EVALUATION OF THE CERCLAGE CABLE FORCE

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Submission date: 14/12/2020

Resubmission date: 02/02/2021

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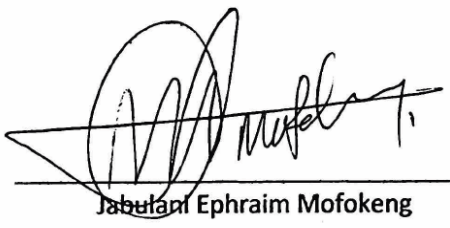
DECLARATION OF AUTHORSHIP

I, Jabulani Ephraim Mofokeng with student number 2015103936, declare that the coursework Master's Degree EVALUATION OF CERCLAGE CABLE FORCE that I herewith submit in a publishable manuscript format for the MMed qualification in Orthopaedic Surgery at the University of the Free State is my independent work, and that I have not previously submitted it for a qualification of another institution of higher education.

All sections of the paper that use quotes or describe an argument or concept developed by another author have been duly referenced including all secondary literature used.



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16/12/20

Date

ACKNOWLEDGEMENTS

I would like to express my sincerest gratitude to my supervisor and to my head of department for their support and guidance throughout this study.

Thank you to Mr van Rooyen – biostatistician, for patience and guidance in my research study.

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ABSTRACT

INTRODUCTION:

Cerclage cable systems are manufactured by different companies to assist in fracture reduction and fixation; their usefulness extends to various specialties, including trauma, tumour surgery and arthroplasty, especially in revision total hip replacements. Two types of systems exist, namely, monofilament and multifilament systems. Multifilament cables grip systems are reported to have good outcomes; however, these attractive fixation devices are not without complications, with a reported failure rate that ranges from 27% to 44%. Loosening is one the modes of failure that can occur intraoperatively, after clamp fixation, or postoperatively because of micro motion and displacement caused by soft tissue interposition and bone resorption. The aim of this study is to determine whether the initial force that is applied to the cylindrical structure reflects the value of the force indicated by the manufacturer of the tensioning device.

METHOD

This is a descriptive study that was undertaken during January 2020 at the University of the Free State, Universitas Academic Hospital's Department of Orthopaedics. A measuring device was manufactured to measure the true force exerted by the cable systems. The researcher used five different cerclage cable systems from different companies in order to evaluate the forces exerted by these systems. The measuring device had a cylindrical structure to which these forces we applied at four different sites. The force applied was measured and compared to the forces indicated by the manufacturer of the tensioning device. These values were recorded on the data collection sheet.

RESULTS

Out of the five cable systems evaluated, only one cable system indicated the correct force at all four different sites. However. the other four cable systems reflected higher forces on the tensioning device when the true measured forces were lower. Retensioning the cables more than twice caused fraying of the cables.

CONCLUSION

The force applied to the bone by the cerclage cable system is not a true reflection of the force indicated by the manufacturer of the tensioning device. Cables should not be retensioned more than twice as this may cause fraying and lead to failure of the implant.

KEYWORDS AND GLOSSARY OF TERMS

Orthopaedics: The branch of surgery broadly concerned with the skeletal system.

Orthopaedic surgeon: Surgeons devoted to the prevention, diagnosis and treatment of disorders of the bones, joints, ligaments, tendons and muscles.

Monofilament cable: Material made up of a single, continuous strand (filament) of synthetic fibre.

Multifilament cable: Material made up of a number of monofilament strands arranged in bundles.

Periprosthetic fracture: Fractures associated with an orthopaedic implant, whether a replacement or internal fixation device.

Implant failure: The total failure of the implant to fulfil its purpose because of mechanical or biological reasons.

Cerclage cable systems: Cable systems that function as implants; they may be used alone or together with a protecting device, for example, external or internal splints such as plates, nails, stems of prosthesis or a combination of thereof.

LIST OF ABREVIATIONS

CCS – Cerclage cable system

CC – Cerclage cable

DMCGS – Dall-Miles cable grip system

THA – Total hip arthroplasty

CoCr (Z) – Cobalt chrome (Zimmer)

Ny (K) – Nylon (Kinamed)

PE – Polyethylene

Lb – Pound

Kg – Kilogram

UFS – University of the Free State

CHAPTER 1: LITERATURE REVIEW

Background

Five extremely well-known principals of osteosyntheses have been developed since the mid-19th century. Wire was the earliest material used for osteosynthesis; successfully applied for the first time in 1827 by Rodgers in New York and systematically by Lister in Glasgow from about 1870. Wire was later used in the form of various 'bone sutures' and cerclages. In 1963 Weber (St. Gallen) developed the excentric wire tension band which, for the first time, provided technical knowledge on the treatment of fractures. In 1978 Labitzke introduced cables instead of the rigid cerclage wire. His lateral cable tension band, which compresses the entire fracture area by itself, clearly improved functional results[1]. The Dall-Miles cable grip system (DMCGS) was developed in 1983 by Dall and Miles for use during total hip arthroplasty (THA) to reattach the greater trochanter[2]. The DMCGS comprises of a multifilament cable system that incorporates an H-shaped vitallium grip for improved fixation and stability[2]. The developers, Dall and Miles, reported 3.1% breakage and 1.5% non-union rates in 130 hip procedures[2]. These results clearly demonstrate that the cerclage cable grip system offers the strongest fixation; resulting in lower rates of non-unions and trochanteric migration. The material properties of cerclage cable grip systems appear to be superior to those of monofilament wire systems; however, these newer and more attractive devices appear to demonstrate potential complications, including debris generation and third-body polyethylene wear[3]. The use of monofilament wires has decreased because of the availability of the cerclage cable grip systems; however, these systems may still be preferred in certain circumstances[3]. Cable fraying and debris generation associated with the use cerclage cables results in a degree of hesitation on the part of surgeons to use these systems[3]. The use of monofilament wires in order to avoid debris generation is advised when cerclage cables become frayed, because continued debris generation may lead to third body polyethylene wear[3].

Cerclage cable systems (CCSs) are used in a variety of clinical situations; primarily in the fixation of bony fragments[4]. CCSs are used in various specialties; including tumour surgery, arthroplasty, trauma and fracture fixation[4]. The development of the CCSs for use in the osteotomy of the greater trochanter in primary total hip arthroplasty (THA) was initially proposed by Charnley, who demonstrated that such systems allow for proper muscle tensioning of the hip abductors and improved hip stability. Since then, the development of

CCSs has evolved from monofilament wires to multifilament cables, to cable grip systems and, finally, to cable plate systems. These progressions are categorised as first, second, third and fourth generation wiring systems, respectively.

First-Generation Wiring Systems (Wire Fixation).

First-generation wiring systems are the monofilament wire systems used for greater trochanter reattachment in primary THA. Various wiring techniques, namely, knot twist, square knot or symmetric twist, and various wire sizes have been described in the literature and their ability to resist displacement forces following trochanteric osteotomy differs according to technique applied[3]. Studies dealing with the performance of monofilament wires when loaded at approximately 50 mm of outward strain per minute indicate that 16-gauge wire failed at a mean of approximately 1300 N for the knot twist and square knot techniques, compared to approximately half that value when the uniform symmetric twist method was applied. On the other hand, results obtained when using 18-gauge wire demonstrated failure rates at a mean of approximately 950 N for the knot twist and square knot techniques, compared to approximately half that value when the uniform symmetric twist knot was applied[5].

These results clearly demonstrate that the strength of the wire construct is dependent on the diameter of the wire and on the technique of the knot used.

The literature suggests the use of multiple wires of at least 16-gauge, fixed with a square knot or twist knot in at least two different planes when wire is used for trochanteric fixation[3]. When cement is used, the trochanter must be realigned to ensure bone on bone contact, with limited contact between the wire and the cement mantle[3]. Bone edges must be abraded before reduction and fixation, and sufficient tightness of the wires should be assessed[3].

Monofilament wire configurations generate significantly less metallic debris ($p = 0.0001$) and with reduced rates of migration of debris, which results in osteolysis and volumetric wear, into the articular area when compared to CCSs[6, 7].

Some authors have indicated that there is a need for proper patient selection and the need for the selection of the correct surgical technique when using monofilament wire constructs, so as to reduce the chances of complications associated with their use. The literature also reveals that monofilament wire constructs should be used with caution in patients who have a history failure of such constructs[3].

A number of important technical factors need to be taken into consideration when using wires, including limited surgical expertise, smaller size of the osteotomy fragment, wires that are passed around the lesser trochanter, wires that are poorly tightened and reattachment of the trochanter to a cement bed, since this use may lead to trochanteric non-union [8, 9]. Other problems encountered with monofilament wires is the fact that they have a tendency to kink during their application, which may compromise the biomechanical integrity of the implant, causing breakage and loss of fixation of trochanteric osteotomy. The literature also documents the fact that wire breakage often results in the need for revision surgery, the use of uniplanar osteotomies, simple wiring configuration which, in cases where there is trochanteric non-union[3], has led to the development of new CCSs[10].

Second-Generation Wiring Systems (Cable Fixation).

Second-generation wiring systems are the multifilament cable systems that were first used by Dall and Miles in 1977 for the reattachment of greater trochanter osteotomy[10]. Monofilament wires are only made from stainless steel or cobalt chrome alloy, while titanium multifilament cables are available[3].

Multifilament cables come in various configurations; for example, eight bundles of seven monofilament strands surrounding a central bundle of nineteen monofilament strands, or seven bundles of seven monofilament strands[3]. The cable's material properties and configuration offer more resistance to deforming forces, providing stronger compression at the osteotomy site[3]. In their study, MacDonald et al.[11] performed revision THAs using extended trochanteric osteotomy on 45 hips and followed their patients for at least 2 years. The authors observed that there was a mean trochanteric migration of 2.8 mm when a monofilament wire configuration was used and a mean migration of migration 0.3mm when a multifilament cable configuration was used. The authors found that this difference was statistically significant ($p = 0.025$)[11].

