclage fixation can also pose a serious risk of injury and the subsequent transmission of bloodborne pathogens to hospital personnel.

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osteolysis. The polymer SuperCable generates no such metallic wear debris.

The SuperCable system cables can be re-tensioned effectively when multiple cables are applied. This reduces the need to cut off and discard metal cables that have become loose after additional cables have been applied and tensioned. Over time, this feature will reduce the total number of cables required for a given procedure.

This revolutionary polymer-based cerclage system is designed to solve many of the inherent problems of traditional metallic wire and cabling systems. The SuperCable has fatigue strength superior to both metal wire and cables thereby reducing complications due to breakage. It also eliminates cable-generated metal particle debris that has been shown to greatly increase wear in adjacent total joints. It provides long-term dynamic compressive loading across bone fragments to offer the possibility for better healing and increased construct strength and can be easily retightened to adjust cable tension, especially when multiple cables are applied, both saving time and reducing the number of cables required. The cables are easy and quick to manipulate within the wound. Since the product is made of a

polymer it contains no metal cable that can contact metallic implants and has no sharp ends to irritate patient tissue or cut surgeon's gloves.

Conclusion

Each year, orthopedic surgeons perform an increasing number of surgeries that require the use of cerclage cables to help hold bone fractures together while they heal. Metallic wires and cables fail and fray, exposing both patients and clinicians to sharps injuries. Newer technologies are now available to help minimize tissue damage and prevent unnecessary sharps injuries and bloodborne pathogen exposures. †

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Post operative x-ray of four SuperCables wrapped around an allograft strut and hip prosthesis in revision hip replacement surgery. Note the SuperCables are radiolucent except for their locking clasps.

Ron Stoker is the founder and executive director of ISIPS, the International Sharps Injury Prevention Society, and is a frequent contributor to Managing Infection Control magazine. He speaks frequently at national and international meetings on sharps safety, hand hygiene and infection control issues. He is coauthor of the "Compendium of Infection Control Technologies." For more information on the Compendium, go to www.medicalsafetybook.com. Mr. Stoker is providing a number of webinars focusing on a variety of sharps injury prevention safety products. For more information on the webinars, go to www.isips.org/seminars.html.