Kinamed *SuperCable*®

Overview

About Kinamed

- Established in 1987
- Global medical device Company
  - Products sold in >30 countries
- Focus on Bone & Joint Applications

About Kinamed

Mission Statement

To develop, manufacture, and sell surgical products that offer real clinical benefits and fill an unmet need

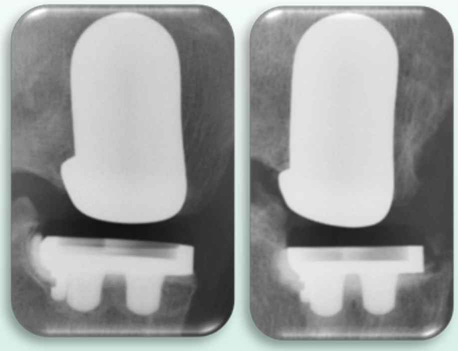
Corporate Headquarters

About Kinamed

- Privately Owned Medical Device Company
- Experienced Management Team
- Ortho, Neuro, and Cardio-thoracic Products
- Commercialization via Distributors & Agents

Product Focus


SuperCable®



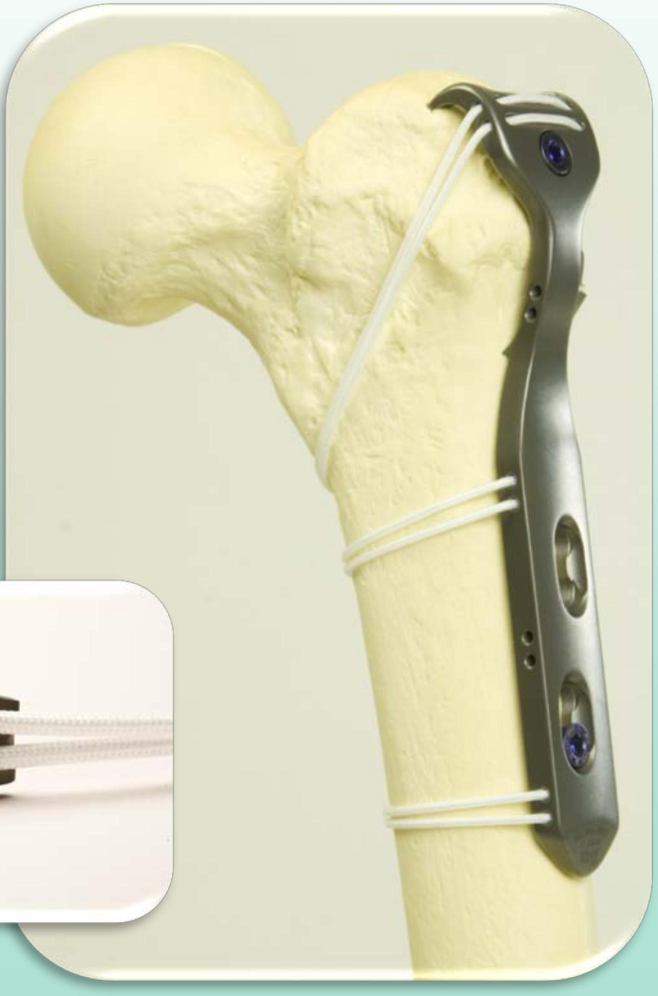
CarboJet®

KineMatch®


NeuroPro®

SuperCable®

Iso-Elastic™, *Polymer* Cerclage Cable



SuperCable History & Facts

- 2004: *SuperCable* (cable system) product launch
- 2008: Grip & Plate system product launch
- Numerous peer-reviewed publications
- Annual sales growth more than 2x global orthopaedic market growth
- Kinamed has sold over 85,000 *SuperCables* worldwide

SuperCable Indications for Use

- Repair of long bone fractures due to trauma or reconstruction
- Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy
- Sternotomy closure
- Sublaminar and intra-facet wiring of the spinal column

SuperCable Grip/Plate Indications for Use

The *SuperCable* Grip and Plate System is indicated for use where wire, cable, or band cerclage is used in combination with a trochanteric grip or bone plate. The *SuperCable* Grip and Plate System is intended to be used in conjunction with the *SuperCable* Iso-Elastic Cerclage System for reattachment of the greater trochanter following osteotomy or fracture, and for fixation of long bone fractures.

SuperCable Cerclage

1. **What is the Clinical Relevance?**
2. What is *SuperCable*?
3. What is the Clinical Evidence?

Problems with Metal Cables

Thurs., 10/18/07 Femur, Paper #5, 1:31 pm OTA-2007

Are Subtrochanteric Cerclage Wires Really the Work of the Devil?

Bruce H. Ziran, MD (n); *Thomas F. Hull, BA (n); Mary-Kate Barrette-Grischow, MA, MPH (n);*
Daneen M. Mace, BSN (n); James A. Shaer, MD (n);
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Problems with Metal Cables

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Complications - Other

Trochanteric Fixation With a Third-Generation Cable-Plate System: An Independent Experience

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ABSTRACT

Background: Greater trochanteric fracture/nonunion can be a devastating complication with significant functional impact after total hip arthroplasty, and their fixation remains a challenge because of the significant forces being transmitted as well as the poor bone quality often associated with these fractures. The objective of this study is to investigate the rates of reoperation and trochanteric nonunion using a third-generation cable-plate system at one center.
Methods: Thirty-five patients, mean age 72.9 years (range 46-98 years) with 24 women and 11 men, underwent fixation of their fractured greater trochanter using a third-generation cable-plate system. The indications were: periprosthetic fracture (n = 17), complex primary arthroplasty (n = 5), and complex revision arthroplasty (n = 13). Primary outcomes included rates of reoperation and radiographic union.
Results: At a mean follow-up of 2.5 years, trochanteric union rate was 62.9% with nonunion rate of 31.4%, and fibrous union in 5.7%. In regard to quality of initial apposition, only 40% achieved a perfect bone on bone reduction. Ten patients (28.6%) had evidence of wire breakage. Five patients (14.3%) required reoperation and removal of the internal fixation because of lateral hip pain.
Conclusion: Fixation of the trochanteric fractures remains a challenge with a relatively high reoperation rate. Poor bone quality and capacity to maintain a stable reduction continue to make this complication after total hip arthroplasty a difficult problem to solve.

Big Clinical Problems with Metal Cables

1. Breakage (due to fatigue)
2. Loosening (due to in-elasticity)
3. Bone Cut-Through (due to in-elasticity)
4. Corrosion and Debris (due to fretting)
5. Sharps Hazards for Patients and Surgeons (due to sharp ends from broken or trimmed ends)

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Problem: Breakage

1979

Trochanteric Osteotomy

Analysis of Pattern of Wire Fixation Failure and Complications

RUSSELL P. CLARKE, JR., M.D., WILLIAM D. SHEA, M.D. AND BENJAMIN E. BIERBAUM, M.D.

Since the middle of 1969, total hip replacement using trochanteric osteotomy has been a frequently performed procedure at New England Baptist Hospital. We find that greater exposure and the ability to improve the biomechanics of the hip outweigh the recognized disadvantages of increased operating time and increased blood loss.[5,9,10,11]

We wish to discuss the problems and complications that are directly related to trochanteric osteotomy. These include: loss of trochanteric position, osteotomy non-

Thompson[11] is 17.5% and is 9.9% as Johnson[8] reported although other authors would dispute these high figures.

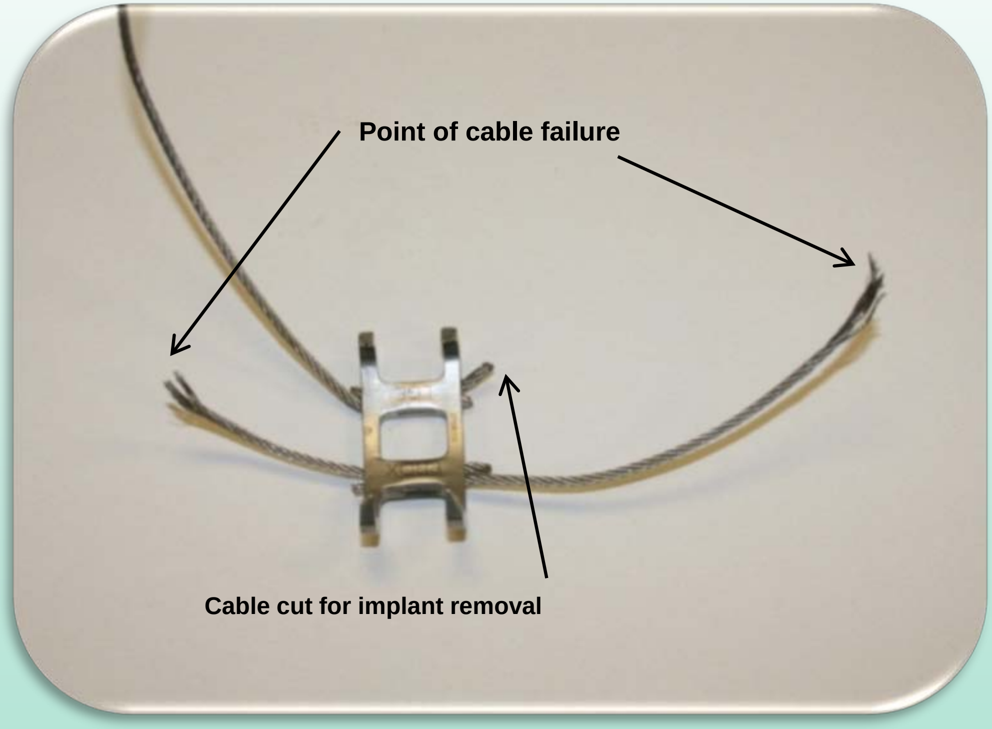
We realize that most of these complications and problems arise due to local irritation within a wound caused by wire and the fatigue properties of wire. Wire knots and twists can produce intractable pain, for which wire removal becomes necessary. Wire breakage is ordinarily due to fatigue failure. Charnley states, "Wire breakage is never due to tension except at the moment of tightening by the surgeon."[5] We could,

Problem: Breakage and Loss of Fixation

- Metal cables have high rates of fatigue failure (Ritter reported 32.5% breakage)

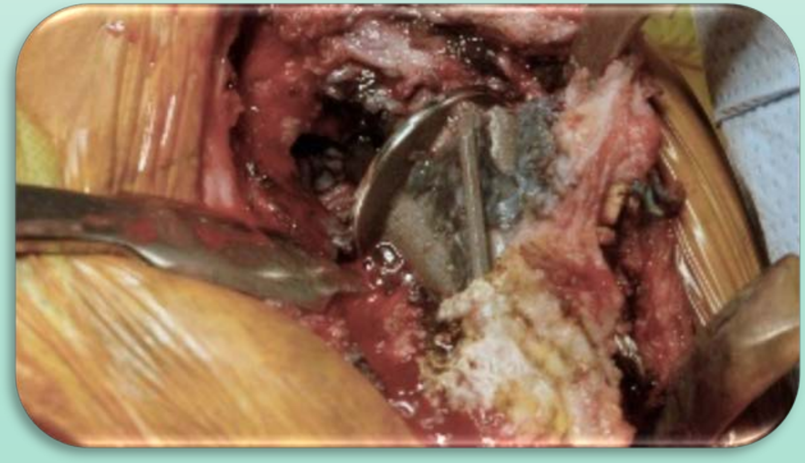
- Broken cables result in fixation loss, can be painful, and can require additional surgery for removal

Problem: Breakage and Loss of Fixation



Broken cables result in loss of fixation and require additional surgery for hardware removal

Problem: Breakage and Irritation



Photos and x-ray courtesy of:
Tom Norris, MD
San Francisco, California USA

2057

MIGRATION OF A BROKEN CERCLAGE WIRE FROM THE PATELLA INTO THE HEART

A CASE REPORT

BY FLAVIO BIDDAU, MD, MASSIMO FIORITI, MD, AND GIOVANNI BENELLI, MD

Investigation performed at Ospedale Misericordia e Dolce Prato, Prato, Italy

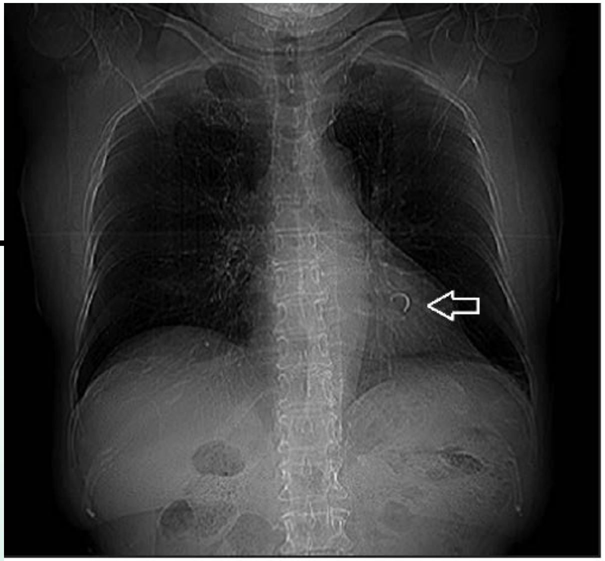
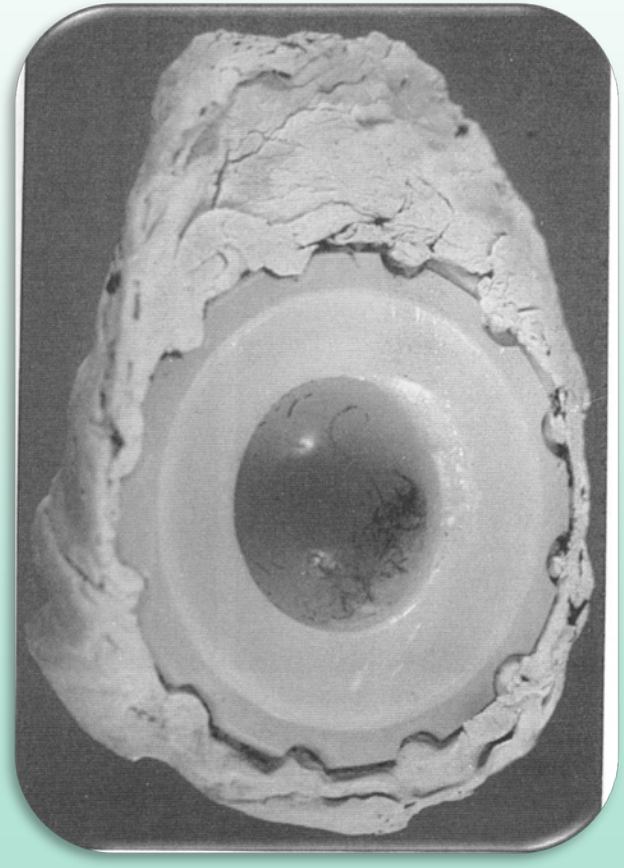


Figure: Chest radiograph showing a metallic wire in the left ventricle (arrow).

Problem: Metal Debris



Macro debris from failed metal cables

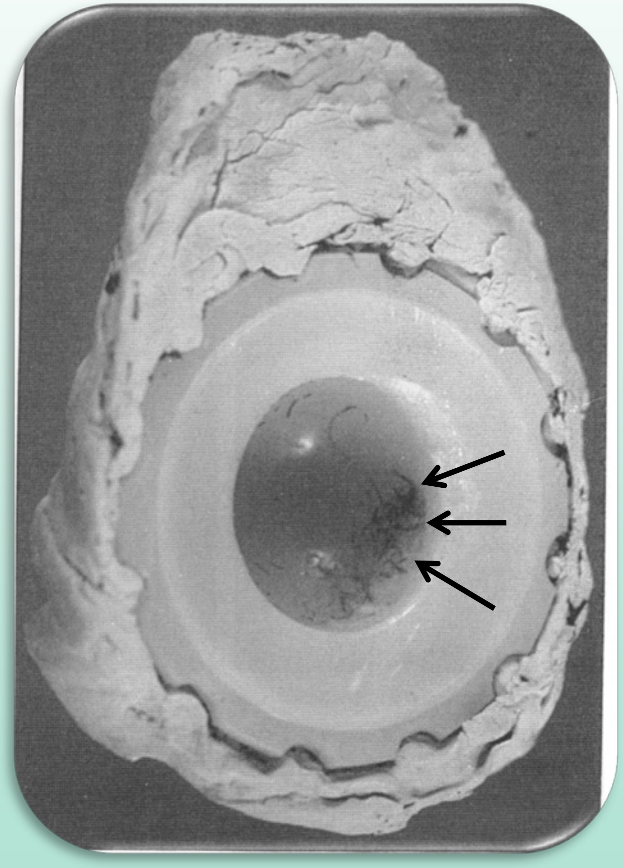
The Frank Stinchfield Award 1997

Contribution of Cable Debris Generation to Accelerated Polyethylene Wear

Jon D. Hop, MD; John J. Callaghan, MD; Jason P. Olejniczak, BS; Douglas R. Pedersen MS; Thomas D. Brown, PhD; and Richard C. Johnston, MD

Migration of metallic debris generated from cable used for trochanteric reattachment was seen in the extraarticular and intraarticular areas of the hip long term. Cases with cable greater trochanteric reattachment showed significantly increased amounts of acetabular volumetric wear, osteolysis, and radiographic acetabular loosening compared with the same surgeon's cases where wire reattachment was used. To the authors know-ledge this is the

Problem: Metal Debris



Macro debris from failed metal cables

- Pieces of the wire filament components of a braided metal cable are embedded in this acetabular cup
- These pieces of wire become what are termed “third body abraders” in the bearing, causing accelerated bearing wear
- The study documented a significantly higher failure rate for THA in which a braided metal cable was implanted

Problem: Metal Debris

The Journal of Arthroplasty Vol. 11 No. 4 1996

Complications of a Cable Grip System

Craig D. Silverton, DO, Joshua J. Jacobs, MD, Aaron G. Rosenberg, MD, Laura Kull, MS, Arthur Conley, MD, and Jorge O. Galante, MD

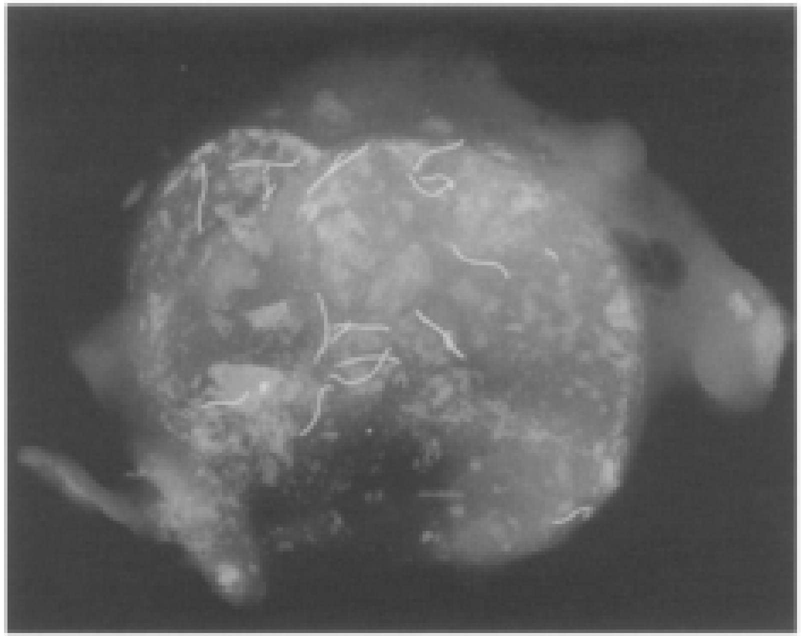


Fig. 2. Contact roentgenogram of a gross specimen of pseudocapsule removed at revision surgery. Note the multiple metallic filaments of various lengths as well as finer particulate metal (arrow) (original magnification × 3.5).