Shaw et al.[12] conducted a study which assessed the compressive forces that are generated by monofilament wires and cable cerclage systems[12]. They found that titanium cerclage cables demonstrated mean compression forces of 260 N, compared to 11 to 136 N for the 18-gauge monofilament wire and 10 to 89 N for the 20-gauge monofilament wire, depending on the knot technique used[12]. Their results demonstrate the superiority of the cerclage cable configuration over the monofilament configuration. In their study, Kelley et al.[13] assessed 322 THAs and observed a monofilament wire breakage rate of 12% and a cerclage cable

breakage rate of 43%[13]. Kelley et al. also found that monofilament wire fixation and cerclage cable fixation non-union rates were 15% and 8%, respectively[13].

Unlike monofilament wires, cables cannot be tied into tight, secure knots because they unravel, leading to loss of fixation[3]. To overcome this problem, sleeves through which cables are threaded and tensioned and a dedicated sleeve crimp is used to hold the fixation[3]. Cables should not cross over each other in order to avoid debris generation caused by micromotion between the crossed cables, thereby generating third body wear[3]. When applying monofilament wires or cerclages cables, it is suggested that compression must be perpendicular to the plane of the osteotomy; this will help to minimise both shear and rotational deforming forces[3]. An effort should be made the avoid passing the cable through a cement mantle since this may not provide a strong fixation[3]. Finally, Multifilament cables provide a stronger construct at the osteotomy interface compared to monofilament wires[3].

Third-Generation Wiring Systems (Cable Grip Fixation)

Third-generation wiring systems include the cable grip system, which was introduced by Dall and Miles. This system consists of an H-shaped gripping device that supplements the multifilament cables[10]. Cable grip devices perform better at reattaching the greater trochanter and resisting destabilising forces in the peritrochanteric area than wires and cables do[10]. In their study undertaken to compare the relative strengths of orthopaedic wires, cables and the cable grip system, Hersh et al.[14] observed that cable grip systems could withstand 1.5 times the maximum load that could be borne by wire or cable alone[14]. The authors examined the loads required to induce 1 or 2 cm of trochanteric displacements[14]. Their results demonstrated that the cable grip system required 1397 N to induce a 1 cm displacement, while the wire required 757 N and the cable required 771 N to achieve the same results. This demonstrates that the cable grip system required almost twice the load required by wire or cable alone to cause a 1cm displacement. For a 2 cm displacement to be achieved, the cable grip system required 1900 N, the wire 757 N and the cable 1100 N, which translates into 2 to 2.5 times the load required by the wire or cable to cause a 2 cm displacement[14].

In addition, the size of the cable used when using this cable grip system has been shown to have an impact on the performance and outcome. When 1.6 mm cables were used, the breakage rate was initially reported to be 6.2%; however, when the authors used 2.0 mm cables, the breakage rate was reduced by 50%, i.e., a breakage rate of 3.1%[10]. The authors also found that, after bone union, cable breakage was not seen.

Ritter et al.[15] observed a cable breakage rate of 32.5% when the cables were passed through the cement mantle of the femoral prosthesis[15]; while Silverton et al.[16] reported a cable breakage rate of 22%[16]; and McCarthy et al.[17] reported a cable breakage rate of 10% with no significant difference shown between the breakage rates of stainless steel and vitallium cables[17].

Placement of the cables when assembling the cable grip constructs plays a role in the performance and outcome of the cables. This was shown in the results of a study by McCarthy et al., where they varied the placement of the cables through the bridge in the grip[17]. Two placement approaches were use in this study. In the first approach, the cable was pulled through the anterior side of the grip and around the medial aspect of the proximal femur. The second approach involved pulling the cable through the posterior side of the grip and around the lateral aspect of the proximal femur[17]. The authors found that the cables that were positioned posterolaterally broke 23 times more often than those placed anteromedially[17]. This study clearly shows that cable placement plays a crucial role in the optimum performance and outcome.

Archibeck et al.[18] recommend that, if a cable grip system is used, the cables should be separated by 2 to 3 cm at the medial aspect of the proximal femur; with the distal cable placed below the lesser trochanter in order to avoid proximal medial migration of the trochanter[18]. This has been reported in the literature as one of the complications of the cable grip system. In their study, Dall and Miles also reported a 5.4% non-union rate when one horizontal 1.6 mm cable was used; a 4.8% non-union rate when two horizontal 1.6 mm cables were used; and a reduction in non-union rate to1.5% when 2 mm horizontal cables were used[10]. When cable fixation was directly applied against the host bone, and not threaded through the cement mantle or attached to allograft bone, the non-union rate was significantly less[3].

There are some contraindications associated with the use of cable grip systems. If there are no soft tissue attachments to the trochanteric fragment, then there is no blood supply to it and the implant does not need to be placed[3]. In addition, in order to achieve a proper fixation an intact medial cortex, distal to the lesser trochanter, must be present[3]. When cementless femoral implants are used together with an osteotomy of the greater trochanter, care must be taken to ensure that wires are not in contact with the prosthesis. Additionally, when medial bone loss from the proximal femur is present, similar care must be taken to ensure that wires

are not in contact with the prosthesis, since such a contact could lead to the generation of third body metallic debris and premature wire failure[3].

Fourth Generation Wiring Systems (Cable Plate System)

The hope is that the development of the fourth-generation cable systems will reduce cable fraying and breakage that occurred with previous cable systems[3]. These implants have some advantages over traditional cable grip systems, including their ability to be tightened and then retightened as needed. Fourth-generation cable systems use a 19 × 7 multifilament construct pattern in order to overcome the challenge faced with earlier generation systems that could not be loosened and then retightened at a later stage, which proved to be inconvenient[3]. The fact that earlier systems could not be loosened and retightened proved to be problematic when securing a long strut graft because , the first cable may have become loose by the time the last cable was tightened[19]. The only way to address this problem was to cut the loose cable, since it could not be retightened, and replace it with another one; however, doing this could lead to a loss of position or fixation of the construct[19]. In their study, Barrack et al.[20] compared a fourth-generation cable plate system to a cable grip system, to cables and to wires, and found significantly lower incidences of cable breakage ($p < 0.025$) and trochanteric non-union ($p < 0.05$) with the cable plate system when compared to other systems[20].

Cable plate systems have a potential disadvantage in that they are difficult to use with osteopenic bone or with small bony fragments[3]. In addition, if the construct fails it will likely require a revision to remove the hardware[3]. In addition, using a cable plate system will require a more extensive surgical dissection and cable plate systems are more expensive than cables with sleeves or wire systems [3].

CCSs are composed of stainless steel, chrome cobalt, titanium alloy and nylon[21]. When compared to screws, CCSs have little resistance to torsional forces but have better resistance to bending forces[22]. The literature is unclear on how many CCSs are required to accomplish a stable fixation. Although they have limitations, CCSs play an important role as stabilisers; preventing the propagation of cortical defects, fractures and cracks in revision THAs[22]. Combination cerclage cables with locking plates ensure a more stable fixation, avoiding the complications resulting from revision surgeries, especially in the elderly[23]. Two types of combination cerclage cable systems with locking plates exist, namely monofilament and multifilament systems. Multifilament cables are constructed in a number of configurations, as

mentioned above; for example, eight bundles of seven monofilament strands surrounding a central bundle of nineteen monofilament strands, or seven bundles of seven monofilament strands[3]. The Dall and Miles multifilament cable system, used in the fixation of the greater trochanter after osteotomy as a technique used in hip in total hip arthroplasty[24], has shown excellent results; however, published failure rates of this system ranges from 27% to 44%[4], an indication that these attractive fixation devices are not without complications[24].

Loosening of the cable may occur postoperatively as a result of the micromotion and displacement created by the interposition of soft tissue and bone resorption. Loosening of cables can also occur intraoperatively, immediately after clamp fixation[25]. In their study of force relaxation and spring back of novel elastic orthopaedic cables, Canet et al.[26] demonstrated that cable loosening contributes to poor fixation and delayed osteotomy or fracture healing[26]. To achieve adequate stabilisation, tension in the cables must be maintained so as to minimise micromotion between fragments[26]. Poor spring back of multi-braided metallic cables prevents them from adjusting to bone resorption or to the micro motion associated with *in vivo* loading[26]. Other factors that contribute to the loosening of the cerclage cables are associated with instrumentation and implant design, which need to be addressed and better understood in order to optimise the performance of the cerclage cables[25]. In a study that evaluated initial tension loss of different cerclage cables, Menard et al.[25] observed that the locking mechanism comprising a set screw deforming sleeve and a cobalt chrome (Z) cable was the least effective in maintaining its tension, resulting in more than 50% tension loss. Intraoperatively, a surgeon who tightens the cobalt chrome (Z) cable system up to 100 lb of tension would, in fact, be getting only half of the force, or around 50 lb of tension[25]. The nylon (K) cable system also demonstrated a significant loss of tension of almost 50%. Menard et al. also observed the limited ability of cobalt chrome cables to tolerate displacement as a result of their steep force or elongation curves and high degree of stiffness, noting that minimal displacement is required to cause a significant loss of tension[25].

When using cerclage cables, the multifilament structure of the cable may be damaged by the crimp, causing cable rupture at the crimping site[25]. Techniques that can reduce the tension on the cerclage lock and improve the load resistance of the cerclage cables should be considered[25]. In their study of biomechanical performance of different cables and cerclage wire configurations, Lenz et al.[27] used the double loop technique based on the tackle principle, which states that a higher travel during cerclage cable loosening is required in the

double loop technique, compared to a single loop technique, until loss of pretension occurs[27]. Since most tension is achieved at the end of cerclage cable tightening, which results in a logarithmic relationship with the amount of displacement, tension loss caused by a slight loosening in a single looped cerclage cable could be prevented by this principle. This would improve maintenance of pretension as demonstrated in both double looped cerclage cable groups[27]. However, the major disadvantage associated with the use of double looped cerclage cables is the necessary double looping around the bone. This means that the surgical procedure necessary for a single looped cerclage cable has to be performed twice, regardless of a minimally invasive or open surgical technique, including the risk of nerve or vascular damage[27]. In high-risk areas, it is advised that anatomical structures should be visualised first, before application of the cerclage cable[27].