Problem: Metal Debris

Micro debris from orthopedic implants

DePuy
ASR Metal on Metal Hip

Stryker
Modular “Rejuvenate” Hip

Problem: Metal Debris

Micro debris from orthopedic implants

Both devices produced fine metallic debris that caused unusual and significant tissue reactions!

Braided Metal Cerclage Cables:
Anatomy of "The Perfect Metal Debris Factory"

Metal cerclage cables have been implicated as a significant source of metallic debris that, along with other sources such as modular junctions and metal-on-metal (MoM) articulations, contributes to the joint replacement patient's total systemic metal debris load.[1] Analysis of the construction of a braided metal cable reveals a very large number of potential wear sites formed where adjacent wire filaments composing the braided cable contact one another along the length of the cable. It is expected that these numerous contact sites result in "fretting wear" as the patient ambulates and loads the cable.

> Fretting is defined as "*A special wear process that occurs at the contact area between two materials under load and subject to minute relative motion by vibration or some other force.*"[2]

In addition to fretting wear as a source of metal debris, dissolution of metal ions due to galvanic corrosion should also be considered. It has been shown that fretting can greatly enhance galvanic corrosion rates of implant materials due to fretting wear's removal of the passive oxide layer that confers electrochemical stability as well as "biocompatibility" to the cable material.[3] Metal cerclage cable materials are often "dissimilar" to one or more of the large masses of metal joint prostheses implanted nearby, creating an environment for galvanic corrosion.

> "**Galvanic Corrosion** occurs when a metal or alloy is electrically coupled to another metal or conducting nonmetal in the same electrolyte. The three essential components are: materials possessing different surface potential, a common electrolyte and a common electrical path."[4]

Cross-sectional images of two common metal cerclage cables reveal a surprisingly large number of potential sites for fretting wear. The 7 x 7 wire bundle format (Fig. 1) tends to be used in older cable designs while the 19 x 7 (Fig. 2) format is utilized in some newer designs. The 7 x 7 wire bundle cable yields a total of 96 sites where individual wires filaments interact and "articulate" with adjacent filaments when the cable is loaded as the patient ambulates. The 19 x 7 bundle contains 263 of these wire filament wear sites.

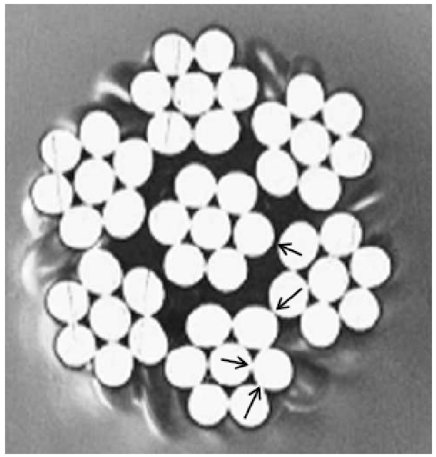


Fig. 1. Cross-section of a "7 x 7 wire cable bundle".[5] Arrows show where adjacent wire filaments interact with their neighbors under load. A total of 96 paired wire filament wear couples are present.

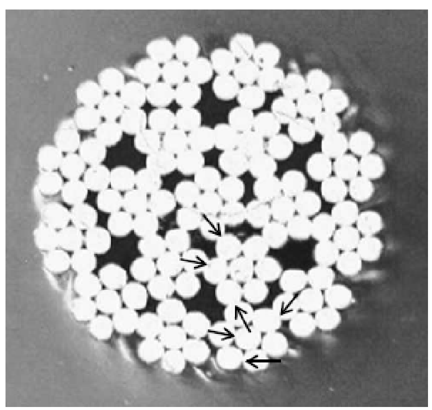


Fig. 2. Cross-section of a "19 x 7 wire cable bundle".[5] Arrows show where adjacent wire filaments interact with their neighbors under load. A total of 263 paired wire filament wear couples are present.

These wear sites are actually lines of contact that run the length of each pair of wire filaments making up the wear couple (Fig. 3). Taking a typical 11 cm circumferential length of cable as used in the femur, and multiplying this length by the total number of these wear couples, a 10.56 meter "total articular length" for the 7 x 7 bundle and a 28.93 meter "total articular length" for the 19 x 7 bundle is derived. Since the wires are wound in a helical shape these lengths are actually greater. Of course in many orthopedic constructs more than one cable is used, resulting in a multiple of these total articular lengths.

Was the unintended consequence of attempting to design a metal cerclage cable that offered improved strength, flexibility and handling characteristics, as compared to older wire cerclage, the creation of "the perfect metal debris factory"?

An understanding of the extent of these MoM articulations present in braided metal cables, along with the recognition that these wire filaments were not engineered to be optimized MoM articulations, raises serious concerns about braided metal cerclage cable's contribution to systemic metal wear debris loads in joint replacement patients. Wear debris from metal implants are known to cause osteolysis that contributes to early implant failure. Metal wear debris from implants also yields metal oxides, hydroxides and phosphates which become systemic throughout the body and have poorly understood potential toxic effects.[6]

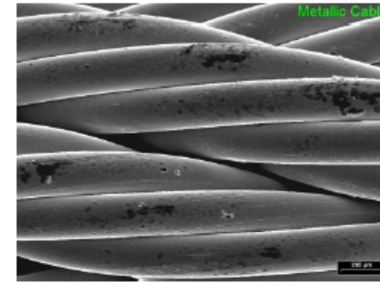


Fig. 3. SEM photo of a metal cerclage cable. Strands of braided metal cable exhibit substantial metal-on-metal interface area.

1. Jacobs et al (2004). Accumulation in Liver and Spleen of Metal Particles Generated at Nonbearing Surfaces in Hip Arthroplasty. J. of Arthroplasty 19:94.
2. ASM Handbook, Volume 19: Fatigue and Fracture. ASM International p.321.
3. Urish et al (2013). The Challenge of Corrosion in Orthopaedic Implants. AAOS Now, April 2013.
4. ASM Handbook, Volume 13A Corrosion: Fundamentals, Testing, and Protection. ASM International p 210.
5. Barrack et al (2005). Current Status of Trochanteric Reattachment in Complex Total Hip Arthroplasty. Clin Orthop 441:237.
6. Keegan et al (2007). Orthopaedic Metals and Their Potential Toxicity in the Arthroplasty Patient. J Bone Joint Surg 89-B:567.

Polymer Cerclage Eliminates a Significant Source of Metallic Debris in Revision Arthroplasty

Fretting from ancillary fixation devices, such as braided metal cerclage cables, can generate a substantial volume of metallic debris that contributes to local and systemic particulate burden (Fig. 1).[1] Fretting is defined as *"A special wear process that occurs at the contact area between two materials under load and subject to minute relative motion by vibration or some other force."*[2] Metal cerclage cables are highly susceptible to fretting because they are comprised of bundles of metal wire filaments that wear against each other during cyclic loading. These wire filaments (Fig. 2) act as wear couples and sites for initiation of fretting wear. In addition, existing metal cable/bone-plate combinations allow for direct contact between the fixed plate or grip and the cyclically loaded metal cable.

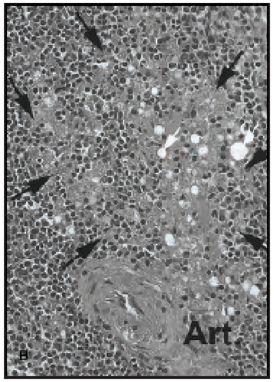


Fig. 1. Postmortem photomicrograph of white pulp of the spleen shows macrophages (black arrows) containing abundant submicrometer particles of cobalt-chromium-nickel-tungsten alloy generated by metal cerclage cables.[1]

Released metal particles are thought to have a cumulative effect on the body. When threshold levels of metal particulate are exceeded in an arthroplasty patient, hypersensitivity, "ALVAL" and other forms of toxicity can result.[1,3,4] Since metal particles are generated from various implant interfaces (including braided metal cerclage cables, MoM articulations, modular junctions, and implant/bone interfaces), and are cumulative, care should be taken to reduce or eliminate sources of debris generation wherever possible so that the overall metal particulate burden is minimized.

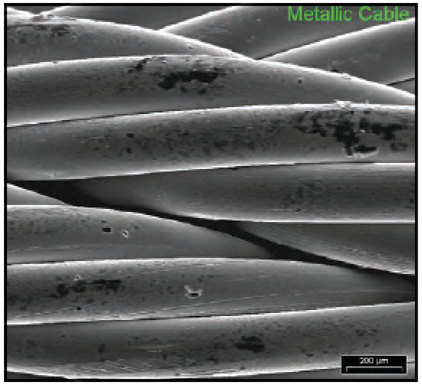


Fig. 2. SEM photo of a metal cerclage cable. Strands of braided metal cable exhibit substantial metal-on-metal interface area that can produce metallic particles and debris during cyclic loading *in situ*.

The polymer SuperCable system (Fig. 3) offers an alternative cerclage cable that eliminates cerclage fixation as a source of metal debris burden. Constructed from high-strength polyethylene fibers and nylon, and fixed with a titanium clasp, immunogenic metals such as chromium and cobalt are avoided. The pliable polymer fibers offer extraordinary fatigue strength and resistance to abrasion.[7] The "Iso-Elastic" nature of the SuperCable is designed to allow it to move with the bone during cyclic loading in order to help prevent "digging in" and to remain tight during the bone healing phase.

Fig. 3. Polymer SuperCable comprised of UHMWPe fiber and nylon filament with a titanium locking clasp.

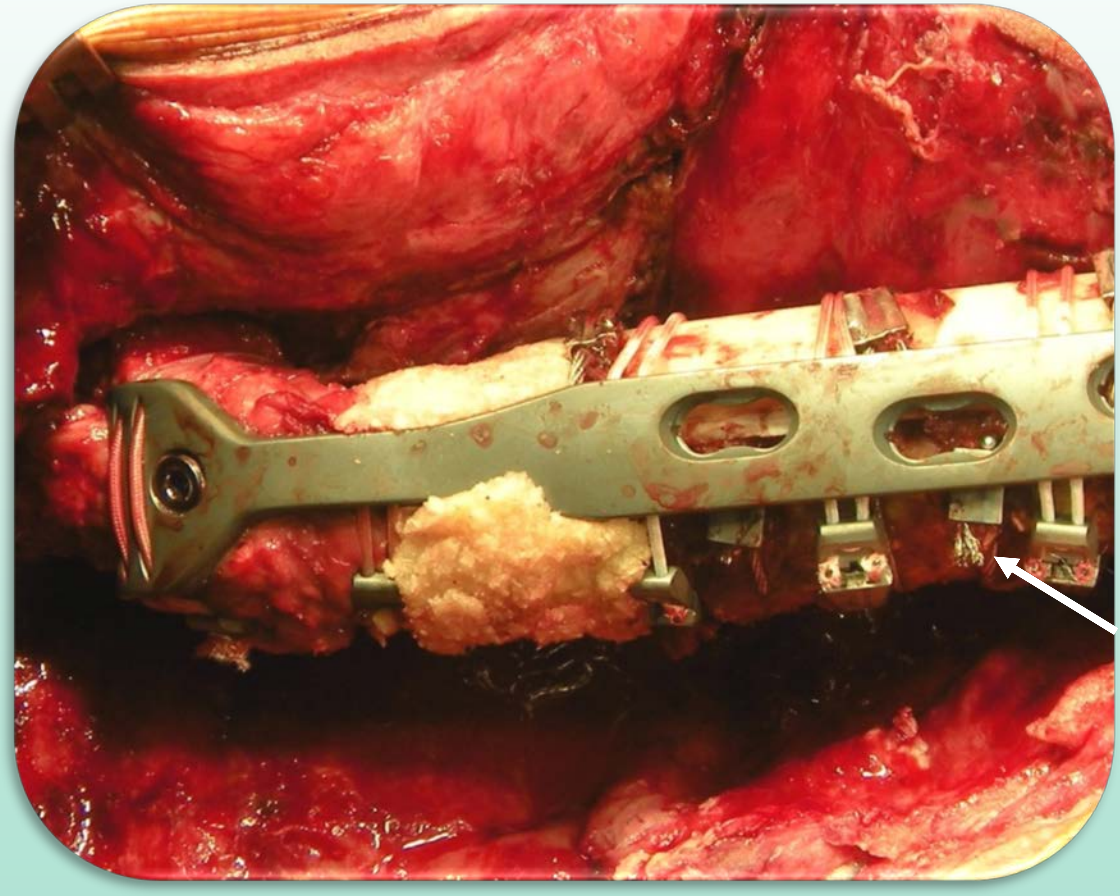
Fig. 4. Radiograph showing broken and frayed metallic cable.[5]

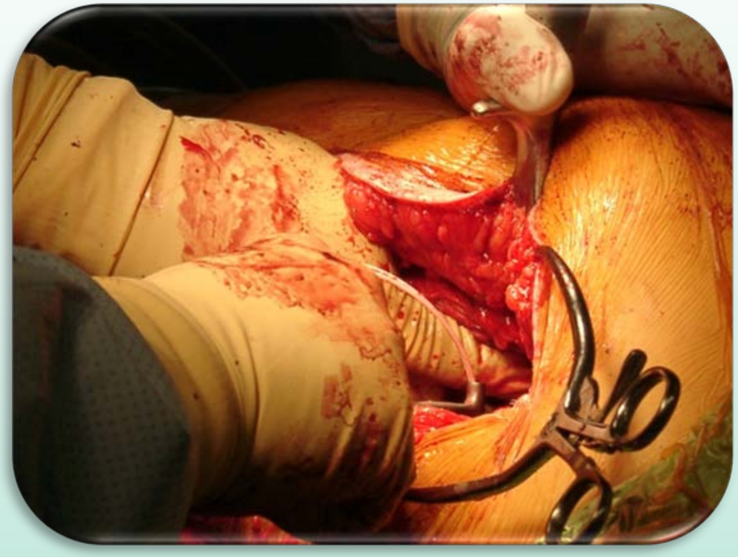
Braided metal cables have also been shown to release large amounts of metallic debris when individual constituent wires fail due to metal fatigue (Fig. 4). Such particles can become 3rd body abraders in implant articulations, leading to significant additional wear and contributing to osteolysis and implant loosening (Fig. 5).[6] The polymer SuperCable system eliminates the potential for this type of 3rd body abrasion and thus eliminates the potential for catastrophic prosthesis failure and bone loss attributable to metal cable debris.

Fig. 5. Retrieval of Charnley acetabular component with metal cable debris embedded in its articular surface.[6]

1. Jacobs et al (2004). Accumulation in Liver and Spleen of Metal Particles Generated at Nonbearing Surfaces in Hip Arthroplasty. J. of Arthroplasty 19:94.
2. ASM Handbook, Volume 19: Fatigue and Fracture. ASM International. p.321.
3. Bolognesi et al (2010). Aseptic Lymphocyte-Dominated Vasculitis-Associated Lesion - A Clinicopathologic Review of an Underrecognized Cause of Prosthetic Failure. Am J Clin Pathol 134:886.
4. Keegan et al (2007). Orthopaedic Metals and Their Potential Toxicity in the Arthroplasty Patient. J Bone Joint Surg 89-B:567.
5. Barrack et al (2005). Current Status of Trochanteric Reattachment in Complex Total Hip Arthroplasty. Clin Orthop 441:237.
6. Hop et al (1997). Contribution of Cable Debris Generation to Accelerated Polyethylene Wear. Clin Orthop 344:20.
7. Sarin et al (2004). A Novel Iso-Elastic Cerclage Cable for Treatment of Fractures. ORS: 739.

Problem: Sharps Hazard





Sharp frayed end of previously placed metal cable

(This surgeon elected to leave metal cables in rather than risk their removal)

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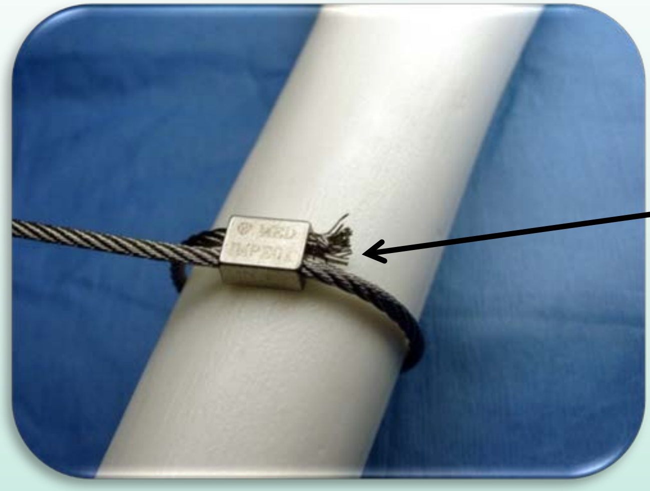
Problem: Sharps Hazard

- **Metal cable breakage may require revision surgery for cable removal**
- **Even when unbroken, the stub of cable, where excess cable was cutoff after tightening, can cause tissue irritation and significant pain**
- **Sharp cable ends irritate patient tissue**

Problem: Sharps Hazard



- Metal cable ends "fray" as soon as they are cut, exposing sharp ends of fine wire
- Metal cables and wires cause "wire stick" injuries to surgeon and surgical staff
- These wire sticks expose surgeon and staff to increased blood borne pathogen risk

Problems: Sharps Hazard

- Sharp cable tends to tear surgeon's gloves
- Re-gloving slows down the procedure and increases surgery time
- Torn gloves expose patients to increased infection risk (hospitals are very concerned about infection rates!)
- White Paper: Avoid Sharps Injury with SuperCable

SuperCable Cerclage

1. What is the Clinical Relevance?

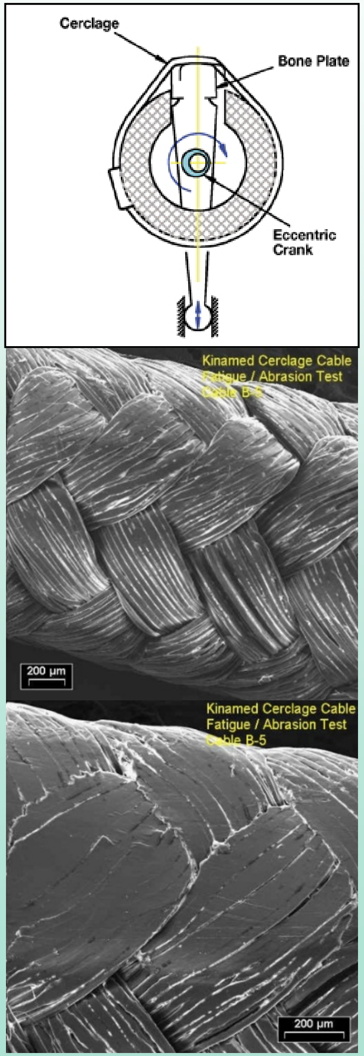
2. **What is *SuperCable*?**

3. What is the Clinical Evidence?

What is *SuperCable?*

- The only available polymer cerclage cabling system
- Cable is made with Nylon core and UHMWPE sheath (non-resorbable)
- Clasp is made from Titanium alloy (Ti6Al4V)
- Cable diameter = 1.5mm x 2 strands

Why Polymer instead of Metal?



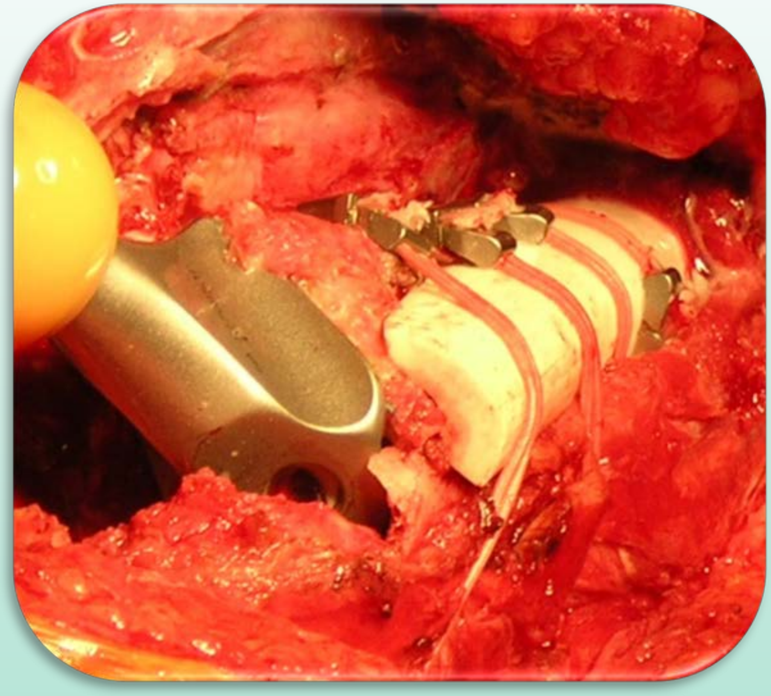
- **UHMWPE has superior fatigue strength versus a metal cable**
- **Wear / Fatigue test (>1 million cycles)**
- **SuperCable is tough, soft, and durable**

Why Polymer instead of Metal?

"Iso-Elastic"

- **SuperCable has engineered elasticity**
- **Elasticity provides dynamic compression across the surgical construct offering the possibility of improved fixation and healing**

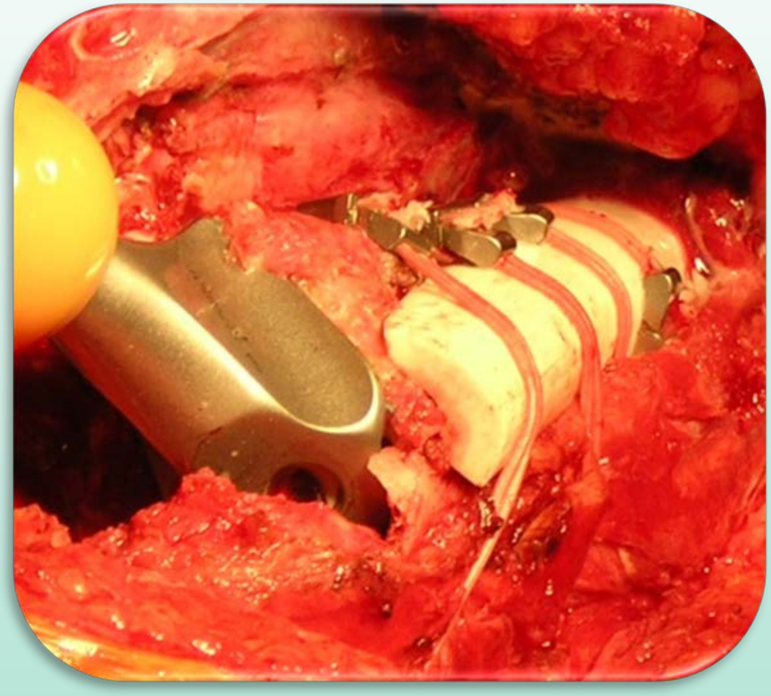
Why Polymer instead of Metal?



“Iso-Elastic”

- **Metal cables dig into bone**
- **Metal cables then become loose and micro-motion ensues**
- **SuperCable compensates because it stores elastic energy**

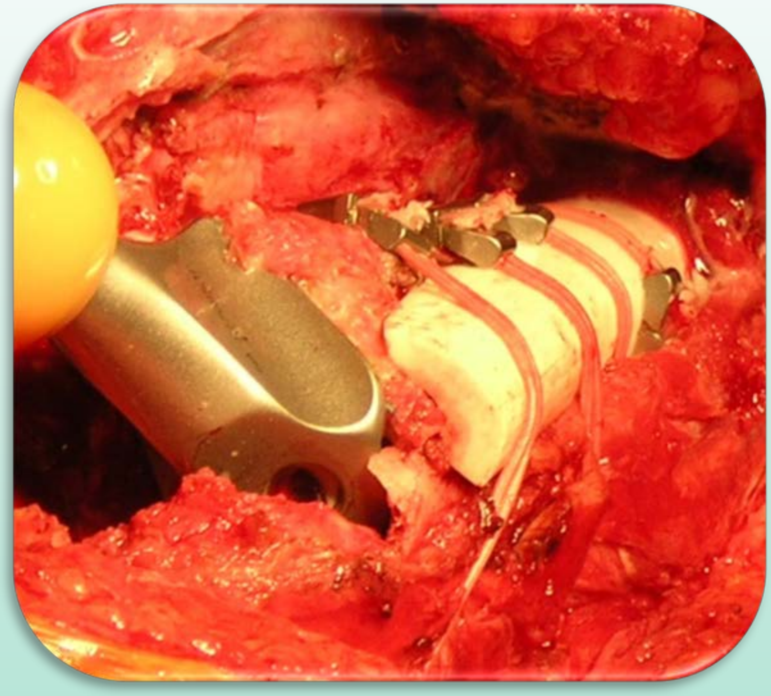
Why Polymer instead of Metal?



"Iso-Elastic"

- **The elastic *SuperCable* can stretch with bone when bone flexes as well as contract against the bone to maintain tension**
- **In contrast, crimped metal cables are a fixed loop that cannot stretch & flex with the bone or contract to accommodate construct settling**

Why Polymer instead of Metal?



"Iso-Elastic"

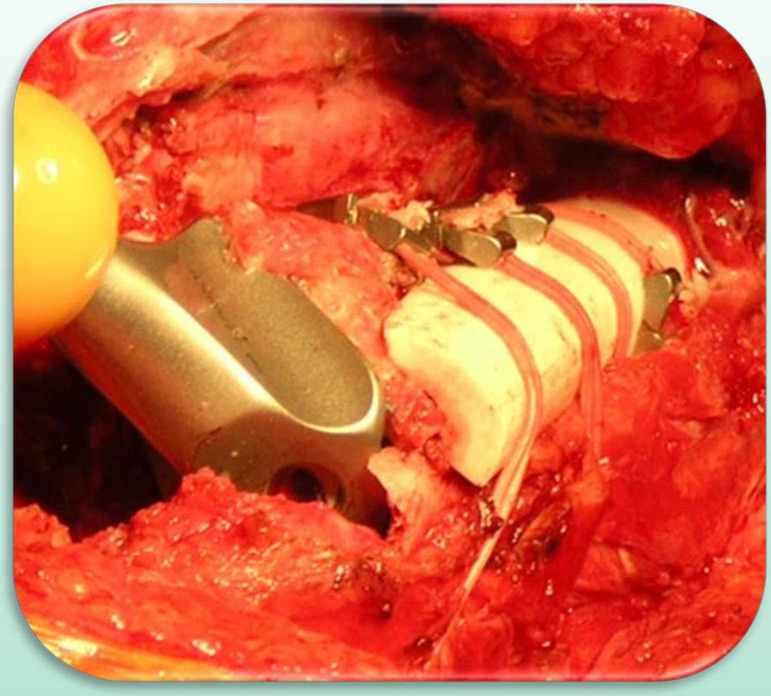
- **Because metal cables lack elasticity, they tend to dig into bone as it flexes and become loose**
- **Also, the repaired bone construct may "settle" as healing occurs, resulting in loose metal cables**

Why Polymer instead of Metal?

"Iso-Elastic"

- **This cable looseness allows for cable micromotion and thus fatigue failure of the metal cable**
- **Metal cables have high rates of fatigue failure**

Why Polymer instead of Metal?

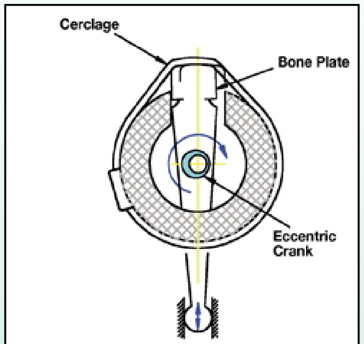


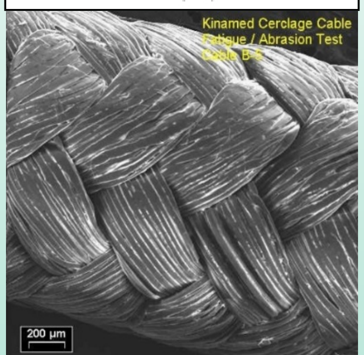
"Iso-Elastic"

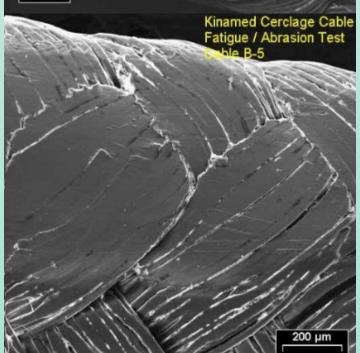
- ***SuperCable*** **can accommodate this bone flexing and settling via the elasticity of the tensioned cable, maintaining tension and fixation over time**

- **Additionally, the polymer cable is extremely resistant to fatigue failure as demonstrated by *in vitro* testing for > 1 million cycles under high load**

SuperCable Fatigue Strength







Wear test fixture shown running “dry” (actual test was “wet”) to >1 million cycles. SEM image, below left, shows cable that was adjacent to the corner of the articulating bar in the test fixture. Test demonstrates the substantial fatigue strength and abrasion resistance of *SuperCable*.

Why Polymer instead of Metal?

- Revision surgery may be required for hardware removal or to treat infection
- *SuperCable* has no sharp cable ends to irritate patient tissue or cut surgical gloves

Why Polymer instead of Metal?

Sharps Hazard

- **Glove tears**
- **“Wire stick” injuries to surgeon**
- **Exposes surgeon and patient to increased infection risk**

Why SuperCable?

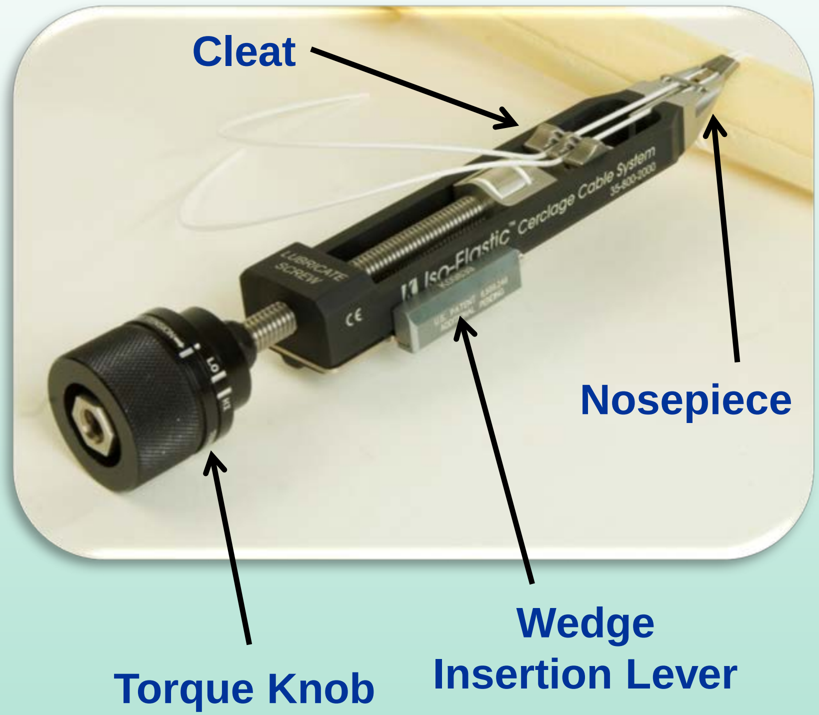
Each cable provides two strands instead of one:

- **Spreads the compressive load over twice the area**
- **This “snowshoe” effect may reduce the bone cutting or grooving often seen with metal**

SuperCable: Key Features

- Iso-elastic Compression of Bone Fragments
- Superior Fatigue Strength
- No Metal Particle Generation
- Can be Retightened to Adjust Cable Tension
- No Metal Cable Contacting Metallic Implants
- No Sharp Cable Ends / No “Sharps Injuries”
- Cable Strands Not Visible on X-rays
- US & International Patents