Cerclage cables can also break with subsequent loss of fracture reduction and risk of migration, especially migration into the vascular system. Cerclage cables also have the potential to strangulate periosteal blood supply[28]. There is a historical notion within the orthopaedic community that cerclage wiring will lead to more soft tissue damage and periosteal ischemia which, in turn, will lead to poorer healing (delayed and non-union) and higher rates of infection[29]. The Dall and Miles multifilament cable system with a trochanteric grip for fixation is susceptible to fraying or breakage in up to 47% of applications and result in non-union rates ranging from 1.5% to 38%. Cable fragmentation can be a source of metallic debris that may cause third-body polyethylene wear[30]

Indications

Orthopaedic trauma surgery; temporary fixation during open reduction and internal fixation; femur fractures; periprosthetic fractures; olecranon fractures; patella fractures; ankle and humerus fractures; acromioclavicular dislocations; hip and acetabular fractures; prophylactic banding in THAs; and reattaching the greater trochanter following osteotomy in THAs or fractures are all indications related to the use of cerclage cables.

Contraindications

If the size of the cerclage cable is 1 mm, it may not be used for fractures of the femur or for prophylactic banding during total hip arthroplasty[21]. The recommendation regarding the use of the DePuy cerclage cable system is that, for 1 mm cable, tension should not exceed 40 kg and not more than 50 kg for 1.7 mm cable[21].

In this study the researcher used the third-generation cerclage cable systems with their dedicated crimping devices. The aim of this study is to determine whether the initial force that is applied to the cylindrical structure, using different cerclage cable systems from various companies, will consistently be reflected by the value of the force indicated by the tensioning device. The hypothesis is that this value will not be consistently reflected as these cables are loaded to their manufacture's recommended forces; also that the structural integrity of the cable will deteriorate with retensioning of the cable more than once, which may lead to cable fraying, breakage and ultimately implant failure. In addition, the study aimed to demonstrate the point at which the maximum force is applied by the cerclage cable system.

REFERENCES

1. Labitzke R. (1995). From “bone suture” to modern osteosynthesis – a chronology, Der chirurg; Zeitschrift fur alle Gebeite der operative Madizen 66. 452-8.
2. Naonobu T, Moritoshi I, Katsufumi U, Sumitaka T, Kensuke F. Reattachment of the greater trochanter in total hip arthroplasty: the pin-sleeve system compared with the Dall-Miles cable grip system. International Orthopaedics (SICOT) (2010) 34:793–797.
3. Jarit GJ, Sathappan S, Panchal A, Strauss E, Di Cesare PE. Fixation Systems of Greater Trochanteric Osteotomies: Biomechanical and Clinical Outcomes. *Journal of the American Academy Orthopaedic Surgeons* 2007;15:614-624
4. Dall DM, A Biomechanical and Clinical Review: The Dall–Miles Cable System. University of Southern California, Los Angeles, CA, USA.
5. Bostrom MP, Asnis SE, Ernberg JJ. Fatigue testing of cerclage stainless steel wire fixation. *Journal of Orthopaedic Trauma* 1994;8:422-428.
6. Hop JD, Callaghan JJ, Olejniczak JP, Pedersen DR, Brown TD, Johnston RC. The Frank Stinchfield Award: Contribution of cable debris generation to accelerated polyethylene wear. *Clinical Orthopaedics and Related Research* 1997;344:20- 32.
7. Kelley SS, Johnston RC. Debris from cobalt-chrome cable may cause acetabular loosening. *Clinical Orthopaedics and Related Research* 1992;285:140-146.
8. Boardman KP, Bocco F, Charnley J. An evaluation of a method of trochanteric fixation using three wires in the Charnley low friction arthroplasty. *Clinical Orthopaedics and Related Research* 1978;132:31- 38.
9. Schutzer SF, Harris WH. Trochanteric osteotomy for revision total hip arthroplasty: 97% union rate using a comprehensive approach. *Clinical Orthopaedics and Related Research* 1988;227:172-183.
10. Dall DM, Miles AW. Re-attachment of the greater trochanter: The use of the trochanter cable-grip system. *Journal of Bone and Joint Surgery British* 1983;65:55-59.
11. MacDonald SJ, ColeC, Guerin J, Rorabeck CH, Bourne RB, McCalden RW: Extended trochanteric osteotomy via the direct lateral approach in revision hip arthroplasty. *Clinical Orthopaedic Related Research* 2003;417:210-216.
12. Shaw JA, Daubert HB. Compression capability of cerclage fixation systems: A biomechanical study. *Orthopedics* 1988;11:1169-1174.

13. Kelley SS, Johnston RC. Debris from cobalt-chrome cable may cause acetabular Ritter MA, Eizember LE, Keating EM, Faris PM. Trochanteric fixation by cable grip in hip replacement. *Journal of Bone and Joint Surgery British* 1991;73:580-581.
14. loosening. *Clinical Orthopaedics and Related Research* 1992;285:140-146.
15. Hersh CK, Williams RP, Trick LW, Lanctot D, Athanasiou K. Comparison of the mechanical performance of trochanteric fixation devices. *Clinical Orthopaedics Related Research* 1996;329:317-325.
16. Silverton CD, Jacobs JJ, Rosenberg AG, Kull L, Conley A, Galante JO. Complications of a cable grip system. *Journal of Arthroplasty* 1996;11:400-404.
17. McCarthy JC, Bono JV, Turner RH, Kremchek T, Lee J. The outcome of trochanteric reattachment in revision total hip arthroplasty with a Cable Grip System: Mean 6-year follow-up. *Journal of Arthroplasty* 1999;14:810-814.
18. Archibeck MJ, Rosenberg AG, Berger RA, Silverton CD. Trochanteric Osteotomy and Fixation During Total Hip Arthroplasty. *Journal of the American Academy of Orthopaedic Surgeons* 2003;11:163-173.
19. Patel S, Soler JA, El-Husseiny M, Pegg DJ, Witt JD, FRCS, Haddad FS. Trochanteric Fixation Using a Third-Generation Cable Device: Minimum Follow-Up of 3 Years. *The Journal of Arthroplasty* Vol. 27 No. 3 2012.
20. Barrack RL, Butler RA: Current status of trochanteric reattachment in complex total hip arthroplasty. *Clinical Orthopaedics and Related Research* 2005;441:237-242.
21. DePuy Synthes Cable System Surgical Technique. www.depuysynthes.com/ifu.
22. Van der Spuy DJ, de Jongh H. Periprosthetic fractures of the femur associated with hip arthroplasty. *South African Orthopaedic Journal Spring* 2011, Vol 10, No 3.
23. Ebraheim NA, Sochacki KR, Liu X, Hirschfeld AG,Liu J. Locking Plate Fixation of Periprosthetic Femur Fractures with and without Cerclage Wires. Orthopaedic Surgery 2013;5:183–187 • DOI: 10.1111/os.12052.
24. Dall DM, A Biomechanical and Clinical Review: The Dall–Miles Cable System. University of Southern California, Los Angeles, CA, USA.
25. Menard J Jr, Emard M, Canet F, Brailovski V, Petit Y, Laflamme GY. Initial Tension Loss in Cerclage Cables. *The Journal of Arthroplasty* 28 (2013) 1509–1512.
26. Canet F, Baril Y, Brailovski V, Petit Y, Bissonnette G, Laflamme G. Force Relaxation and Sprinback of Novel Elastic Orthopedic Cables, International Conference of the IEEE EMBS,Boston, Massachusetts USA, August 30 - September 3, 2011.

27. Lenz M, Perren SM, Richards RG, Muckley T, Hofmann GO, Gueorguiev B, Windolf M. Biomechanical performance of different cable and wire cerclage configurations. *International Orthopaedics* (SICOT) (2013) 37:125–130.
28. Wahnet D, Lenz M, Schlegel U, Perren S, Windolf M. A Biomechanical Study on the Twisting Procedure. acta chirurgiae orthopaedicae et traumatologiae cechosl. 8, 2011.
29. Fauconnier S, Van Lieshout M, Victor J. Evaluation of cerclage wiring in the treatment of subtrochanteric fractures. Acta Orthopædica Belgica, Vol. 86 - 1 – 2020.
30. Koo K, Zhou Z, Andy KS, Koh JSB, Howe TS. A Biomechanical Study Comparing Cerclage Wiring Performed with a Power Tool versus the Manual Method. Ann Acad Med Singapore 2015;44:554-7.

CHAPTER 2 (Publishable Manuscript)

Abstract

Objective: The aim of this study was to determine whether the initial force applied to the cylindrical structure reflected the value of the force indicated by the tensioning device.

Methods: This experimental study was conducted at the Universitas Academic Hospital, Bloemfontein, South Africa. The study involved five commonly used cerclage cable systems from five different companies. The individual cerclage systems were applied to a cylindrical measuring device which measured the force applied at one locus (the measuring locus). The cerclage systems were placed with the wires crossing at four different loci in relation to the measuring locus.

Results: Of the five cable systems evaluated, only two cable systems reproduced the correct or near-correct force, as determined by the manufacturer, at all four different sites. The remaining cable systems did not perform as expected. The forces measured when using these devices were consistently lower than those indicated by the manufacture for the particular cerclage tensioning device. Retensioning of the cables more than twice caused fraying of some of the cables. Two of the cerclage cable systems exerted a significantly larger maximum force than the other three systems. There was a pattern of increase in the forces closer to the point at which the cables crossed.

Conclusions: The force applied to the bone by the cerclage cable system is not a true reflection of the force indicated by the manufacturer of the tensioning device. Cables should not be retensioned more than twice as this may cause fraying and lead to failure of the implant. The device connecting the cable should be placed on the strongest part of the bone as this is the area where the maximum force is exerted. The amount of tension that should be applied should generally be left to the discretion of surgeon, taking into consideration the quality of the bone.

Introduction

Cerclage cable systems (CCS) have been used in many clinical situations, mainly to assist with the fixation of bony fragments[1]. The usefulness of these systems extends to various medical specialties, including trauma and fracture fixation, tumour surgery and arthroplasty, and especially in revision total hip replacements[2]. As a standalone implant, the CCS is too weak to

fulfil the requirements of functional aftercare[3]. An internal plate or endoprosthesis shaft will help provide splinting as a major element in stabilising the fracture, while the cerclage cables will assist by reducing and fixing the fracture fragments, exerting additional stability via a centripetal force.[3]

The CCS is composed of stainless steel, chrome cobalt, titanium alloy and nylon[4]. Only two types of system exist, namely, the monofilament system and the multifilament system. For decades, monofilament wires have been used; it was not until the late 1970s that Dall and Miles[1] used these wires in the fixation of greater trochanter following osteotomy as an approach to the hip in THAs[5] Even though good results were reported with the use of the multifilament metallic cable grip system, a high failure rate was associated with these devices, ranging from 27 to 44%[6].