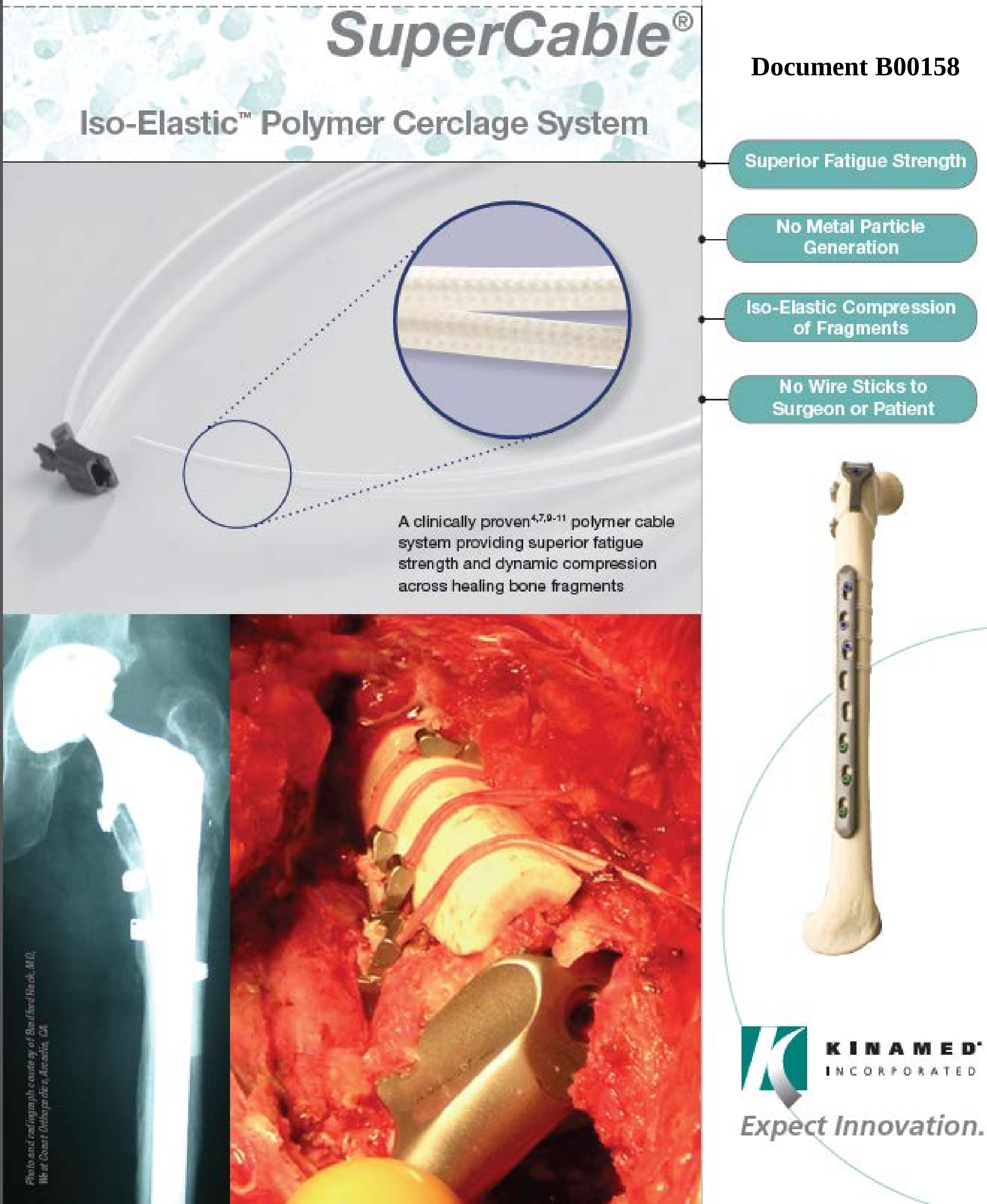
The Key Instrument



- Tensioner is simple, quick, and easy to use
- Cable tensioner is also the cable locking device
- Cables can easily be retightened after locking
- Faster, simpler system eliminates cumbersome tension retaining devices
- No need for bulky bolt or wire cutters

Click Here For More Terminology

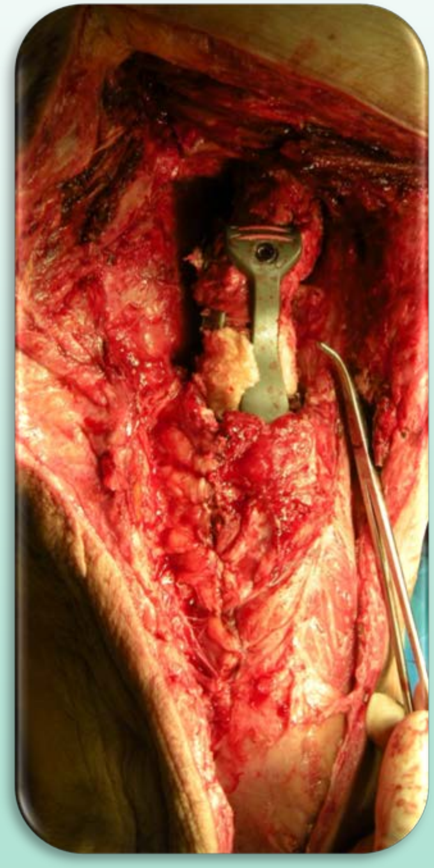
Document B00158



SuperCable Brochure

Instructions for Use (IFU)

SuperCable "Grips & Plates"

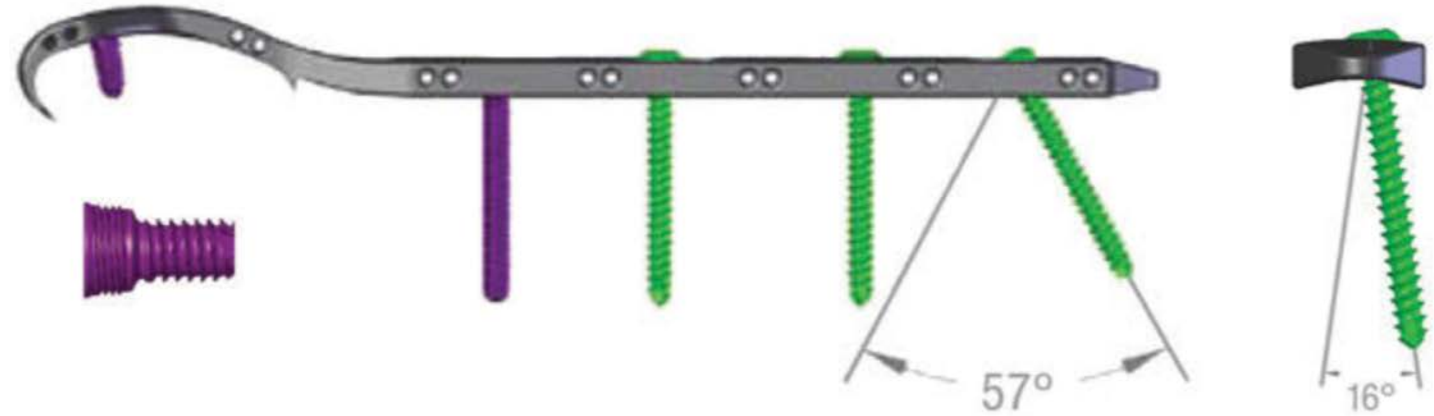


SuperCable Grips & Plates

4 Grip Options
(Short, 2-Hole, 4-Hole, 6-Hole)
“Combi” Holes

3 Straight Plates (6-Hole, 8-Hole, 10-Hole)
2 Curved/Anatomic Plates (8-Hole, 10-Hole)
“Combi” Holes

SuperCable Grips & Plates



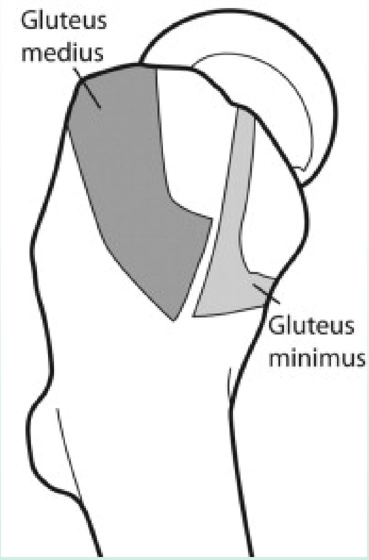
- Compression screws can be angled up to 57º and 16º to optimize bone fixation
- Peri-prosthetic locking screws (10 to 16mm) for use adjacent to intramedullary implants
- Proximal Grip hole allows Locking Screw for added fixation!

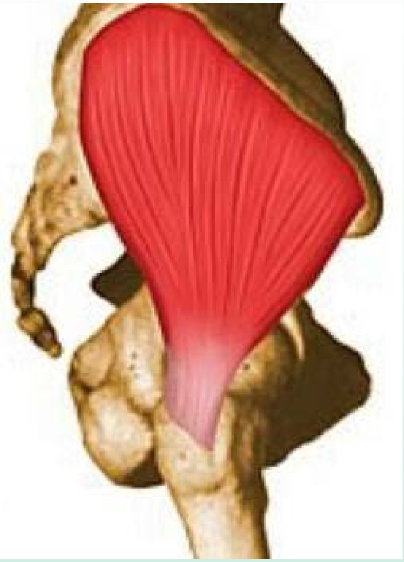
SuperCable "Grips & Plates"

What are they?

- Grips to re-attach the greater trochanter (lateral side)
- Plates for fractures of the femur
- All grips, plates and screws are made from Titanium alloy (Ti6Al4V)
- Paired cable holes designed specifically for *SuperCables*

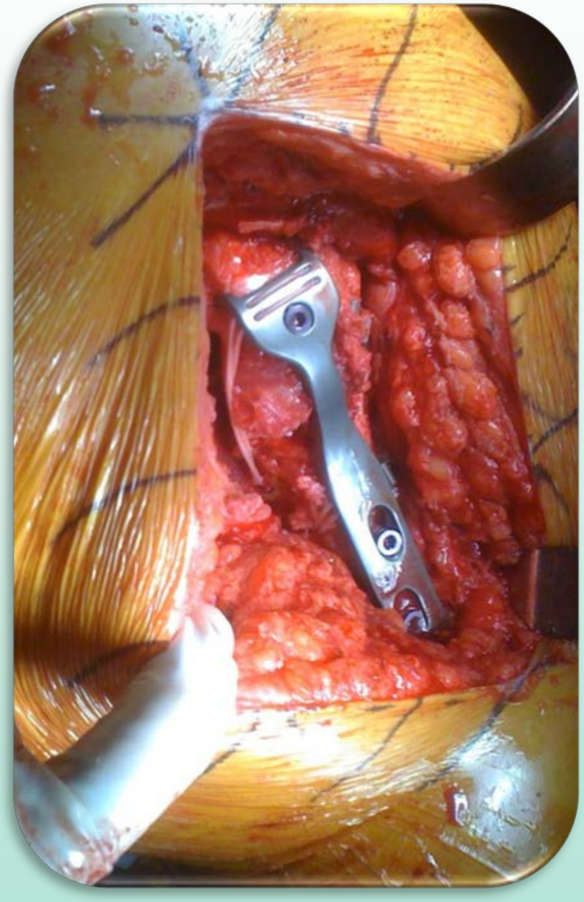
SuperCable Grip Design Rationale

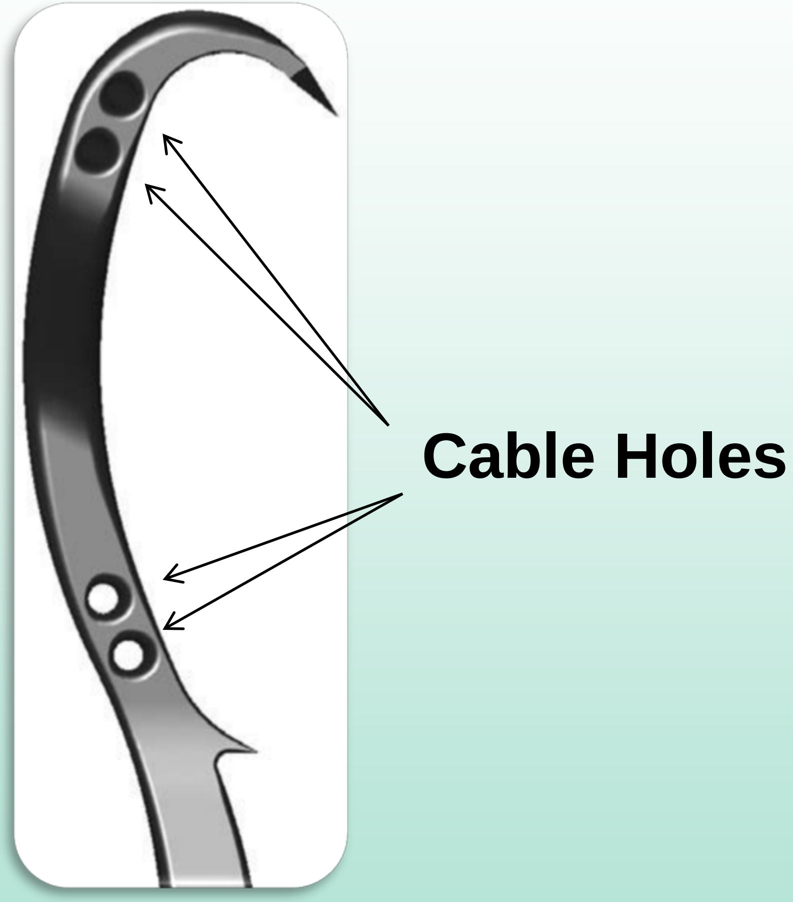




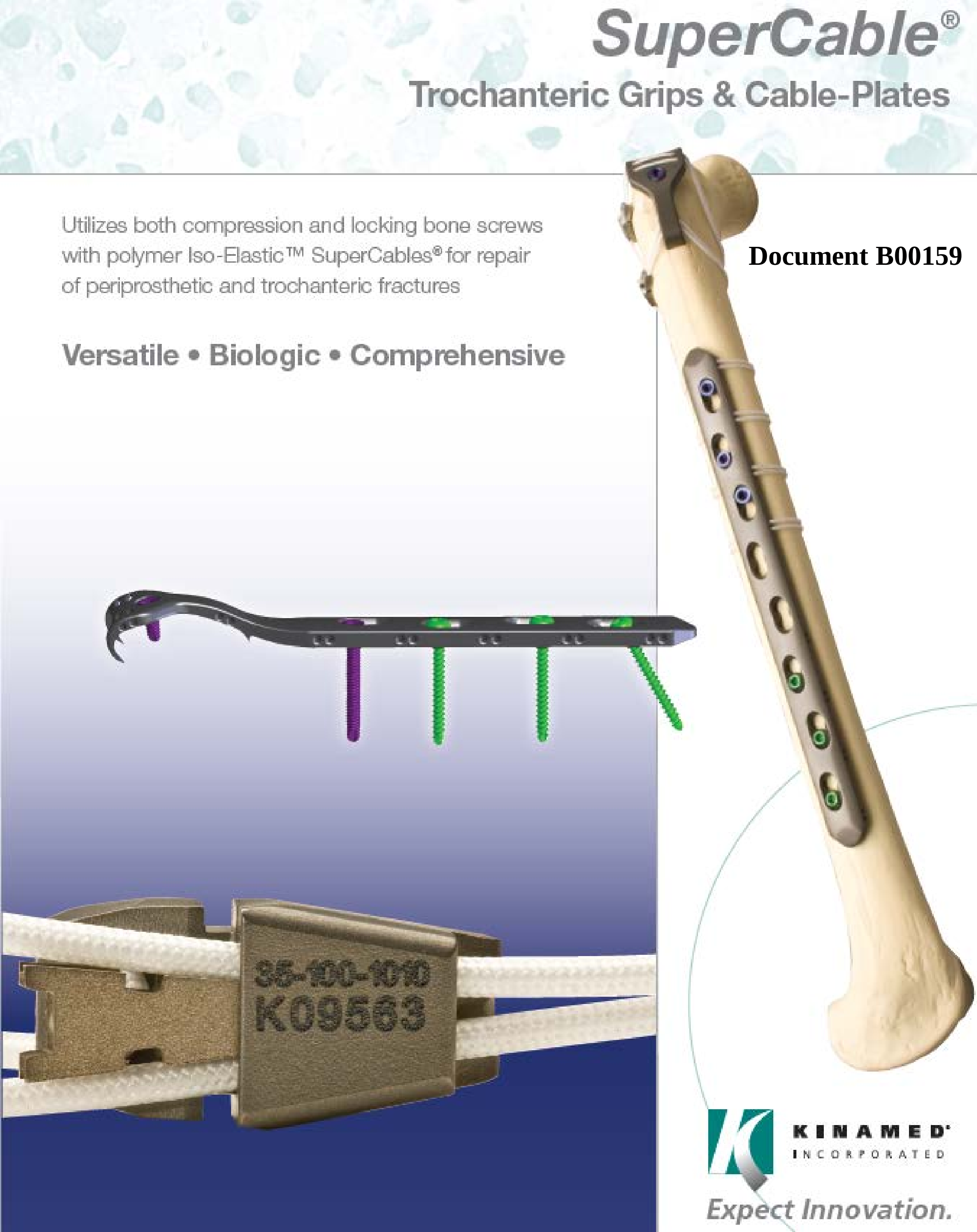
- "Over-the-top" versus Lateral Design
- Bending (Contouring) not required
- Anatomically friendly (better clearance for muscle attachment)
- Long, sharp tines

Click Here For Pro-Tips





Cable holes optimized for use with polymer *SuperCable*



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Grip & Plate Brochure

Instructions for Use (IFU)

SuperCable Cerclage

1. What is the Clinical Relevance?

2. What is *SuperCable*?

3. **What is the Clinical Evidence?**

Clinical Evidence

1. Peer-Reviewed Clinical Studies
2. Case Reports
3. Case Examples

Typical Uses

- Revision Total Hip Arthroplasty - trochanteric osteotomy
- Revision Total Hip Arthroplasty - femoral osteotomy, ETO, etc.
- Revision Total Hip Arthroplasty - onlay grafting
- Primary Total Hip Arthroplasty - prophylaxis
- Revision Total Shoulder Arthroplasty - onlay grafting
- Peri-prosthetic fractures (hip, knee, shoulder)
- Olecranon and Patella fractures
- Fracture Repair with Grips & Plates as indicated

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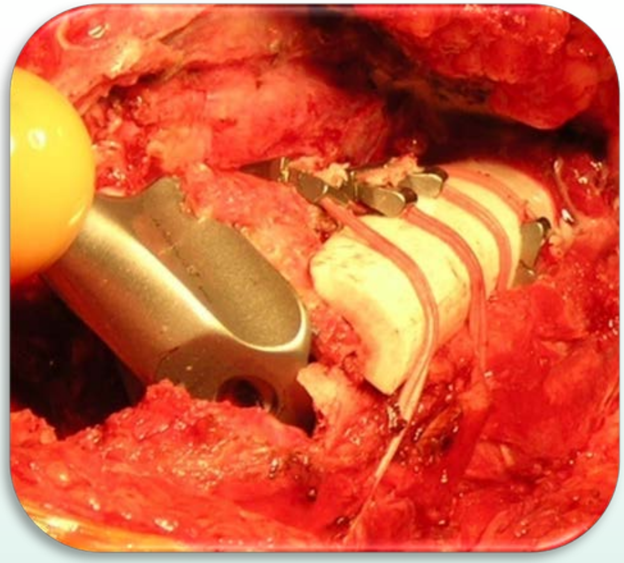
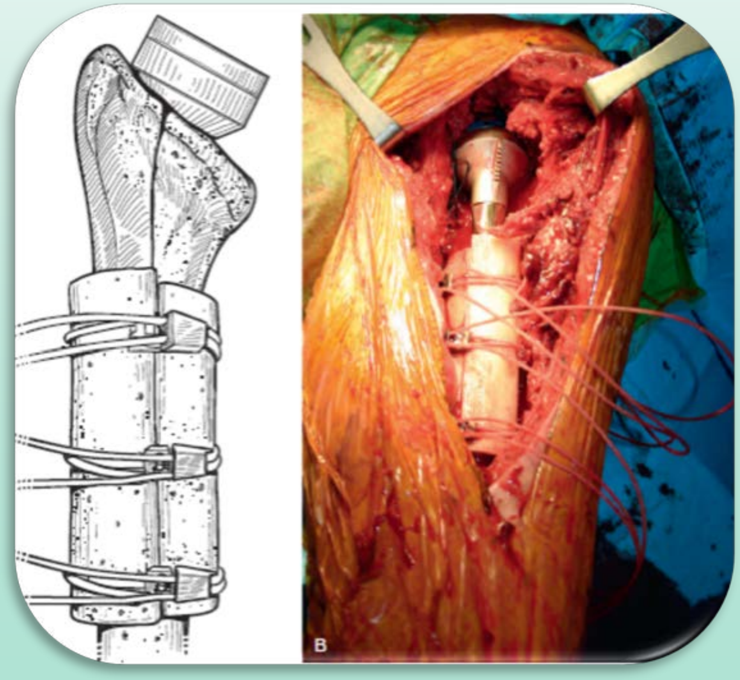
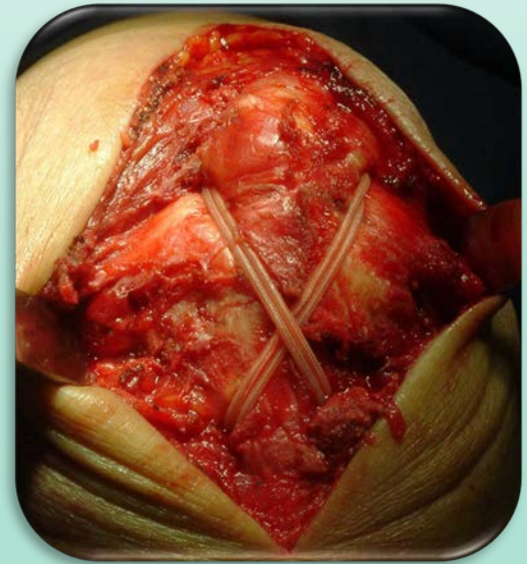
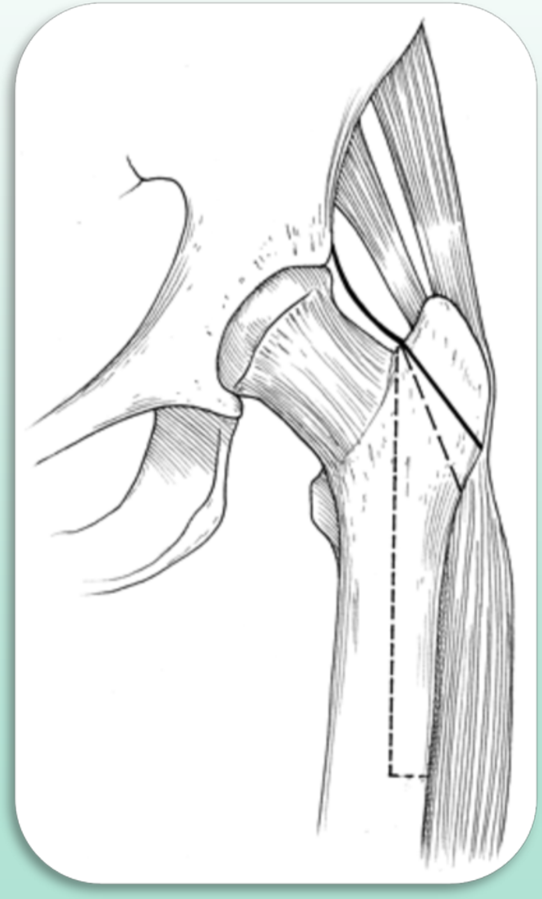


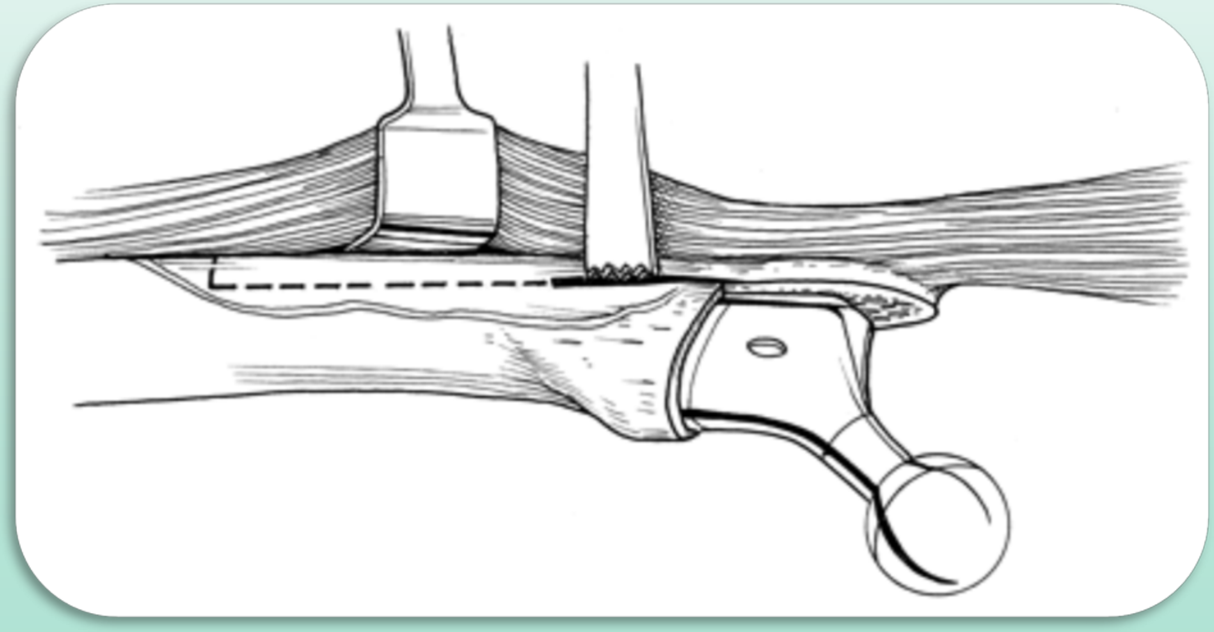




Typical Use



Extended Trochanteric osteotomy (ETO)



Typical Use

***SuperCable* can be placed over metal implants without metal-on-metal interaction**

(sharp edges are to be avoided)

Clinical Studies

- Revision Hip (Della Valle)
- Revision Hip (Berend)
- Revision Shoulder (Edwards)
- Olecranon (Rosenwasser)

Clinical Studies

- Revision Hip (Hao-China)
- Scapular Fusion (Ozturk)
- Revision Hip (Lombardi)
- Revision Hip (Westrich)

Clin Orthop Relat Res (2010) 468:2382–2386
DOI 10.1007/s11999-010-1284-x

SYMPOSIUM: COMPLICATIONS OF HIP ARTHROPLASTY

Early Experience with a Novel Nonmetallic Cable in Reconstructive Hip Surgery

Nicholas T. Ting BA, Glenn D. Wera MD,
Brett R. Levine MD, Craig J. Della Valle MD

- 29 revision THA patients were followed for a mean of 21 months (range, 13 to 30 months)
- Mean age 63.9 years (34 to 94), 18 women and 11 men
- The average number of cables per case was 3.1 (1 to 6)

- **The cables provided adequate early fixation strength to allow for both osteotomy and fracture healing**

- **There were no complications directly related to the cables**

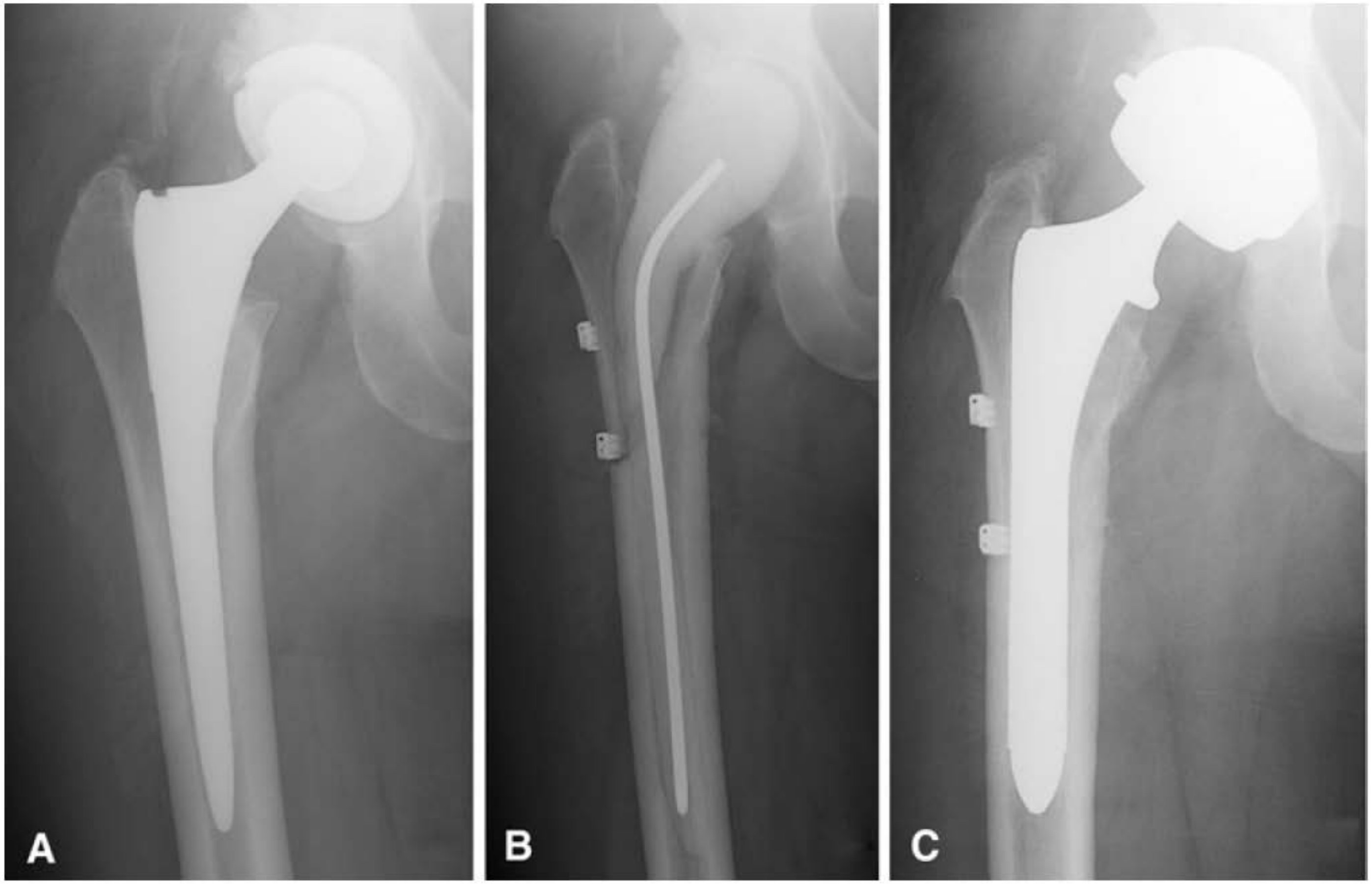


Fig. 2A–C (**A**) A preoperative AP radiograph shows an infected THA. (**B**) A radiograph taken 6 weeks postoperatively after ETO for removal of the well-fixed cementless femoral component and antibiotic spacer placement; nonmetallic cables were used to repair the ETO. (**C**) A 1-year followup radiograph shows healing of the ETO and stable components.

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Complex Revision Hip

Orthopaedic Surgery
SURGICAL TECHNOLOGY INTERNATIONAL XXV

Polymer Cable/Grip-Plate System with Locking Screws for Stable Fixation to Promote Healing of Trochanteric Osteotomies or Fractures in Revision Total Hip Arthroplasty

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MOUNT CARMEL HEALTH SYSTEM
NEW ALBANY, OHIO

- 27 revision THAs (26 patients) were followed for a mean of 2.5 years (0.1 to 5.1)
- Mean age was 63 years (44 to 89), 14 women
- Average 3.1 cables per case (max 7)

- At average 2.5 year follow-up, grip-plate fixation was considered successful in 22 hips (81%) with five failures
  - In one hip, short grip with trochanteric slide
  - In two hips, short grip fixed to intra-operative trochanteric fractures
  - In two hips, trochanteric escape in hips with pre-revision bony necrosis of the trochanter
- Three grip-plates were removed electively for soft-tissue irritation and pain but with successful fixation and healing (70% free of reoperation due to grip-plates)

- There were no complications directly related to the cables

- The authors concluded that the cable-grip system and iso-elastic SuperCables provide reliable fixation for adequate healing of difficult ETO and trochanteric fractures with an 81% rate of mechanical success with radiographic and clinical healing observed. The ability of the construct to utilize multi-modal fixation with locked screws appears to aid in its success.

Figure 1. Complex reconstruction using Supercable and grip-plate system. The patient had undergone a two-stage treatment of infection with a 10-inch, bowed, cylindrical stem which failed from aseptic loosening and failure of ingrowth. Subsequent revision was complicated by infection requiring a second two-stage exchange with ETO and massive proximal bone loss. During the reimplantation, multiple fractures of ectatic trochanteric fragment occurred. A 2-hole (135 mm) grip-plate with Supercables and locked screws was used during the final reconstruction. At four years, the trochanteric fixation is healed and solid and the patient has no complaints related to the construct.

Figure 2. a. Preoperative radiograph of a patient with failed cemented femoral fixation with long cement mantle. b. The patient underwent femoral revision requiring ETO for cement removal. The procedure was without fracture of the trochanteric fragment and thus three cables were used without grip-plate for ETO fixation. A fourth Supercable is seen distal to the osteotomy as prophylaxis against fracture. At five years, complete radiographic and clinical healing of the ETO is seen.