These attractive fixation devices are not without complications. The most common complications found in the use of these devices include loosening of the cable, which may occur in the postoperative period when cables are subjected to micro motion, and displacement created by soft tissue interposition and bone resorption[2]. Also loosening of the cable can also occur intraoperatively, immediately after clamp fixation. Cable loosening contributes to delayed fracture or osteotomy healing and poor fracture fixation[2]. A study undertaken by Canet et al.[7] reported that, for adequate stabilisation, tension in the cables must be maintained in order to minimise micro motion between bony fragments[7].

Haddad et al.[8] observed that the loss of tension in the cables was significant and occurred immediately following clamp fixation, rather than as a result of bone relaxation over time[8]. Other factors mentioned in the literature that contribute to tension loss, such as design of the cerclage cable system itself and the material composition of the cable. Ménard et al.[3] compared the performance of different cerclage cable systems with different compositions, such as multifilament cobalt chrome cables, with four different crimp or clamp devices (DePuy, Stryker, Zimmer and Smith & Nephew) and one non-metallic nylon cable system from Kinamed[3]. The authors found that the locking mechanism with a set screw deforming sleeve and a cobalt chrome (Z) cable was the least effective in maintaining its tension, resulting in tension loss of more than 50%[3].

Koo et al.[2] found that intraoperatively, if this cobalt chrome cable system (Z) was loaded up to 100 lb, the surgeon would, in fact, be getting only 50 lb of tension[2]. These authors also observed that the nylon cable system (K) was likely to show an almost 50% loss of tension[2]. One of the mechanical properties of a cobalt chrome cable is that it has high stiffness and limited ability to tolerate displacement because of its steep or elongation curves; only a minimal displacement is needed to cause a significant loss of tension[2]. One study reported that cerclage cables can break with subsequent loss of fracture reduction and risk of migration, especially into the vascular system, with the potential to strangulate periosteal blood supply[8].

Despite all this, there is little information in the literature about the outcome of the CCS-use when loaded according to their manufacturer's recommended tensions and then, simultaneously, measuring these forces being applied to see whether they are consistent with the manufacturer's recommended forces. Doing so can help to exclude an error created by the manufacturer as a possible reason for CCS loosening or failure. Therefore, the aim of this study was to assess the performance of five cerclage cable systems with their dedicated crimp or locking device from different companies by loading them to the manufacturer's recommended tensions and using our designed weighing scale to measure the true forces applied to a cylindrical structure. In addition, this study intended to determine whether the measured force matched the force reflected by the manufacturer of the tensioning device, and to see where on the cylindrical structure the maximum force is applied.

Materials and Methods

Study Design

This study was carried out in the Department of Orthopaedics at the Universitas Academic Hospital, in the Free State Province of South Africa in April 2020. The hospital is situated in Bloemfontein and is the teaching facility for the University of the Free State (UFS).

Procedure

Five commonly used cerclage cable systems (CCS) were selected from five different companies, each with a dedicated crimp or locking device, randomly labelled A, B, C, D and

E. Cable sizes ranged between 1.5 and 2 mm in diameter. One cable was tested four times at four different sites on a cylindrical structure. Two cables, namely cables A and B, were tested four times (each a total of eight trials); three cables for cables C and D were tested four times (each a total of twelve trials); and one test was done for cable E (a total of four trials). Cables were first loaded to the manufacture's recommended tension at four different sites. A weighing scale was used to measure these forces and compare them to the force each company suggested applying to the tensioning device. The results were recorded on a data sheet. Following the initial recommended loading, the cables were loaded to maximum tension and the measured tension was captured and recorded on the datasheet. Cables that displayed fraying or that failed were replaced with a new cable and re-tested. The testing sequence of the cables is shown in Figure 2.

Figure 1: Measuring Device – Transducer measured in kg

As illustrated in Figure 1**,** this weighing scale device was designed and used to measure these forces. The forces were applied to the cylindrical structure at four different sites (Figure 2) and the performance of each cable was measured as the true forces applied, recorded and compared to the forces suggested by the manufacturer of the tensioning device. In this setting, the measurements were made in kilograms (kg)

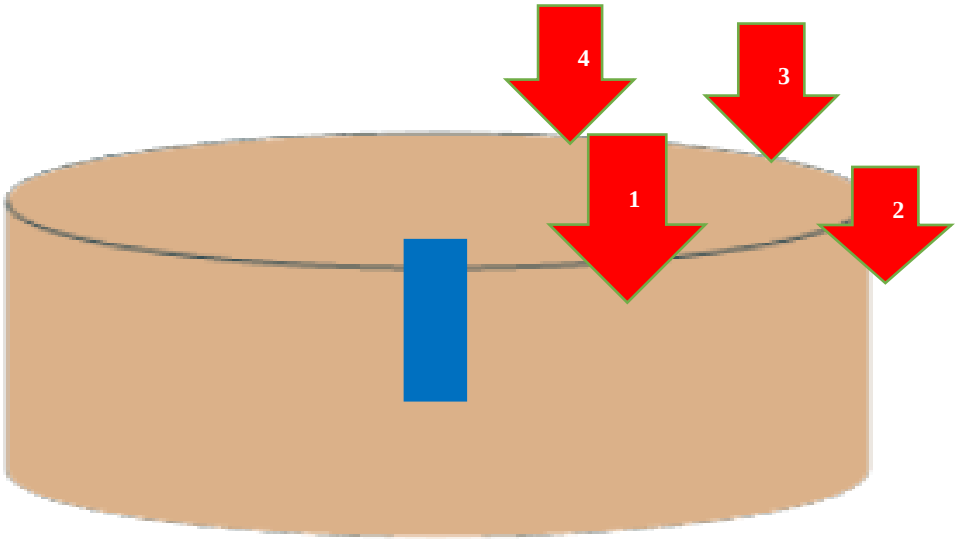

Figure 2: Cylindrical Structure indicating the sequence of testing

Data Collection and Analysis

Data collected was captured directly on a Microsoft Excel spreadsheet by the researcher and summarised in tables, showing different forces as measured by the device at different loci. An analysis was performed by a statistician from Department of Biostatistics at the University of the Free State.

Ethical Considerations

Ethical approval to conduct the study was obtained from the University of the Free State's Health Sciences Research and Ethics Committee. Permission to conduct the study was sought from the Head of the Department of Orthopaedics at the hospital and from the companies which produced the materials. Since this study is a biomechanical study performed on the models, permission from the Provincial Department of Health of the Free State was not requested. A pilot study was undertaken on the initial two structures to assess whether reproducible results could be obtained and whether the method of data capturing was applicable or whether modifications were required. The two cases making up the pilot study were included in the main study.

Results

As recorded in Table 1, cables were measured at four different sites from loci 1 to 4, as shown in Figure 1, with the tensioner indicated as recommended by different manufacturers. cable A was measured at four different sites with the tensioner, indicating 100 kg as recommended by the manufacturer. The true force measured was consistantly less than the manufacturer's recommendations at all four sites, with tensioner at 100 kg, the third and fourth loci measured

57 kg (43% less than recommended) each, while first and second loci measured 68 kg (32% less than recommended) and 67 kg (33% less than recommended), respectively. When the cable was retensioned, the values became smaller; no cable fraying was noticed. Values measured for cable A were not consistant at all four loci and were less than the value reflected by the manufacturer of the tensioning device. The cable was then tensioned to a maximum, beyond the manufacturer recommendations, and the values measured exceeded the limits of the tensioning device; however, these values at all four sites were just above 100 kg. No cable failure or breakage was noted at these larger values. Larger forces were measured at loci one and two, and slightly smaller forces were measured at loci three and four. These findings correlate with the results seen at 100 kg tension.

Table 1: Summary of cable A tensioners at different locus

	Loci (kg)			
	1	**2**	**3**	**4**
Tensioner at 100 kg	68	67	57	57
Tensioner max tension	120	114	111	108

Cable B was measured with the sleeve at four different loci, with the tensioner at 100 kg, as recommended by the manufacturer. The initial value measured was less than the value indicated by the manufactorer of the tensioner and, with retensioning, the force measured became less, notably on loci three and four. Cable fraying was noted on the third measurement. However, the force measured at the fourth loci was not reduced (Table 2). Following cable fraying with the tensioner at 100 kg, a new cable was used with the tensioner at 75 kg, measured at four different sites. All measured values were less than the value recommended by the manufacturer for the tensioning device. A decrease in force measured was also noted with subsequent retensioning and no cable fraying was noted at 75 kg. The perfomance of cable B at all four sites did not match the value indicated by the manurafctuer for the tensioning device, both at 100 kg and 75 kg.

Table 2: Summary of cable B tensioners at different locus

	Loci (kg)			
	1	**2**	**3**	**4**
Tensioner at 100 kg	55	60	53	53
Tensioner at 75 kg – new cable	45	43	43	33

Similarly, cable C was measured at four different sites with the tensioner at 50 kg, the manufacturer's recommended maximum force; the force measured at all sites was less than the

recommendations by the manufacturer. We also noted fraying of the cable during the last measurement (Table 3). A new cable was used following failure of the cable, with the tensioner set at 50 kg again. No difference in the perfomance of these two cables was observed. All values were less than the value indicated by the manuracturer of the tensioning device. This excludes the possibility that a faulty cable was used initially and no cable fraying was noted. However, there was a slight increase in the forces measured at loci three and four with the use of a new cable. This finding differs from the findings seen with cables A and B. The cable was then tensioned to a maximum value beyond the manufacturer's recommendations and the values exceeded the 50 kg mark at all loci, except for the first measurement, which was below 50 kg.

Table 3: Summary of cable C tensioners at different locus

	Loci (kg)			
	1	**2**	**3**	**4**
Tensioner at 50kg	41	37	40	37
Tensioner at 50kg new cable	40	37	42	43
Tensioner maximum tension	40	65	80	77

Cable D was also measured with the sleeve at four different sites and the tensioner indicating 45 kg. The measurements were obtained at all four sites and they closely reflected the measurement indicated by the manufacturer of the tensioning device (Table 4). Loci 1 and 3 measured the exact amount, and loci 2 and 4 were found to be slightly higher. No cable fraying was noted. The cable was then measured at four different sites with the tensioner now at 68 kg, the maximum value recommended by the manufacturer. The cable's true forces, as measured by the transducer, also closely reflected the value indicated by the manufacturer of the tensioning device. Slightly higher values were seen at loci 1 and 2. Cable D was at maximum tension, which was beyond the recommendations of the manufacturer. All forces measured at different sites were higher than the 68 kg mark indicated on the device and no cable fraying or breakage was noted. In addition, higher values were seen at loci 1 and 2, as observed with the other cables. As opposed to the previously tested cables, the values obtained for cable D matched the manufacturer's recommended values.

Table 4: Summary of cable D tensioners at different locus

	Loci (kg)			
	1	**2**	**3**	**4**
Tensioner at 45 kg	45	47	45	47

Tensioner at 68 kg	40	67	60	65
Tensioner at max tension	40	112	110	110

For cable E the measurements on the tensioning device were in pounds (lb), and converted into kilograms (kg) as 1 lb = 0.45359237 kg. Measurements were taken with the sleeve at four different sites. Two of the measured forces reflected the value indicated by the tensioning device as recommended by the manufacturer. The other two values closely reflected the manufacturer's recommended value. However, cable fraying was noted during the last measurement. In addition, the overall performance of cable E matched the manufacturer's recommended values.

Table 5: Summary of cable E tensioners at different locus

	Loci (kg)			
	1	**2**	**3**	**4**
Tensioner at 100 lbs (45 kg)	45	49	45	44

Discussion

This study aimed to determine whether the initial force that is applied to the cylindrical structure reflects the value of the force indicated by the manufacturer of the tensioning device. Previous studies that compared the capacity of different types of orthopaedic cable systems to maintain tension found a significant tension loss with crimping for all cable systems, where a simple cobalt chrome cable system (DePuy) outperformed the more sophisticated locking devices because of its significantly better ability to prevent tension loss (Ménard et al., 2013). Similarly, in this study, significant variance was observed between the forces that the different devices were able to apply. Cable A consistently measured less force than the force reflected by the manufacturer on the tensioning device; this was seen at all four loci, with a decrease in the force measured at loci 3 and 4.

When cable B was loaded to the manufacturer's recommended maximum force, the values measured were also consistently less than the values reflected on the tensioning device, with loci 1 and 2 measuring slightly higher values than loci 3 and 4. Cable fraying was seen, which could be attributed to higher forces (100 kg) being used and to retensioning. When the researcher used a new cable with less tension (75 kg) applied, surprisingly the findings were

similar to those obtained with the cable at 100 kg, in other words, lower values were measured at all four loci demonstrated the same pattern of a decrease in force at loci 3 and 4.

Because cable fraying was seen at the manufacturer's recommended values, the researcher did not maximise tension beyond these recommendations. Cable C was loaded in a similar fashion to cable B and results showed lower values than those indicated by the manufacturer for the tensioning device. When maximally tensioned beyond the manufacturer's recommendations at locus 1, cable C performed differently to other cables, measuring less force than the reflected value recommended by the manufacturer for the tensioning device. The researcher, however, attributed that to operator error. Cable D showed better performance than cables A to C. The researcher measured the exact values as indicated by the tensioning device at loci 1 for both 45 kg and 65 kg. Other values were closer to the manufacturer's recommended value for the tensioning device, slightly higher or lower for both 45 kg and 65 kg loading. Loading beyond the manufacturer's recommendations showed an increase in maximum values, especially at loci 1 and 2. With respect to cable E, the tensioning device measured in pounds, which we converted to kilograms. Cable E also displayed a good performance, matching the manufacturer's recommended values reflected on the tensioning device, with a slightly higher value at loci 2 and lower at loci 4.

Cables A and D showed persistently larger maximum forces than the other cables did. However, these were not recommended by the manufacturer. Cables B, C and E became frayed after being retensioned more than twice. Cables D and E demonstrated good performance compared to other cables, with values closely reflecting the values indicated by the manufacturer; while the other cables performed poorly, with values lower than the values reflected by the manufacturer of the tensioning device. This finding could be one of the reasons for failure of CCSs *in vivo*, i.e., the force applied by the tensioning device may not be a true reflection of the force indicated by the manufacturer of the tensioning device, leading to loosening, non-union or malunion.

Menard et al.[3] in their study looked at initial tension loss of different cerclage cables. They observed that the locking mechanism with a set screw deforming sleeve and a cobalt chrome cable system (Z) was the least effective in maintaining its tension, with tension loss of more than 50%[3]. The upshot of this is that, in an operating room setting, a surgeon loading this cobalt chrome cable system (Z) to 100 lb of tension would effectively only be getting around 50 lb of

tension. The nylon cable system (K) also showed a significant loss of tension of almost 50%[3]. Similarly, in this study, the researcher noticed that, as the cerclage cables were loaded to the manufacturer's recommended tension, lower forces than what was recommended by the manufacturer were consistently measured. Silverton et al.[10] observed that, of 68 patients who received attention, cable fraying was seen thirty-two (32) patients (47%) and fraying with fragmentation was found in thirty (30) patients (44%)[10]. Eight (8) hips of the patients with fragmentation were found to have large deposits of metal debris at the inferior border of the acetabulum[10]. Bauer et al.[11] noted in their three case reports that cable fraying with breakage of individual wire filaments was evident in one of the retrieved specimens and could also be visualised on several radiographs[11]. Their results show that broken filaments of the wires can migrate into the articular space, become trapped between the articulating surfaces of the femoral and acetabular components, resulting in abrasive third-body wear[11]. In their case report on a revision surgery of the hip, Krauset et al.[12] found that fragments of cerclage cable were observed within the polyethylene (PE) surface inside the cup, with several scratches on the bearing surface[12]. They strongly recommended a follow up of the patients at least every 6 months, up to 2.5 years post operation, if multifilament cerclage cables are used[12]. These recommendations were based on the fact that cerclage cables break frequently and commonly between 3 and 23 months postoperatively, with a mean of 18 months[12]. In this study, cable fraying was also noted in three of the five cables that were tested. However, in this study, cable fraying was seen with retensioning of the same cable more than twice.

Conclusion

When retensioning a device, care should be taken to inspect the cable for fraying, as observed with cables B, C and E, since this can lead to fraying and polyethylene third body wear in total hip replacements. A trend of increasing force closer to the point of crossing of the cables was observed. In addition, a trend of decreasing force with subsequent retensioning was observed. The amount of tension applied should generally be left to the discretion of surgeon, with the quality of the bone taken into consideration.

REFERENCES

1. Dall DM, A Biomechanical and Clinical Review: The Dall–Miles Cable System. University of Southern California, Los Angeles, CA, USA.
2. Koo K, Zhou Z, Andy KS, Koh JSB, Howe TS. A Biomechanical Study Comparing Cerclage Wiring Performed with a Power Tool versus the Manual Method. Ann Acad Med Singapore 2015;44:554-7.
3. Menard J Jr, Emard M, Canet F, Brailovski V, Petit Y, Laflamme GY. Initial Tension Loss in Cerclage Cables. *The Journal of Arthroplasty* 28 (2013) 1509–1512.
4. DePuy Synthes Cable System Surgical Technique. www.depuysynthes.com/ifu.
5. Ozan F, Koyuncu F, Pekedis M, Altay T, Yildiz H, Toker G. Greater Trochanteric Fixation Using a Cable System for Partial Hip Arthroplasty: A Clinical and Finite Element Analysis. BioMed Research International Volume 2014, Article ID 931537.
6. Lenz M, Perren SM, Richards RG, Muckley T, Hofmann GO, Gueorguiev B, Windolf M. Biomechanical performance of different cable and wire cerclage configurations. *International Orthopaedics* (SICOT) (2013) 37:125–130.
7. Canet F, Baril Y, Brailovski V, Petit Y, Bissonnette G, Laflamme G. Force Relaxation and Sprinback of Novel Elastic Orthopedic Cables, International Conference of the IEEE EMBS,Boston, Massachusetts USA, August 30 - September 3, 2011.
8. Hadda FS, Barrack RL, Ries MD. Factors influencing cerclage cable tension loss during surgery. American Academy of Orthopaedic Surgeons scientific exhibit. Annual meeting. San Francisco, CA, *American Academy of Orthopaedic Surgeon* 2004.
9. Wahnet D, Lenz M, Schlegel U, Perren S, Windolf M. A Biomechanical Study on the Twisting Procedure. acta chirurgiae orthopaedicae et traumatologiae cechosl. 8, 2011.
10. Silverton CD, Jacobs JJ, Rosenberg AG, Kull L, Conley A, Galante JO. Complications of a cable grip system. *Journal of Arthroplasty* 1996;11:400-404.
11. Bauer TW, Ming J, D'Antonio JA, Mrawa LG. Abrasive three body wear of polyethylene caused by broken multifilament cables of a total hip prosthesis. *Journal of bone and joint surgery*. Vol 78a No.8 August 1996.

12. Kraus MJ, Nowakowski AM. Cerclage breakage in Trochanteric revision, high risk for hip endoprosthesis? Acta Orhtop Traumatol Cech. 84, 2017, No.2 p. 138-140.

Appendices

Appendix A (Letter of Approval from Research Ethics Committee)

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

21-Jan-2020

Dear **Dr Jabulani Mofokeng**

Ethics Clearance: **Evaluation of cerclage cable force**
Principal Investigator: **Dr Jabulani Mofokeng**
Department: **Orthopaedics Department (Bloemfontein Campus)**

APPLICATION APPROVED

Please ensure that you read the whole document

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is:**UFS-HSD2019/1890/2502**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension.

We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerely

Dr. SM Le Grange
Chair : Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
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Appendix B (Letter from the Department of Biostatistics)

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

13 September 2019

For attention: Ethics Committee

Faculty of Health Sciences

Title of project:

EVALUATION OF A CERCLAGE CABLE FORCE AT UNIVERSITAS ACADEMIC HOSPITAL, BLOEMFONTEIN.