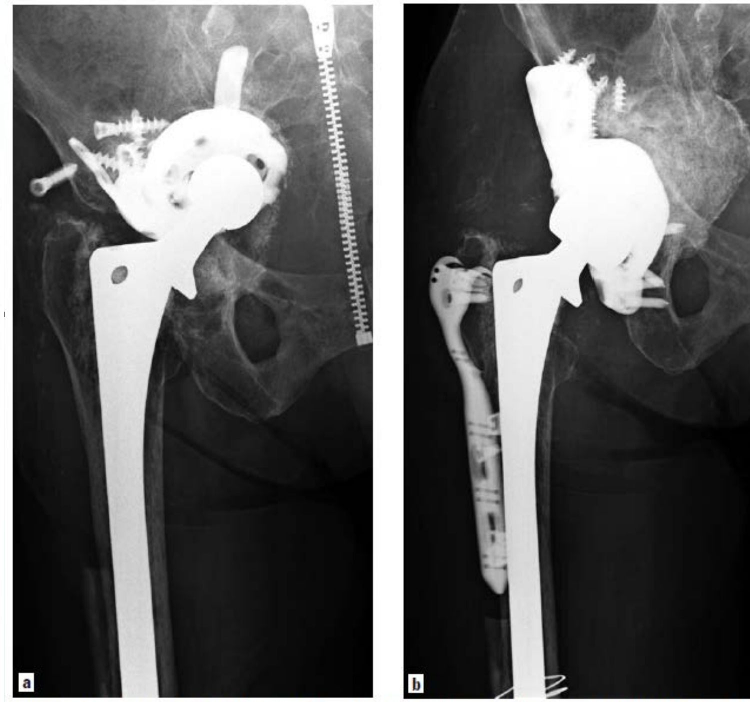


Figure 3. Trochanteric Slide Osteotomy for acetabular exposure. a. Preoperative radiograph of the right hip of an elderly female patient demonstrates complete migration of the acetabular component and femoral head through the acetabular wall, and loosening of acetabular screws and plate. b. A custom acetabular triflange component was designed and required trochanteric slide osteotomy for exposure and insertion. Given the patient's advanced age, osteoporosis, and multiple surgical history, a 2-hole (135 mm) grip-plate with locked screws and Supercables was used. At four years postoperative, stable trochanteric fixation and healing is present.

- The 81% success rate is impressive because these cases are extremely complex, and revision THA is fraught with complications in general.
- The authors of this study are highly experienced and well-respected, and they conclude in this paper that *SuperCable* Grip & Plate System is a good solution for these types of cases. It is also noteworthy that their actual usage of *SuperCable* and Grips & Plates increased after the study was completed.

APRIL 2011 | Volume 34 • Number 4

ORTHOPEDICS | ORTHOSuperSite.com

Utility of Polymer Cerclage Cables in Revision Shoulder Arthroplasty

T. Bradley Edwards, MD; Kyle D. Stuart, MD; George J. Trappey, MD;
Daniel P. O'Connor, PhD; Vineet K. Sarin, PhD

PDF

- 13 revision TSA patients were followed for a mean of 20.4 months (12 to 37)
- Mean age was 66 years (50 to 82), 7 women and 6 men
- Average number of cables per case was 2.8 (1 to 4)
- The cables provided adequate early fixation strength to allow for both osteotomy and fracture healing (Mean time to healing was 4.0 months)

- **No patients experienced loosening or migration of hardware or allograft failure**

- **There were no complications directly related to the cables**

Figure 3: AP radiograph of a reverse total shoulder arthroplasty with a long-stem humeral component surrounded proximally by allograft struts and fixed with 5 polymer cables. The cables are radiolucent but the metal clasps are clearly visualized. (Reprinted with permission from Gartsman GM, Edwards TB. *Shoulder Arthroplasty*. Philadelphia, PA: Saunders; 2008. Copyright © 2008, Elsevier.)

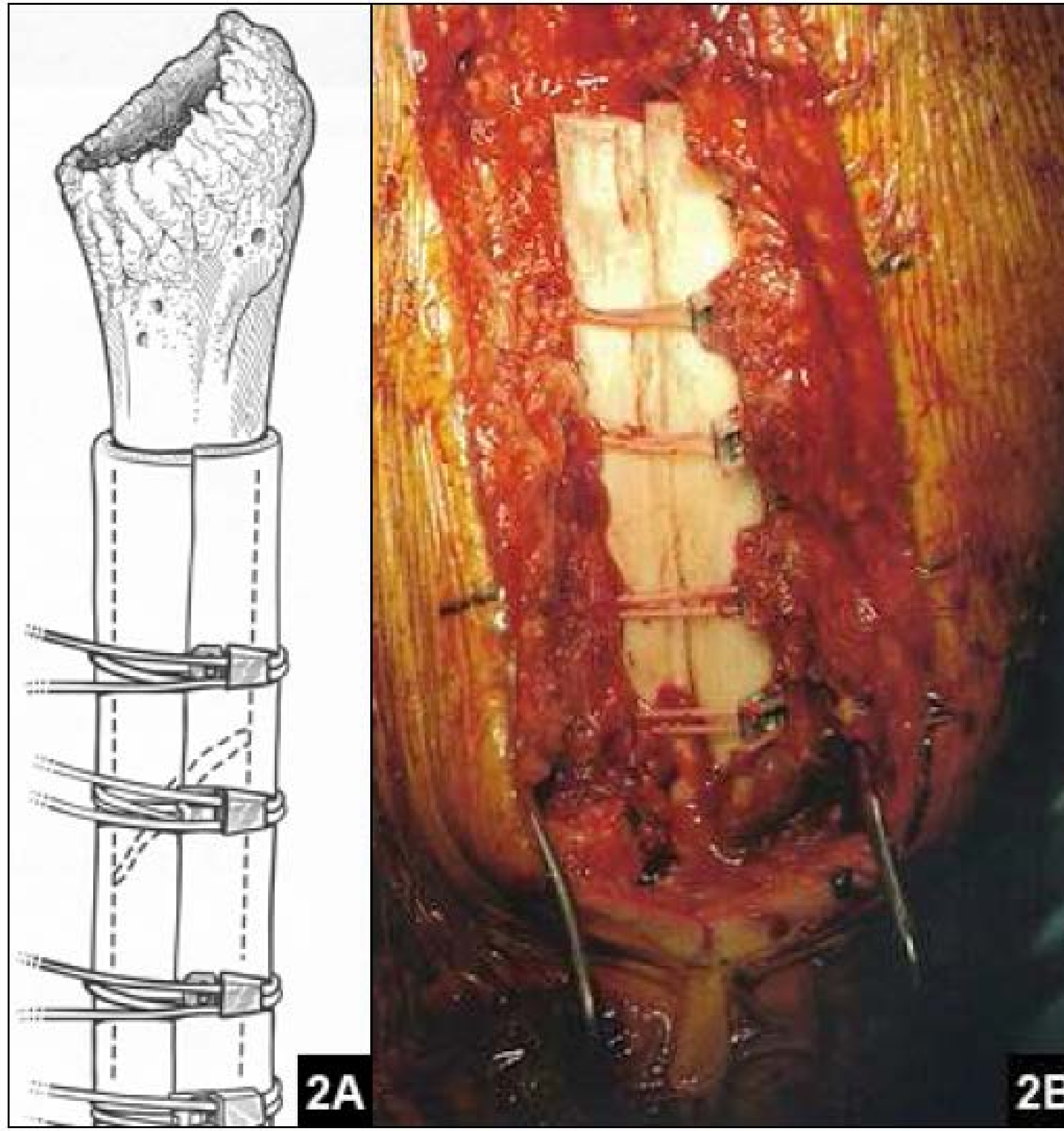


Figure 2: Illustration (A) and intraoperative photograph (B) showing the final construct appearance of 4 polymer cables around an allograft strut. (Reprinted with permission from Gartsman GM, Edwards TB. *Shoulder Arthroplasty*. Philadelphia, PA: Saunders; 2008. Copyright © 2008, Elsevier.)

Case Reports

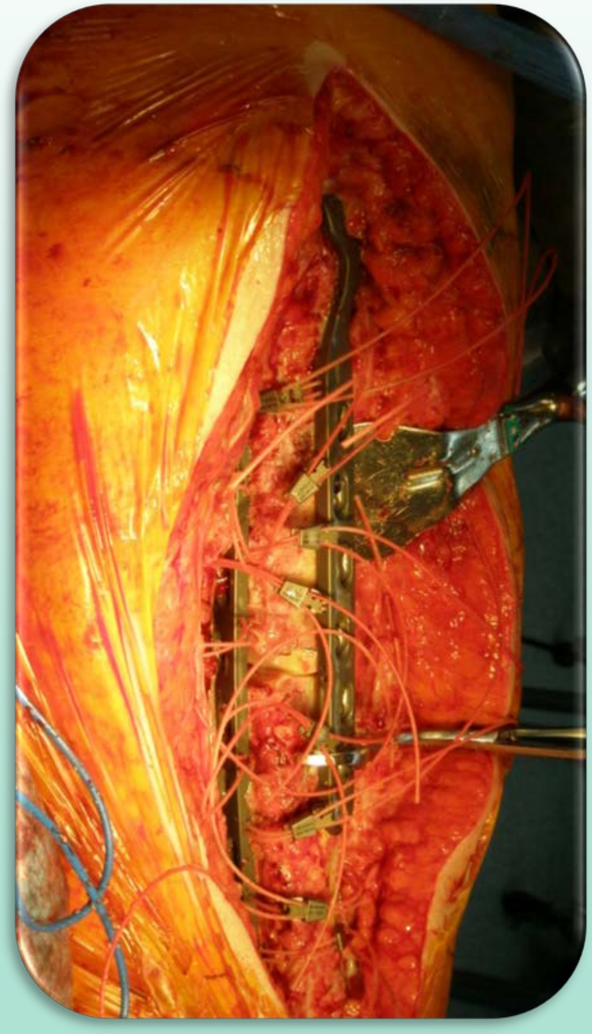
- Grip and polymer cable fixation for inter-trochanteric fracture
- Femoral mid-shaft peri-prosthetic fracture
- Revision of a recalled hip stem, with infection
- Other Case examples

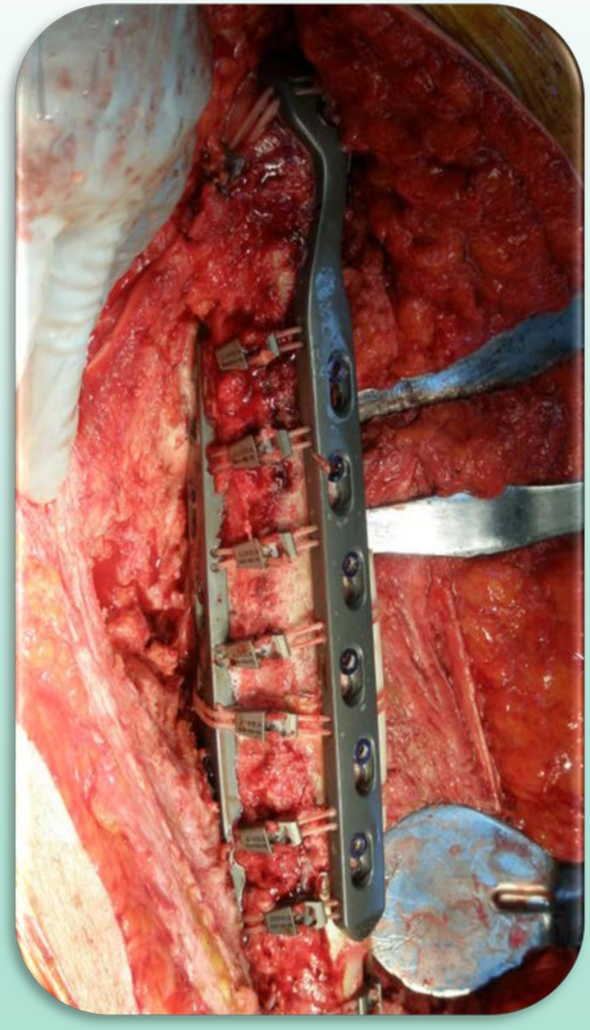
Example Case

84 year old female
- **THR 7 years prior**
- **Revision Hinge-TKR 1 year ago**
- **ORIF peri-prosthetic femoral fracture**

Courtesy of:
Vincent Fowble, MD
Jupiter, Florida USA

Intraoperative

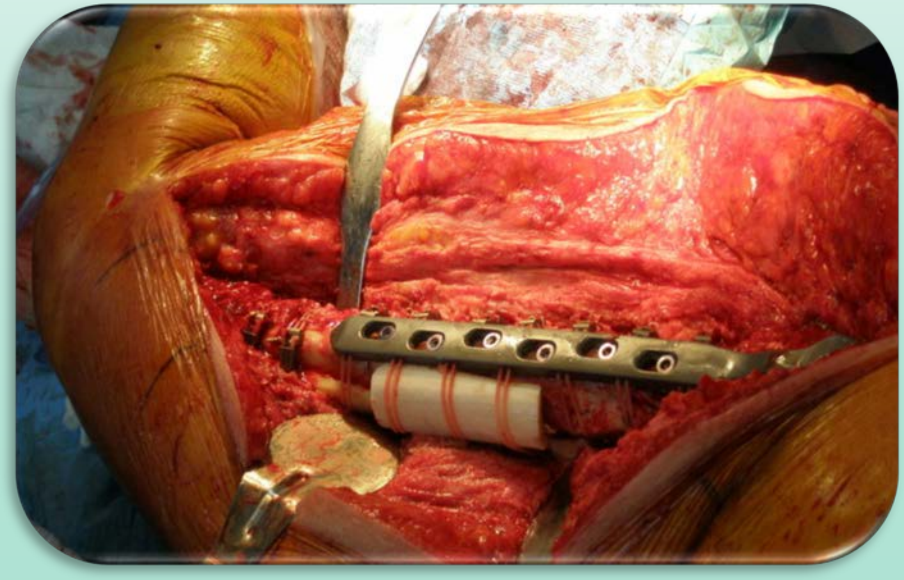


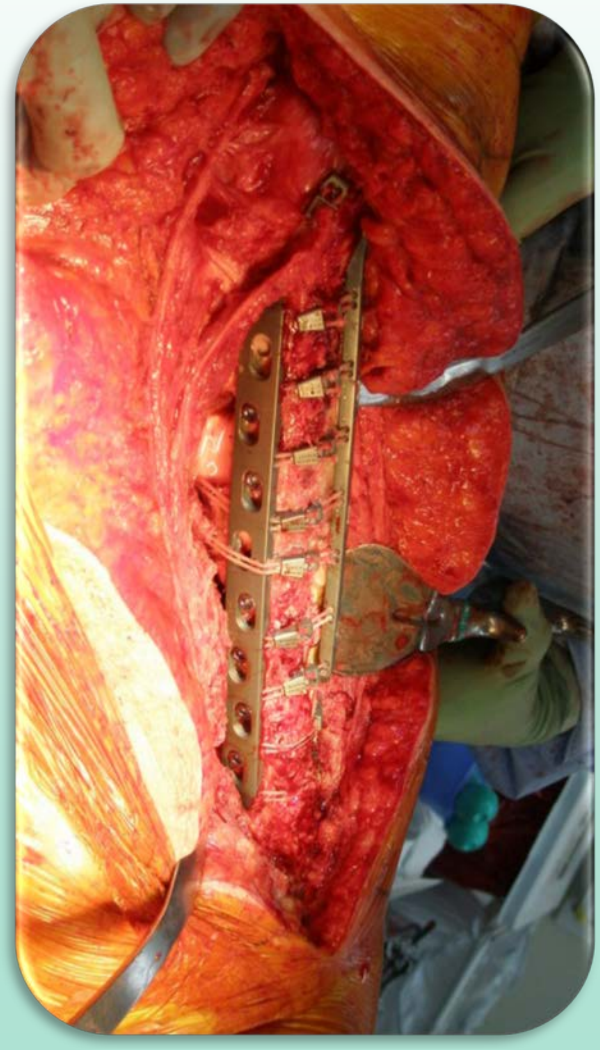


Intraoperative

Final Construct:

- **6-hole *SuperCable* Grip**
- **7 *SuperCable* locking screws**
- **8-hole straight *SuperCable* Plate**
- **7 *SuperCable* locking screws**
- **10 *SuperCables***





2 Year Post-op



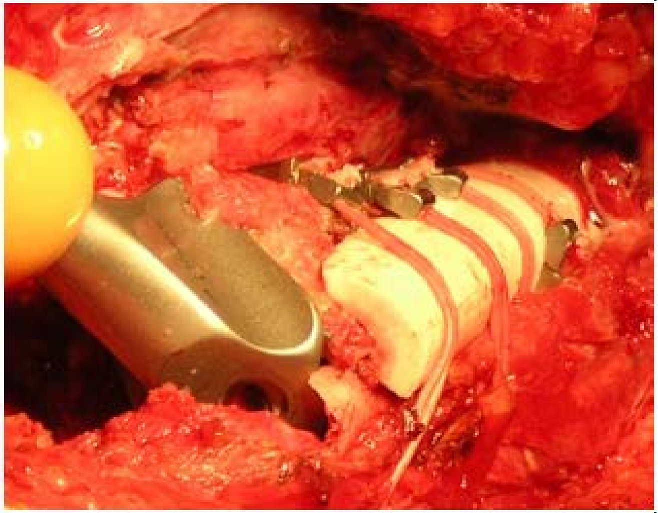
Surgical Technique

Document B00110

SuperCable®

Polymer Iso-Elastic™ Cerclage System*

Photo and radiograph courtesy of Bradford Hack, MD, West Coast Orthopedics, Arcadia, CA