Researcher:

DR JE MOFOKENG

I have given input regarding the above mentioned project's protocol on the following aspects of the protocol, namely the study design, sample, measurement, and statistical analysis.

The input will be implemented under supervision of the study leader.

Yours faithfully

FC van Rooyen

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205 Nelson Mandela Drive/Rylaan, Park West/Parkwes, Bloemfontein 9301, South Africa/Suid-Afrika
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Appendix C (Copy of the protocol)

UNIVERSITY OF FREE STATE

DEPARTMENT OF ORTHOPEDIC SURGERY

EVALUATION OF A CERCLAGE CABLE FORCE AT UNIVERSITAS ACADEMIC HOSPITAL, BLOEMFONTEIN, 2019

Study Protocol

INDEX

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LITERATURE REVIEW

The cerclage cable systems have been used in many clinical situations, mainly to provide or assist in fixation of bony fragments[5]. Its usefulness extends through the various specialties including trauma and fracture fixation, tumour surgery and arthroplasty, especially in revision total hip replacements[1]. As a stand-alone implant, cerclage cables are usually too weak to fulfil the requirements of functional aftercare[3]. An internal plate or endoprosthesis shaft provides splinting as a major element stabilizing the fracture while the cerclage cable reduces and fixes the fragments exerting additional stability via a centripetal force[3].
They are composed of stainless steel, chrome cobalt, titanium alloy and nylon[6]. Two types exist, the monofilament and the multifilament. Monofilament wires have been used for many decades, but it was not until the late 1970_s that Dall and Mile were the first to use a multifilament cable in the fixation of the greater trochanter when osteotomized as an approach to the hip in total hip arthroplasty[5]. Although they reported excellent results with their multifilament metallic cable grip system, the published failure rate that is associated with these devices ranges from 27% to 44%[4]. These attractive fixation devices are not without complications[5].

Loosening of the cable may occur during the postoperative period when cables are subjected to micro-motion and displacement created by soft tissue interposition and bone resorption[2]. However, significant loosening has also been reported during surgery immediately after clamp fixation[2]. The mechanical advantage of the cable tensioning device and the crimping tool believed to be superior

may in fact compromise the secure fixation of the cable through the grip device. Cerclages can also break with subsequent loss of fracture reduction and risk of migration especially into the vascular system, also the potential of strangulating periosteal blood supply[7].

Indications

Orthopaedic trauma surgery e.g periprosthetic fractures, femur fractures, olecranon fractures, patella fractures, humerus and ankle fractures, Acromioclavicular dislocation, Hip and acetabular fractures, Prophylactic banding in total joint replacements, Temporary fixation during open reductions, Reattachment of the greater trochanter following osteotomy in total hip arthroplasty or fractures[6].

Contraindications

The cerclage cable of size 1.0 mm may not be used for fractures of the femur, or for prophylactic banding during total joint replacements[6].

The majority of studies done in the literature are to compare the mechanical performance of different cerclage materials and different cerclage closure techniques. Our study will focus on comparing the forces applied by these cerclage systems. The recommendations from Depuy cerclage cable system is that for 1mm cable, tension should not exceed 40kg and not more than 50kg for 1.7mm cable[6].

These devices can also be used in combination with intramedullary nails, a prosthesis stem and with plates as internal splinting, they can also be used for allograft fixation and compression[7]. In our institution at Universitas we used them largely in periprosthetic fractures when revising the total hip arthroplasty.

Research question

We want to see at which locus on the cylindrical structure is maximum force applied

Aim and Objectives

We want to compare if the initial force that is applied to the cylindrical structure reflect the value of the force indicated by the tensioning device.

Hypothesis:

Cables that are tensioned more than once, loose their strength and may require more than the suggested force on the tensioning device to gain optimal strength of fixation

METHODOLOGY

This is a descriptive type of study that will be carried out at the University of Free State, Universitas Academic Hospital, to illustrate at which locus on the structure is the maximum force applied.

We hypothesize that the value of the force indicated by the tensioning device will not be consistently reflected when forces are applied at different locus on the cylindrical structure.

As supported by the literature:

- Loosening of the cables
- Fraying and breakage of the cables

We will approach five different companies that manufacture these cables and obtain informed consent to utilize their products to conduct our study. We will design a weighing scale device that can measure these forces that will be applied to the cylindrical structure at different sites and compare them to the forces suggested on the tensioning device. These forces are shearing type of forces; meaning

that they are pushing forces that act close together but not directly opposing each other, they cut an object by sliding its molecules apart sideways. Five different cerclage cable systems from five different companies will be used and labelled as cable A, B, C, D and E, each cable as labelled we will use at least 4 cables, e.g for cable A we will use 4 cables or more and the same for other cables B, C, D and E, the performance of each cable will be measured and recorded as forces are being applied at 4 different sites on the cylindrical structure (representing bone), comparing these true forces with the suggested forces on the tensioning device. The measurements will be in Newton and will be converted to kilograms since 1kg equals 9.81N.

Informed consent will be obtained from the head of department of orthopaedics, also from the University of Free State health science research ethics committee.

Study design

Descriptive study

The study will consist of five commonly used cerclage cable systems, from five different companies, these cables will be labelled A, B, C, D and E. True forces will be applied to a cylindrical structure at four different sites, a weighing scale will be used to measure these forces and compared to each company suggested force on the tensioning device.

Study Location

The study will be conducted at Universitas Academic Hospital, Orthopaedic Department, Bloemfontein in 2019

Data collection

Data collection will be done by the researcher with the involvement of the Department of Biostatistics at the University of Free State in Bloemfontein.

Analysis

Descriptive statistics namely means and standard deviations or medians and percentiles will be calculated for continuous data. Frequencies and percentages will be calculated for categorical data. The analysis will be done by the Department of Biostatistics.

Data management

The data will be captured using excel spreadsheet and summarized using charts that will clearly show the force differences as measured by the device at different loci, assessing for the association between the obtained results and our hypothesis. Inclusion criteria is unused, new cables. Exclusion criteria is faulty cables and previously used cables.

Ethical considerations

Submission of the protocol to the University of the Free State Health Sciences Research and Ethics Committee to seek approval. Informed consent from the Head of Department of Orthopaedics and from the companies which we will be utilizing their products. This is a biomechanical study done on models, consent from the Department of Health will not be requested.

Pilot study

Pilot study will be done on the initial two structures being tested to assess if reproducible results are obtained and method of data capturing is applicable or requires modifications. Those two cases will form part of the study.

Time schedule

This is a biomechanical study done on models with immediate results obtainable, we anticipate to carry it out in about two or three days

ESTIMATED DURATION	
Literature review and protocol	May and June 2019

Ethics submission	July and September 2019
Data collection	October/November 2019
Data analysis	December 2019
Writing of article	January 2020

Budget

The estimated expenditure for the entire study is approximately R1500 to R2000, mainly for the design and manufacture of the measuring device and stationery. The companies will be requested to sponsor the study with cerclage cables and tensioning devices, if any financial expenses incurred, it will be the responsibility of the primary researcher to settle them.

Dissemination of results

The results of the study will be made available to the Department of Orthopaedics, the companies that participated in the study and will also be published.

References

1. Kevin Koo, Zhihong Zhou, Andy KS, Joyce SB Koh, Tet Sen Howe. A Biomechanical Study Comparing Cerclage Wiring Performed with a Power Tool versus the Manual Method. Ann Acad Med Singapore 2015;44:554-7

2. Jeremie Menard Jr., Maxime Emard, Fanny Canet, Vladimir Brailovski, Yvan Petit, George Y. Laflamme. Initial Tension Loss in Cerclage Cables. The Journal of Arthroplasty 28 (2013) 1509–1512

3. Mark Lenz, Stephan Marcel Perren, Robert Geoff Richards, Thomas Mückley, Gunther Olaf Hofmann, Boyko Gueorguiev, Markus Windolf. Biomechanical performance of different cable and wire cerclage configurations. International Orthopaedics (SICOT) (2013) 37:125–130

4. FJrat Ozan, Femmi Koyuncu, Mahmut Pekedis, Taskin Altay, Hasan Yildiz, and Gokhan Toker. Greater Trochanteric Fixation Using a Cable System for Partial Hip Arthroplasty: A Clinical and Finite Element Analysis. BioMed Research International Volume 2014, Article ID 931537, 7 pages

5. Desmond M. Dall. A Biomechanical and Clinical Review: The Dall–Miles Cable System. University of Southern California, Los Angeles, CA, USA

6. DePuy Synthes Cable System Surgical Technique. www.depuysynthes.com/ifu

7. D. Wahnert, M. Lenz, U. Schlegel, S. Perren, M. Windolf. Cerclage Handling for Improved Fracture Treatment. A Biomechanical Study on the Twisting Procedure. ACTA CHIRURGIAE ORTHOPAEDICAE ET TRAUMATOLOGIAE ČECHOSL., 78, 2011

8. Labitzke R. (1995). From “bone suture” to modern osteosynthesis – a chronology, Der chirurg; Zeitschrift fur alle Gebeite der operative Madizen 66. 452-8

9. Naonobu Takahira & Moritoshi Itoman & Katsufumi Uchiyama & Sumitaka Takasaki & Kensuke Fukushima. Reattachment of the greater trochanter in total hip arthroplasty: the pin-sleeve system compared with the Dall-Miles cable grip system. International Orthopaedics (SICOT) (2010) 34:793–797

10. Sigrid Fauconnier, Marno Van Lieshout, Jan Victor. Evaluation of cerclage wiring in the treatment of subtrochanteric fractures. Acta Orthopædica Belgica, Vol. 86 - 1 – 2020.

11. Michael J. Archibeck, Aaron G. Rosenberg, Richard A. Berger, and Craig D. Silverton, DO. Trochanteric Osteotomy and Fixation During Total Hip Arthroplasty. J Am Acad Orthop Surg 2003;11:163-173

12. Gregg J. Jarit, Sathappan S. Sathappan, Anand Panchal, Eric Strauss,Paul E. Di Cesare. Fixation Systems of Greater Trochanteric Osteotomies: Biomechanical and Clinical Outcomes. *J Am Acad Orthop Surg* 2007;15:614-624

13. MacDonald SJ, ColeC, Guerin J, Rorabeck CH, Bourne RB, McCalden RW: Extended trochanteric osteotomy via the direct lateral approach in revision hip arthroplasty. *Clin Orthop Relat Res* 2003;417:210-216.

14. Bostrom MP, Asnis SE, Ernberg JJ, et al: Fatigue testing of cerclage stainless steel wire fixation. J Orthop Trauma 1994;8:422-428.

15. Guadagni JR, Drummond DS: Strength of surgical wire fixation: A laboratory study. *Clin Orthop Relat Res* 1986;209:176-181.

16. Schultz RS, Boger JW, Dunn HK: Strength of stainless steel surgical wire in various fixation modes. *Clin Orthop Relat Res* 1985;198:304-307.

17. Dall DM, Miles AW: Re-attachment of the greater trochanter: The use of the trochanter cable-grip system. *J Bone Joint Surg Br* 1983;65:55-59.

Appendix D (Data sheet)

EVALUATION OF CERCLAGE CABLE FORCE

UNIVERSITAS ACADEMIC HOSPITAL

DEPARTMENT OF ORTHOPAEDICS

DATA SHEET

UNITS in Kg. 9.81Newtons equals 1Kg

CABLE A	**FORCE MEASURED (Kg)**
Loci 1	
Loci 2	
Loci 3	
Loci 4	
CABLE B	
Loci 1	
Loci 2	
Loci 3	
Loci 4	
CABLE C	
Loci 1	

Loci 2

Loci 3

Loci 4

CABLE D

Loci 1

Loci 2

Loci 3

Loci 4

CABLE E

Loci 1

Loci 2

Loci 3

Loci 4

Appendix E

Instructions to authors of South African Orthopaedic Journal (SAOJ)

Author guidelines SAOJ

http://journal.saoa.org.za/index.php/saoj/information/authors

Criteria for publication

- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented in an appropriate fashion and are supported by the data.
- The article is presented in an intelligible fashion and is written in standard English (British usage).
- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

Guidelines for authorship

- Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.
- Other "contributors" can be acknowledged at the end of the manuscript together with their contribution.
- Authors of manuscripts representing a multi-centre study may list members of the group in the footnote on the title page of the published article and their affiliations are listed in an appendix.
- The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients.
- On submission of your article the ORCID (Open Researcher and Contributor ID) identifier of all authors will be required. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and supports automated linkages between you and your professional activities ensuring that your work is recognized. To register and find more information please visit: http://orcid.org

Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes.
- Clinical Trials should be registered in a public trials registry in accordance with International Committee of Medical Journal Editors.
- Trials must register and approved by the relevant authorities before the onset of patient enrolment.

- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

Reporting guidelines

All articles should be prepared in accordance with the guidelines relevant to the study design that was used (listed below).

- Randomised trials (CONSORT)
- Observational studies (STROBE)
- Systematic reviews (PRISMA)
- Case reports (CARE)
- Qualitative research (SRQR)
- Diagnostic/prognostic studies (STARD)
- Quality improvement studies (SQUIRE)
- Economic evaluations (CHEERS)
- Animal pre-clinical studies (ARRIVE)
- Study protocols (SPIRIT)

Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Role of funding source

You are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. If the funding source(s) had no such involvement, then this should be stated.

Formatting of submissions

Text formatting

- Use Arial font, size 11.
- 1,5 spacing throughout the document.
- Pages of the blinded manuscript should be numbered consecutively.
- Use the automatic page numbering function to number the pages.
- Use italics for emphasis.

- When referring to an article with multiple authors please use the following format: Rabinowitz *et al.* published their retrospective review.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations and acronyms should be defined at first mention and used consistently thereafter.

Units

Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Figures

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3 etc.
- The figure should be listed in the text as follows: ... wound irrigation and splinting (*Figure 1*).
- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures should be understandable without the main text.
- For radiographs please ensure you state view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.
- Figures should not be imbedded in the text file, but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of 6 figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have and can supply written permission from the copyright holder to use that content.
- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrollment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

Tables

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in text in consecutive numerical order.
- The table should be identified in the text as follows: Details of results are listed in *Table I*. Or, alternatively, high-energy trauma that is often associated with these fractures (*Table II*).
- Tables should be used to present information in a clear and concise manner. All tables should be understandable without the main text.
- For each table, please supply a table caption (title) explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
- Footnotes to tables should be indicated by superscript lower-case letters and included beneath the table body.
- Please submit tables as editable text and not as images. They should be created using the Table tool in Word.
- Table should not be imbedded in the text file, but should be submitted as separate individual files. Each table should be a separate file, entitled Table 1, Table 2, etc.
- We accept a maximum of 8 tables.
- Do not duplicate information given already in the text.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have and can supply written permission from the copyright holder to use that content.

References

- References should be numbered consecutively in the order that they are first mentioned in the text and listed at the end in numerical order of appearance.
- Identify references in the text by Arabic numerals in superscript after punctuation.
- References should not be a listing of a computerised literature search but should have been read by the authors and have pertinence to the manuscript.
- Authors should add DOIs to all references in articles.
- Accuracy of references is the author's responsibility and the author is to verify the references against the original documents.
- Manuscripts in preparation, unpublished data (including articles submitted but not in the press) and personal communications may not be included in the reference listing. They may be listed in the text in parentheses only if absolutely necessary to the contents and meaning of the article.
- The titles of journals should be abbreviated according to the style used in Index Medicus, obtainable through the website http://www.nlm.nih.govshould
- The following format should be used for references:

Journal Articles:

Sidhu GS, Ghag A, Prokuski V, Vaccaro AR, Radcliff KE. Civilian gunshot injuries of the spinal cord: a systematic review of the current literature. Clin Orthop Relat Res 2013;471:3945-55.

Ideally, the names of all authors should be provided, but the usage of "et al" in long author lists (more than 6 authors) will also be accepted: Fong K, Truong V, Foote CJ, et al. Predictors of

nonunion and reoperation in patients with fractures of the tibia: an observational study. BMC Musculoskelet Disord 2013;14:103.

On-line journal article:
Caetano-Lopes J, Lopes A, Rodrigues A, et al. Upregulation of inflammatory genes and downregulation of sclerostin gene expression are key elements in the early phase of fragility fracture healing. PLoS One 2011;6:e16947.

Web reference (with authors):
Cierny G, DiPasquale D. Adult osteomyelitis protocol.
http://www.osteomyelitis.com/pdf/treatment_protocol.pdf.
(date last accessed 05 March 2013).

Web reference (no authors listed):
No authors listed. International commission on radiological protection. http://www.icrp.org (date last accessed 20 September 2009).

Chapter in a book:
Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD, Waugh T (eds). Spinal Trauma. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

Dissertation:
Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant (MI): Central Michigan University; 2002.

Abstract:
Peterson L. Osteochondritis of the knee treated with autologous chondrocyte transplantation [abstract]. ISAKOS Congress, 2001.

Structure and content of submission

We accept a maximum of 3500 words including abstract, body of the text (excluding references). Exceptions to this rule may be made for systematic reviews and meta-analysis, at the discretion of the Editor-in-Chief.

Please follow the following structure when preparing your submission.

- Title page (Title, authors and affiliations, corresponding author and declarations)

- Blinded Manuscript (Abstract, key words, introduction, methods, results, discussion, funding sources, conflict of interest statement, ethical statement, acknowledgements and references)
- Tables (with headings), each as a separate file.
- Figures (with legends), each as a separate file.

Title page

Title

The title should be concise and informative.

Author names and affiliations:

Please provide the following information for each author:

- Full names and surname, as well as title (please check that all names are accurately spelled)
- Qualifications
- Affiliation and address (indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate affiliation details)
- ORCID ID (see Article Submission section)

Provide the full postal address of each affiliation, including the country name and, if available, the email address of each author.

Corresponding author

Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication.

Ensure that the email address and permanent address is given and that contact details are kept up to date by the corresponding author.

Please note that the corresponding author’s contact details will be provided in the final article.

Please provide the following information for the corresponding author:

- Full names and title
- Affiliation
- Physical address
- Postal address
- Telephone Number
- Email address

Please provide the names and email addresses of two potential reviewers.

Declarations

Authors are to insert a section at the end of the title page entitled declarations. Following the declarations all authors need to sign the document (please provide name of author, signature and date). The following statements is required under the declarations section:

Authorship

The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- Drafting the article or revising it critically for important intellectual content.
- Final approval of the version to be submitted.
- Sound scientific research practice

The authors further confirm that:

- The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere
- No data have been fabricated or manipulated (including images) to support your conclusions
- This submission does not represent a part of single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. “salami-publishing”).

Author contributions

Please state the contributions of each author

• For example: “A.B contributed to study conceptualization, design, data analysis and manuscript preparation. C.D. contributed to data collection and manuscript preparation. E.F. contributed to ….”

• The types of contributions are:

o Conceptualization and design

o Data collection or contribution

o Data analysis

o Manuscript preparation

o Other contribution (please specify)

Plagiarism:

- The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.
- No data, text, or theories by others are presented as if they were the author's own.
- Proper acknowledgements of other's work has been given (this includes material that is closely copied, summarized and/or paraphrased), quotation marks are used for verbatim copying of material.
- Permissions have been secured for material that is copyrighted.

Conflict of interest statement

A conflicting interest exists when professional judgement concerning a primary interest (such as patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It represents a situation in which financial or other personal considerations from authors, reviewers or editors have the potential to compromise or bias professional judgment and objectivity. It may arise for the authors when they have financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. All potential conflicts of interest need to be declared. The conflict of interest statement should list each author separately by name, i.e.

"John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A. Mike Schultz has received a speaker honorarium from Drug Company B and owns stock in Drug Company C."

If multiple authors declare no conflict, this can be done in one sentence

Funding sources

All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; the decision to submit the manuscript for publication. If the study sponsors had no such involvement, this should be stated.

Compliance with ethical guidelines

For all publications:

"The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010."

Available from: http://publicationethics.org/resources/international-standards-for-editors-and-authors

Institutional Review Board (IRB) ethical approval must have been given if the study involves human subjects or animals. Please provide the approval number. IRB documentation should be provided.