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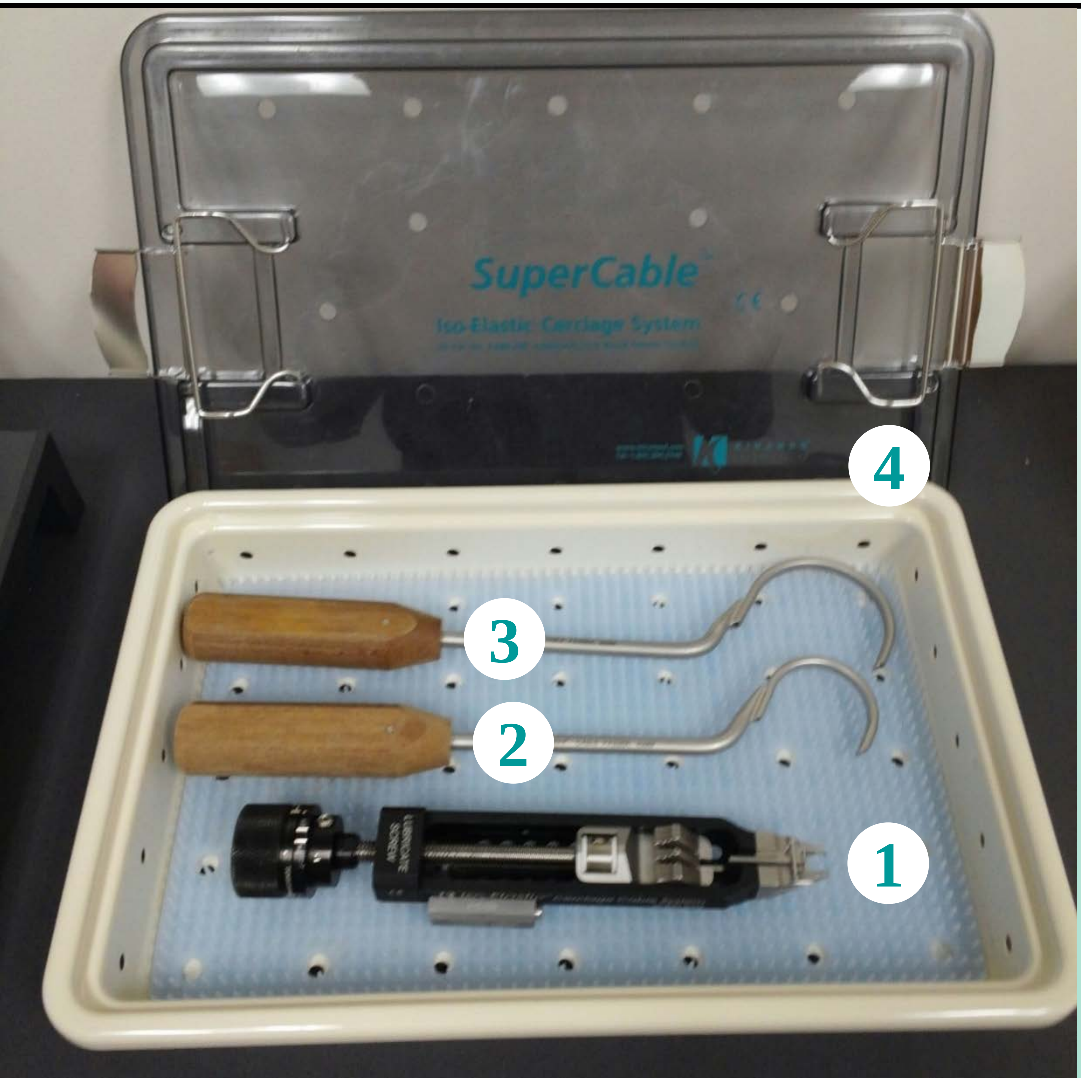
*US Pat. Nos. 6,589,246; 7,207,090; 8,469,967; 9,107,720.
Japan Pat. Nos. 4,829,236; 5,938,095.
Turkey Pat. Nos. TR201309922T4; TR201405440T4 .
Europe Pat. Nos. 1,389,940; 1,781,961; 2,432,401.
Additional US & World Patents Pending.

Basic Instrument Tray



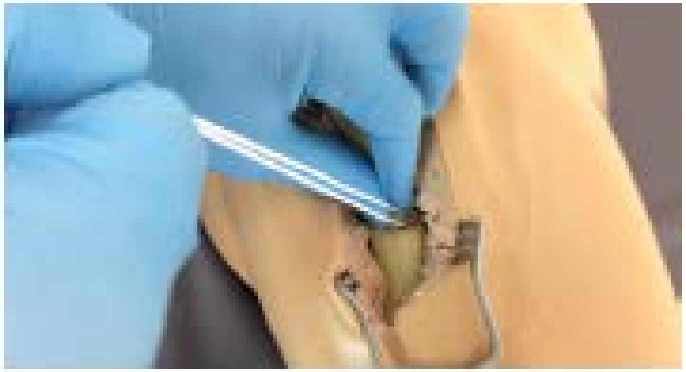
1. Tensioning Instrument (35-800-2020)
2. Cable Passer, 40 mm (35-800-3000)
3. Cable Passer, 60 mm (35-800-3100)
4. Autoclave Case (35-800-4000)

Surgical Technique

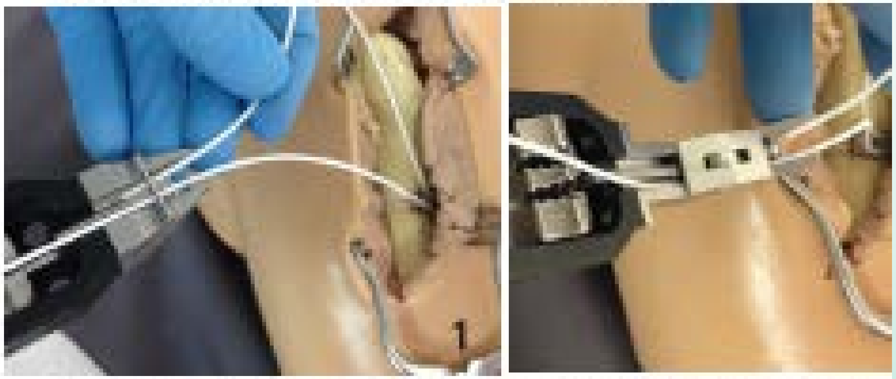
A. Position cable passer around bone.

B. Feed cable through distal passer hole.

C. Feed cable ends through metal clasp.



D. Pull both cable strands taut.



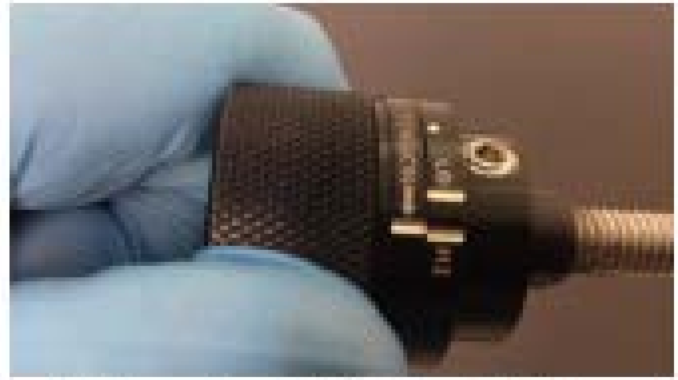
E1. Insert free cable ends under cross-bar, (E2) into opening and through channel.

F. Slide along cables to engage with clasp.

G. Engage nosepiece with clasp.

H. Push free cable ends into cleat.

I. Confirm zero alignment of knob and turn knob clockwise to apply tension.



J. "HI" mark indicates 120 lbs.

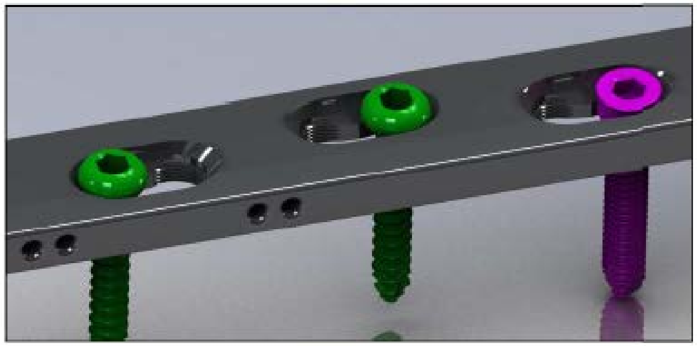
K. Deploy cable locking wedge.

L. Pull back to remove cable from cleat.

Surgical Technique

SuperCable®

Grip and Plate System*



US Pat. Nos. 6,589,246; 7,207,090; 8,469,967. JP Pat. No. 4,829,236. EU Pat. Nos. 1,781,961; 1,389,940; 2,432,401. TUR Pat. Nos. TR201309922T4; TR201405440T4. Additional US & World Patents Pending.

*Featuring Agilock® Technology

Radiographs courtesy of James Nicholson MD, Stony Brook, NY

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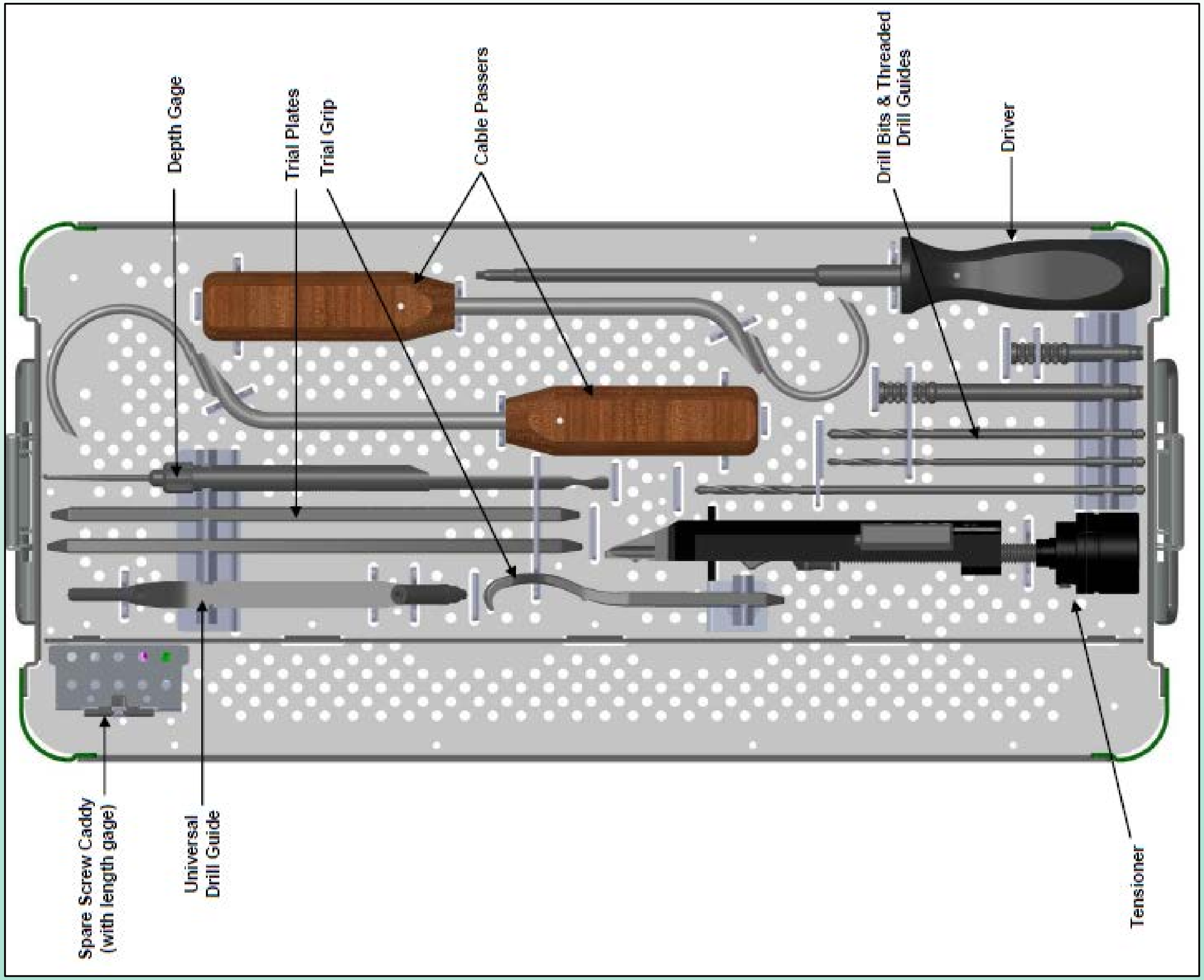
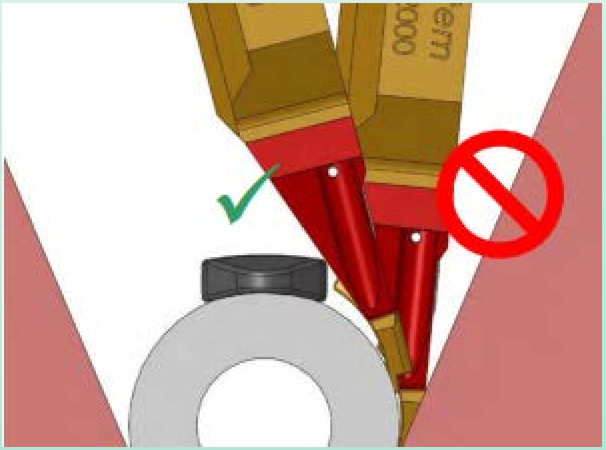
Grip Plate Tray



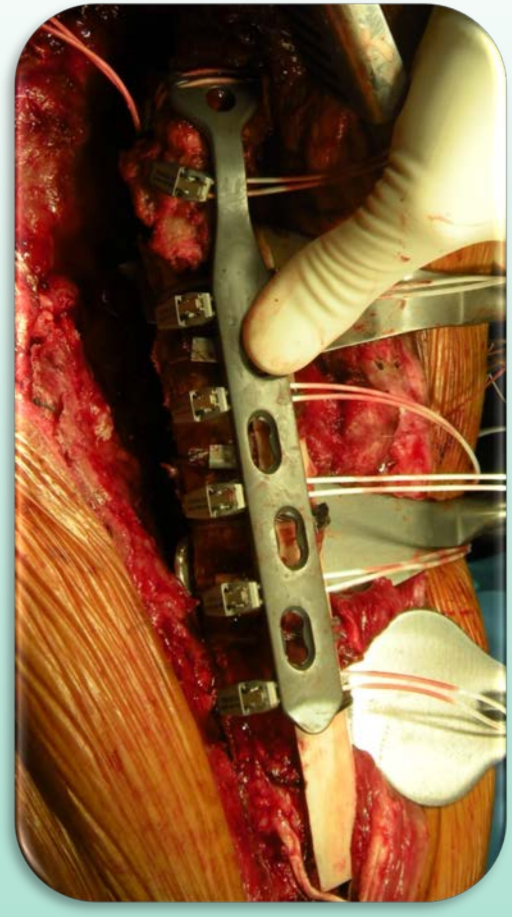
Grip/Plate Technique Tips

- Anticipate the orientation of the *SuperCable* locking clasp (e.g. clasp will be anterior or posterior to the grip/plate)
- Pre-feed the cable ends through the cable holes of the grip/plate
- Pay attention to locking clasp placement for the tensioner

Feed cable through grip, with locking wedge facing towards grip.



Grip/Plate Technique



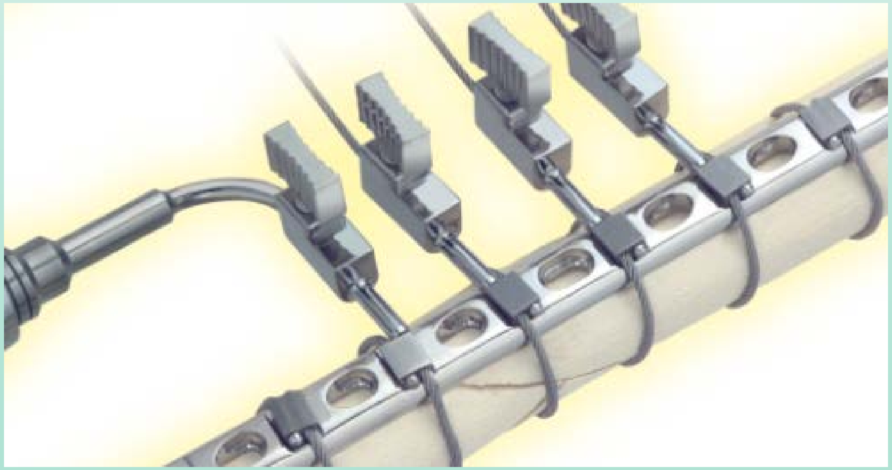
Surgical Videos

- Revision Hip (Extended Trochanteric Osteotomy, ETO)
- Revision Shoulder
- Tension-band wiring of Olecranon Fracture
- Tension-band wiring of Patella Fracture

The Competition

Stryker Dall-Miles®

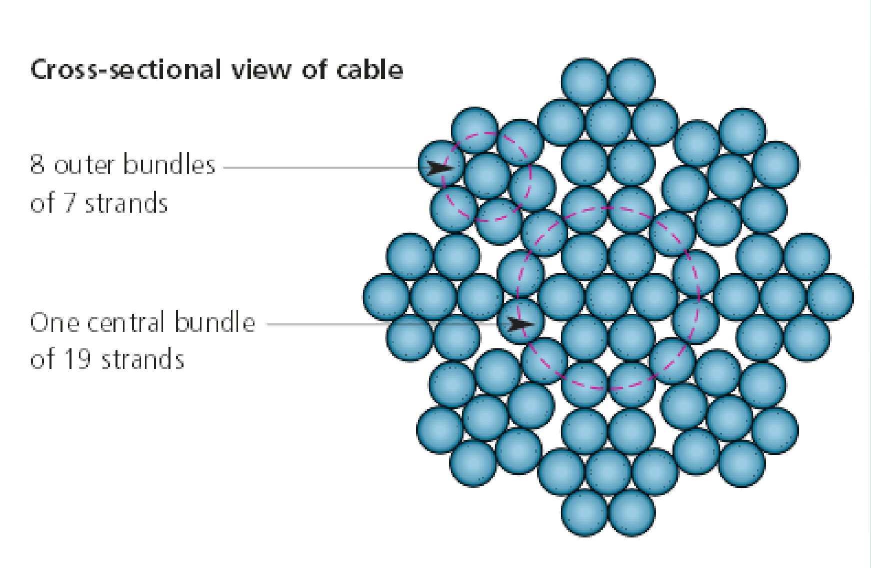
- 40 year old technology!
- 1.6 and 2.0 mm Stainless Steel or CoCr cable
- Crimp lock mechanism
- Leaves sharp cable ends
- Requires device to temporarily hold cable tension
- Generates metal debris
- “Over the Top” grip design
- No proximal locking screw option