"Prior to commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number*"

For studies with human subjects include the following:

"All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008."

"Informed written consent was or was not obtained from all patients for being included in the study."

For studies with animals include the following sentence:

"All institutional and national guidelines for the care and use of laboratory animals were followed."

For articles that do not contain studies with human or animal subjects:

"This article does not contain any studies with human or animal subjects."

If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. If any identifying information about patients is included in the article, the following sentence should also be included: Additional informed consent was obtained from all patients for which identifying information is included in this article. The Helsinki Declaration 2008 can be found at http://www.wma.net/en/30publications/10policies/b3/

Blinded manuscript

Abstract

A structured abstract (maximum of 350 words), summarising the most important points in the article is required.

The abstract consisting of four paragraphs with the subheadings:

- Background (must include the aim of the study)
- Patients and methods
- Results
- Conclusion

References should be avoided. Avoid uncommon abbreviations. If essential they must be defined at their first mention in the abstract itself

Keywords

Immediately after the abstract, provide a maximum of 6 keywords, using standard searchable terms. These keywords will be used for indexing purposes.

Level of evidence

Level 1 to 5.

Please follow the level of evidence guidelines provided by the Oxford Centre for Evidence-Based Medicine (OCEBM); version 2.1.

Available from: OCEBM Levels of Evidence Working Group. "The Oxford Levels of Evidence 2".Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653

Introduction

The introduction should contextualise the study by providing the background to the research; explain the problem that is to be addressed and provide the rationale for the study.

Briefly outline the relevance if the study in respect to the current literature. Avoid a detailed literature survey or a summary of the results.

The last sentence should outline the research question or hypothesis.

Patients (or Materials) and Methods

State the methods, outcome measures, and selection criteria. The following aspects needs to be described:

- The study design and research methodology.
- Whether randomization (with methods) was applied.
- If case controlled, how the controls were selected.
- The time period under review.
- Number of patients/subjects under investigation and why this number was chosen.
- Inclusion and exclusion criteria.
- Case and outcome definitions.
- Description of procedure or intervention, including post-operative protocol.
- The outcome measures or scores were used.
- The minimum follow-up period.
- A statistical analysis section should be included at the end of this section to detail statistical tests and package used, the reasons why these tests were used, and what p-value was considered statistically significant. A power analysis is recommended for studies comparing two or more groups.
- Provide sufficient detail so that another researcher can replicate the study.
- The reader should understand from this description all potential sources of bias such as referral, diagnosis, exclusion, recall, or treatment bias. This includes the manner in which investigators selected the patients. Consecutive inclusion implies all patients with a given diagnosis are included, while selective implies patients with a given diagnosis but selected according to certain explicit criteria (e.g. state of disease, choice of treatment).
- Do not describe standard procedure for common operations. Only include new procedures or adaptations to standard procedure.
- If you name any specific product, then it requires the name, city and state/country of the manufacturer.
- Present in narrative format and use past tense.
- Where relevant, tables or figures may be included to provide information more clearly.
- Generally, no data should normally be presented in this section.

Results

- Describe the relevant results and analysis thereof.
- Provide details of the number of patients included and excluded, as well as the reason for exclusion.
- It is important to state the follow-up period (mean and range).
- The results can be broken down into separate sections, e.g. Treatment, Functional outcome, Complications, etc.
- Tables may be used but avoid repeating data reported in the text in the tables.
- All appropriate data should be presented as means with ranges, not with standard deviations (SDs). Medians should only be used when the data is skewed, accompanied by an interquartile range (IQR).

- Avoid using percentages in studies involving well under 100 subjects.
- All results must be backed-up with p-values or survivorship analysis. All Kaplan-Meier data should be presented with the confidence intervals. Always present exact absolute p-values, whether significant or not, unless $p < 0.001$.
- However, p-values do not always convey the entire picture and where relevant the confidence interval will also be required (in addition to the power of the study reported in the methods section).

Discussion

- The question or hypothesis stated at the end of the introduction should be discussed and supported or rejected.
- The results must be interpreted clearly and any deficiencies expressed. All possible confounding factors, sources of bias, weaknesses in the study should be identified.
- Explore the significance of the results of the work, rather than repeating the results.
- The discussion must point out the relevance of the work described in the paper and its contribution to current knowledge.
- Explain what can be deduced from the results and how will it affect clinical practice should be clearly stated
- Should include a review of the relevant literature, placing the results of the study in the context of previous work in this area.
- Discussion of relevant prior research and references must be concise. Avoid extensive citations and discussion of published literature but put emphasis on previous findings that agree (or disagree) with those of the present study.
- Do not repeat the introduction.
- The limitations of the study must be presented and suggest how the study could have been improved for a future study.
- Authors should avoid making inferences from non-significant trends unless they believe their study is adequately powered to answer the question; in that case, provide a power analysis.

Conclusion

Summary statement which conveys the conclusions of the findings. Do not draw conclusions not supported by the data obtained from the specific study presented.

Conflict of interest

"Author A.B. (*use initials of relevant author, not full name in order for the document to remain blinded*) has received research grants from Company A. Author B.C. has received a speaker honorarium from Company X and owns stock in Company Y. Author C.D. is a member of committee Z."

If no conflicts of interest exists, please state this as follows: "The authors declare they have no conflicts of interest that are directly or indirectly related to the research."

Ethical statement

- For studies involving human subjects please include an ethical statement as follows: “All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.”
- For animal studies please include the following ethical statement: “All applicable international, national, and/or institutional guidelines for the care and use of animals were followed.”
- If the study did not involve human or animal subjects state that: “This article does not contain any studies with human participants or animals performed by any of the authors.”
- Please also include an informed consent statement: “Informed consent was obtained from all individual participants included in the study.”
- Or alternatively, for retrospective studies, please add the following sentence: “For this study formal consent was not required.”
- If identifying information about participants is available in the article, the following statement should be included: “Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.”

Funding sources

List all funding sources as follows: “This work was supported by the xxxx (grant numbers xxxx, yyyy).”

When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding was received please state as follows: “No funding was received for this study.”

Acknowledgements

Should be placed at the end of the discussion and prior to the references. In this section persons who were involved but did not earn authorship can be acknowledged. Should be brief and should not anonymous editors or referees. A person can be thanked for assistance or for comments.

Author contributions

Please state the contributions of each author

• For example: “A.B contributed to study conceptualization, design, data analysis and manuscript preparation. C.D. contributed to data collection and manuscript preparation. E.F. contributed to ….”

• The types of contributions are:

o Conceptualization and design
o Data collection or contribution
o Data analysis
o Manuscript preparation
o Other contribution (please specify)

References

Please refer to formatting of submissions section.

Tables and Figures

Table and figures should not be imbedded in the text file, but should be submitted as separate individual files. Each table should be a separate file, entitled Table I, Figure 2, etc.

Each table and figure should be provided with a heading or legend.

Please refer to the 'Formatting of Submission' section for further guidelines.

Current Concepts Review

Background

In November 2018 the SAOJ Editorial Board commissioned the inclusion of one "Current Concepts Review" paper per issue. All University departments will be scheduled to contribute one paper ever 2nd year. The University via the Head of Department will the nominate expert author to be responsible for preparation the review article. We recommend that multiple authors are involved and in particular advocate collaborating with experts from other institutions to get a broader view on the topic.

General Guidelines

- A narrative review will suffice (and systematic or scoping review not necessary)
- A thorough literature review needs to be done prior to writing the manuscript to ensure that the author is well acquainted with the current concepts related to the topic (with emphasis on the most recent developments)
- A balanced and unbiased view of the current clinical aspects of the topic.
- Focus on clinical aspects like diagnosis and treatment.
- Discuss controversies and state both sides of the argument.

- Avoid extensive discussion of basic science (anatomy/physiology/pathology) aspects, except if there are some really novel and clinically-relevant new developments in the field.
- The topic may be adapted, but only with the permission of the Editor-in-Chief.

Outline of Article

- **Abstract** = One paragraph, no headings, ≤350 words.
- **Introduction** = Brief introduction to the topic
- **Contents** = Please use headings (in bold) and sub-headings (in italics) to structure to manuscript in reader-friendly manner
- **South African context** = Discuss matters which may be particularly relevant or unique to the South African clinical setting.
- **Learning points** = Make use of tables to summarize important learning points
- **Conclusion** = Brief evidence-based conclusion and summary
- **Conflict of interest statement**
- **Funding**
- **References** = As usual

Review Process

- Each submission will be peer-reviewed by 2 members of the editorial board

Appendix F (turnitin summary)

EVALUATION OF THE CERCLAGE CABLE FORCE 3

ORIGINALITY REPORT

19%	12%	11%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	sportssurgerynewyork.com Internet Source	5%
2	Ménard, Jérémie, Maxime Émard, Fanny Canet, Vladimir Brailovski, Yvan Petit, and George Y. Laflamme. "Initial Tension Loss in Cerclage Cables", The Journal of Arthroplasty, 2013. Publication	3%
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4	worldwidescience.org Internet Source	1%
5	Patel, S.. "Trochanteric Fixation Using a Third-Generation Cable Device-Minimum Follow-Up of 3 Years", The Journal of Arthroplasty, 201203 Publication	1%
6	www.achot.cz Internet Source	1%
7	Jérémie Ménard, Maxime Émard, Fanny Canet, Vladimir Brailovski, Yvan Petit, George Y.	1%

	Laflamme. "Initial Tension Loss in Cerclage Cables", The Journal of Arthroplasty, 2013 Publication	
8	Mark Lenz, Stephan Marcel Perren, Robert Geoff Richards, Thomas Mückley et al. "Biomechanical performance of different cable and wire cerclage configurations", International Orthopaedics, 2012 Publication	1 %
9	Desmond M. Dall. "A Biomechanical and Clinical Review: The Dall-Miles Cable System", Treatment of Osteoarthritic Change in the Hip, 2007 Publication	1 %
10	www.ejbjs.org Internet Source	1 %
11	Submitted to University of the Free State Student Paper	1 %
12	F. Canet, Y. Baril, V. Brailovski, Y. Petit, G. Bissonnette, G. Laflamme. "Force relaxation and sprinback of novel elastic orthopedic cables", 2011 Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 2011 Publication	<1 %
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