Stryker Dall-Miles

Synthes®

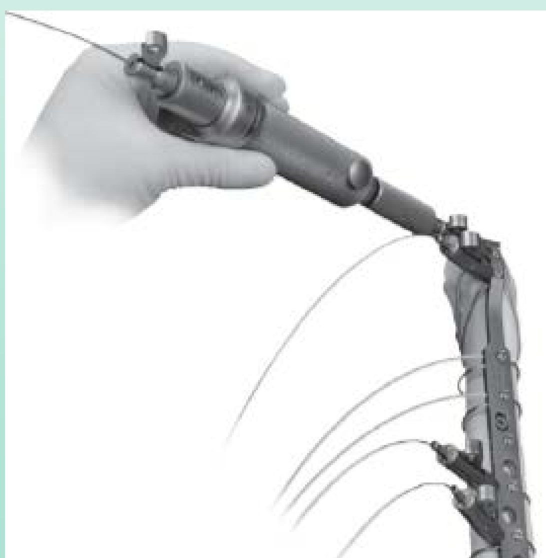
- 1.0 and 1.7 mm diameter
- Titanium, Stainless Steel, or CoCr
- Crimp lock mechanism
- Leaves sharp cable ends
- Uses eyelet to engage plate
- Generates metal debris



Synthes

Zimmer Cable-Ready®

- 1.8mm CoCr cable
- Screw lock mechanism
- Leaves sharp cable ends
- Requires device to temporarily hold cable tension
- Generates metal debris
- “Over the Top” grip design
- No proximal locking screw option



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Zimmer Cable-Ready

I.-S. Kim et al. / The Journal of Arthroplasty 32 (2017) 1965–1969 1967

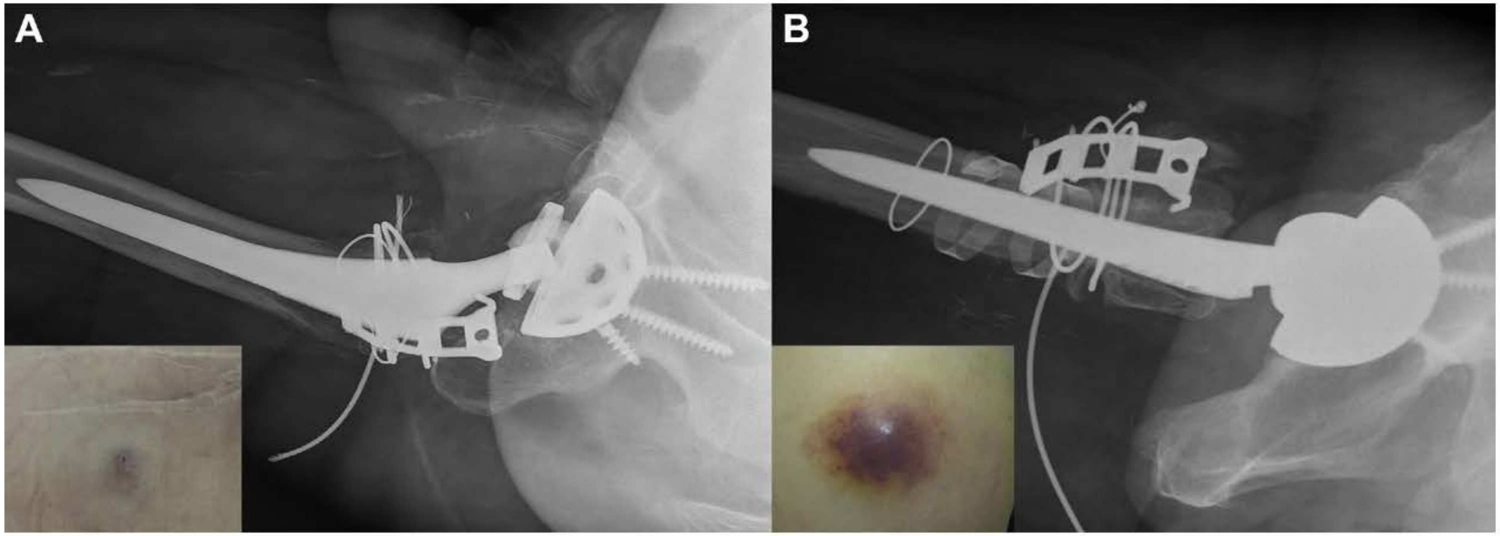

Fig. 1. (A and B) The tip of the broken cable had migrated to the posterior aspect of the thigh and had penetrated the gluteal musculature, which was palpable below the skin posteriorly in 2 hips. This eventually led to hip joint infection in both patients.

Smith & Nephew Accord®

- 2mm CoCr cable
- Screw lock mechanism
- Leaves sharp cable ends
- Requires device to temporarily hold cable tension
- Generates metal debris
- “Over the Top” grip design
- No proximal locking screw option

Smith & Nephew Accord

The Journal of Arthroplasty 32 (2017) 2864–2868

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journal homepage: www.arthroplastyjournal.org

Complications - Other

Trochanteric Fixation With a Third-Generation Cable-Plate System: An Independent Experience

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trochanteric nonunion
total hip arthroplasty
Accord cable-plate
revision

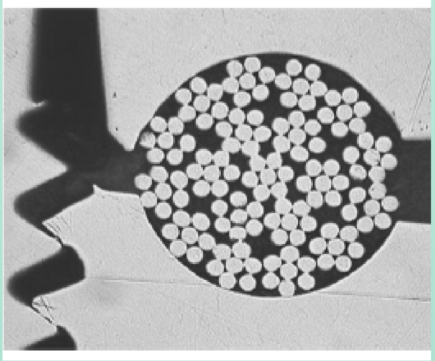
ABSTRACT

Background: Greater trochanteric fracture/nonunion can be a devastating complication with significant functional impact after total hip arthroplasty, and their fixation remains a challenge because of the significant forces being transmitted as well as the poor bone quality often associated with these fractures. The objective of this study is to investigate the rates of reoperation and trochanteric nonunion using a third-generation cable-plate system at one center.

Methods: Thirty-five patients, mean age 72.9 years (range 46-98 years) with 24 women and 11 men, underwent fixation of their fractured greater trochanter using a third-generation cable-plate system. The indications were: periprosthetic fracture (n = 17), complex primary arthroplasty (n = 5), and complex revision arthroplasty (n = 13). Primary outcomes included rates of reoperation and radiographic union.

Results: At a mean follow-up of 2.5 years, trochanteric union rate was 62.9% with nonunion rate of 31.4%, and fibrous union in 5.7%. In regard to quality of initial apposition, only 40% achieved a perfect bone on bone reduction. Ten patients (28.6%) had evidence of wire breakage. Five patients (14.3%) required reoperation and removal of the internal fixation because of lateral hip pain.

Conclusion: Fixation of the trochanteric fractures remains a challenge with a relatively high reoperation rate. Poor bone quality and capacity to maintain a stable reduction continue to make this complication after total hip arthroplasty a difficult problem to solve.



Strategic Advice for the Sales Team

Kinamed Sales Agents Say:

- "The look on my competitor's face when the surgeon told him he shouldn't bother bringing in his old metal cerclage cables anymore because he'll be using these new polymer cables from Kinamed…priceless! And the additional face time it will give me to talk up my joint line is invaluable!"

- "Kinamed really does an outstanding job on highlighting the sales/clinical pearls and advantages of your systems. Not only are your products in a league of their own but your field communication content sows the clinical benefits deep into us, and gives that fire when we share what we know with everyone from the CEO to surgical staff."

Benefits to the Sales Team

Including *SuperCable* in your product portfolio offers multiple benefits:

1. Great "door opener" product that gets sales people appointments with surgeons they otherwise could not easily see!
2. Helps keep competitors out of the operating room!
3. Generates great booth traffic activity at meetings!
4. Having *SuperCable* in your portfolio can have a big impact on sales of your other products!

During your Sales Call

1. Perform a quick “sawbones” demo with surgeon before the case to confirm understanding of instrument usage details
2. Teach proper orientation of cable passer
3. Teach proper orientation of cable clasp
4. **Require** surgeon to use tensioning instrument to tighten and lock a cable on a sawbones
5. Repeat Steps 1-4 for the Surgical Assistant prior to first case

Keys to (*SuperCable*) Sales Success

1. Target your (surgeon) friends first.
2. Identify high-volume revision hip specialists (Users of yours and competitive hip stems).
3. Have confidence knowing that your clinically proven, state-of-the-art cerclage system will give you access to competitive hip stem surgeons.
4. Become an expert (highly proficient) in using the Tensioning instrument.
5. Be present for at least the first 4 to 5 cases for each new surgeon.
6. Keep a second (non-sterile) Tensioner and sample cable with you in the Operating Room should you need to advise the surgeon on Tensioner use, intra-operatively.
7. Anticipate and be prepared to overcome price objections (from hospital personnel and surgeons). Example: Mercedes Benz costs more than Volkswagen because of Quality and Performance.
8. Secure ALL the cerclage cable business via tenders once you've gained product support from 2 or more key surgeons at that hospital/clinic.
9. Expand your cable business. *SuperCable* is applicable for use anywhere a surgeon would use a metal braided cable (Peri-prosthetic hip fractures, revision THR, revision TSA, humeral fractures, olecranon fractures, etc).
10. Kinamed wants you to be successful. Ask for help whenever needed!

Keys to Closing the Deal at the Hospital

Pricing pressure can make selling a premium product a challenge. Rise to that challenge by demonstrating through value analysis that SuperCable is worth the premium per-cable price.

Key *Value-focused* Sales Tools:

1) White Paper: Analysis of Cost

Excellent review of the true-cost of metal cables.

2) Surgeon Request Letter

Get your surgeons to sign this and submit to the hospital.

3) Letter to Value Analysis Committee

It is no longer news that most of the sales process is now spent convincing people who will never use - or even see - the product in action. You need to spell out the benefits that matter most to them – in a language they understand. This VAC letter template focuses on benefits that we don't' go into on our website or brochures, so it's up to you to bring them to the attention of VACs, Materials Managers, and CFOs. Use this message as an email or letter template, or simply incorporate it into your sales pitch talking points.

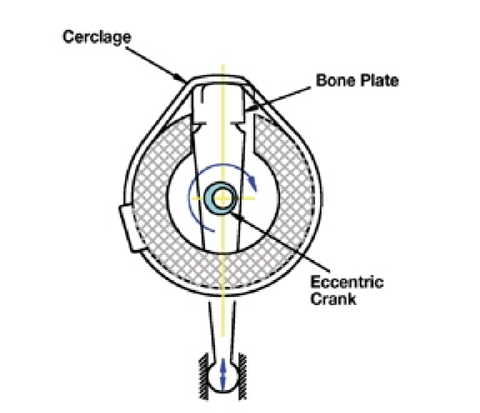
Sales Demo Tips

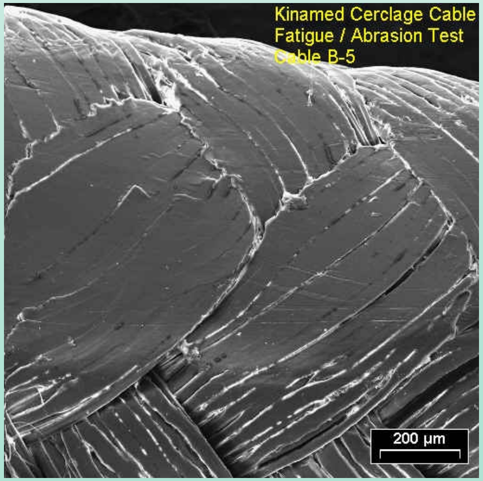
- Sales Demo Items Instruction Guide
- Sales demo wedge removal tool & Replacement cable strands
- Metal Cable vs. ***SuperCable*** Dowel

Click Here For Sales Demo Pro-Tips

Frequently Asked Questions (FAQ)

Frequently Asked Questions

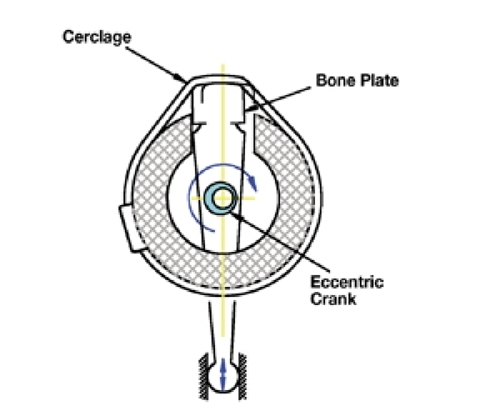


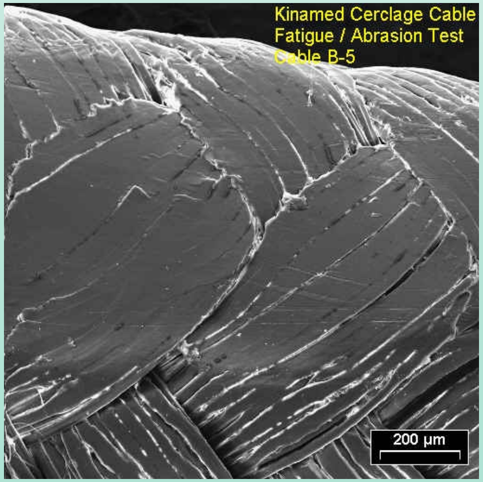


Will the UHMWPE sheath result in poly wear debris?

- **No, the gel-spun poly sheath is extremely resistant to wear as shown by > 1 million cycle testing over a metal plate**
- **In this extreme test, there is very little loss of poly as compared to the volumes lost in total joint implants**

Frequently Asked Questions





How does the strength of *SuperCable* compare to metal cable systems?

- **There are two types of Strength:**
  1. **Tensile Strength (single maximum load)**
  2. **Fatigue Strength (repetitive load)**

- ***In vivo* breakage in cabling systems is caused by <u>fatigue</u> failure, not tensile failure**

Frequently Asked Questions

How does the strength of *SuperCable* compare to metal cable systems?

- **The chart below compares fatigue strength (cycles to failure) of *SuperCable* to that of metal cables and wires**
- **The data for metal cerclage systems were taken from the literature while *SuperCable* data is from Kinamed testing**
- **All metal systems started to fail at 100,000 cycles while *SuperCable* showed no ill effects even after 1 million cycles with higher loading!**

Cerclage Type	Cyclic Load	Cycles to Failure
SuperCable	100 pounds	No failures at 1 million cycles
Stainless steel wire	35 – 80 pounds	100,000 cycles
Titanium alloy cable	20 – 50 pounds	100,000 – 1 million cycles
Cobalt-chrome alloy cable	20 – 50 pounds	100,000 – 1 million cycles

Frequently Asked Questions

How does the strength of *SuperCable* compare to metal cable systems?

Cerclage Type	Tensile Strength
SuperCable	~250 pounds
Stainless steel wire	70 – 150 pounds
Titanium alloy cable	250 – 460 pounds
Cobalt-chrome alloy cable	300 – 700 pounds

Remember:

- **Tensile failure is NOT the problem**
- **Fatigue failure causes breakage of metal cerclage**

Frequently Asked Questions

What are the "LO" and "HI" markings on the Tensioner knob?

- **"LO" = approximately 80 lbs. (360N) of compressive force**
- **"HI" = approximately 120 lbs. (530N) of compressive force**

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Frequently Asked Questions

How do I determine if I should tension to "LO" or "HI"?

- **"LO" may be appropriate for patients that have compromised bone strength (osteopenia, etc.)**
- **"HI" may be appropriate for large bones in high load areas in patients with good bone strength**
- **In all cases, the surgeon should exercise his/her clinical judgment when tensioning the cable**

Frequently Asked Questions

Because of the "Iso-Elasticity" (stored energy), could there be too much energy stored leading to bone necrosis?

- **This has not been seen in the clinical follow-ups that have been published in the peer-reviewed literature**
- **Over 85,000 cables implanted Worldwide since 2004**

Additional Resources

- 30 minute ***SuperCable*** Grip Plate training webinar VIDEO
- New SuperCable/ Grip & Plate User Guide PDF
- Kinamed Website
  - http://www.kinamed.com/products/orthopedic-products/supercable
  - http://www.kinamed.com/products/orthopedic-products/supercable-gripsplates
- SecureDocs Training Portal (for Sales Professionals)
  - Contact Patrick Miller (Kinamed Sales & Marketing Manager), pmiller@kinamed.com

White Papers

- Cost Analysis versus Metal Cerclage
- Fretting of Metal Cerclage Cables
- Avoiding Sharps Injury
- Metal Debris Factory
- Eliminate Metal Debris

Thank You