Design of an In-situ Spinal Rod Cutter for Orthopaedic Surgeons

by
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I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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Abstract

As spine deformities scoliosis and kyphosis progress in severity, surgical treatment is often required. Implant rods are attached by bone screws to the spinal vertebrae to correct these deformities and stabilize the spine. It can be difficult to cut these rods to the ideal length before implantation and sometimes these rods are too long and must be cut *in-situ*. Also, when revision surgery is performed to replace a rod section, *in-situ* rod cutting must be performed. The rods are difficult to cut and only manual rod cutting tools are available. These rod cutters are physically demanding to use and difficult to position while avoiding any spurious with the exposed spine. There is a clear need for an improved *in-situ* rod cutter. Thus, the objective of this thesis is to develop a new and improved design for an *in-situ* rod cutter.

Experimental work was done to show that shear cutting and bolt-cutting techniques produced the most desirable results for cutting spinal rods *in-situ*. The shear cutting techniques required slightly less force than bolt cutting techniques and produced a cleaner rod cut with less deformation. It was found that cutting force increased with the diameter of the spinal rod, regardless of the rod material. Constraints and criteria were established to guide the design of a new in-situ rod cutter. It was decided that any attempt at designing a new in-situ cutter must include a non-manual power source for operation. Two design alternatives, a shear cutting design and bolt-cutting design were presented and scored in an engineering design process. A shear cutter design was initially chosen and work was done to implement the shear cutter design. However, the prototype fractured in initial testing and the shear cutter design was abandoned. A bolt-cutter design was then developed and a 3D printed prototype was made to demonstrate the mechanism involved. Analysis was performed to estimate the mechanical advantage of the mechanism used to amplify the force applied by a pneumatic cylinder used as the power source. Further development was required to implement the bolt-cutting design but initial progress in this design project was achieved. It is recommended that stress analysis, prototyping and testing be done to move this design towards application in spinal surgery.

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1 Introduction

Modern treatment of spinal deformities such as scoliosis and kyphosis began in the late 1950's as Paul Harrington developed the Harrington hook and rod system (Good 2010). The Harrington system used a set of metallic rods and hooks fixed on to the spinal column bones to correct the deformed curvature of the spine. These spinal rods provide the stiffness and strength necessary to fuse the spine into a more normal position, allowing for improved posture, and treatment of medical issues caused by the deformity. Since the late 1950's much work has been done on developing the idea of using spinal rods to correct deformities in the spine. Systems used today involve fixing rods to the spinal column vertebra using specialized bone screws and tooling to achieve the correction necessary for improved quality of life.

Typically, high strength metals (cobalt chromium, stainless steel and titanium alloys) are used to manufacture the spinal rods (Yoshihara 2013). Such materials are necessary as the rods must be able to support the load of the upper body, since the spinal column is weakened by the deformity. Of the available rod materials, the cobalt chrome alloy rods provide the highest amount of stiffness (Noshchenko 2011) and can support these large loads, providing good correction (Lamerain 2014).

The length of these rods must be correctly sized to each patient's anatomy. Since each rod is sized on a case by case basis they must be cut in the operating theatre to the correct length. Surgeons use rough measurements and experience to determine a correct rod length for their patient, and then pre-cut the rod to length using a manual table top rod cutter.

It is sometimes necessary to trim the rod length *in-situ* once it has been installed into the patient. This could occur if the rod was cut too long to start with, or if a patient requires a revision to their original surgery where surgeons replace a section of the rod *in-situ*.

To cut the rod *in-situ*, a surgeon has one tool to rely on. This tool is a large *in-situ* bolt-cutter which is operated manually by the surgeon. This *in-situ* rod cutter is positioned, held and operated manually. The high strength material of the rods makes it physically demanding and difficult to use the *in-situ* rod cutters, so surgeons must not only cut the rod but must avoid any damage to the spinal tissues or to the fixation of the rods they are cutting. The installed rods sit close to the delicate spinal anatomy and it can be precarious to position the large cutting blades of the tool in the desired location.

1.1 Problem Statement

Orthopedic and neurological surgeons need an improved *in-situ* rod cutter for cutting spinal rod implants because the current state of the art *in-situ* spinal rod cutter is difficult to use. The current *in-situ* rod cutter requires significant physical strength to operate and lacks the agility to easily manipulate it inside the patient.

1.2 Motivation

The current state of the art *in-situ* rod cutter is difficult to use according to experts Dr. Victor Yang (Sunnybrook Hospital, Toronto, ON) and Dr. Parham Rasoulinejad (Victoria Hospital, London, ON). The large forces involved in the operation of the *in*-situ rod cutter, and the nimbleness of the cutting blades were a major concern. These issues reduce the safety of the surgery and, even when overt damage is avoided, there may be problems with long term pedicle screw fixation after *in-situ* cutting. There has been some evidence of detrimental effects that *in-situ* rod cutting poses to the patient (Aylott 2006). Additionally, the aforementioned experts are convinced that a better *in-situ* rod cutter would improve overall outcomes. Thus, they have made suggestions for improving the in-situ rod cutting tool which helped to reveal the complexities and limitations which need to be accounted for in design so that *in-situ* cutting can be done safely and easily by the surgeon.

1.3 Thesis Outline

Spinal anatomy and various surgical implants are examined in Chapter 2, so that the demands and practices of surgery can be understood, but little academic literature was available on spinal rod cutting because it is considered a mere technical detail of surgery. Thus, preliminary experimental work was conducted to assess how rod cutters cope with cutting the materials used to fabricate spinal rods. In addition to the bolt cutting technique employed by the current *in-situ* rod cutters, shear cutting is investigated as research suggests such a technique may be capable of cutting with precision (Breitling 1997). A novel approach of pipe cutting for rods was also investigated, but ultimately this technique was incompatible with the design problem. The shear cutting and bolt cuttings were further investigated and the forces needed to cut spinal rods were determined. With the foundation developed from this experimental work, design constraints and criteria could be established and the engineering design processes was applied to develop a new design for an *in-situ* spinal rod cutter.

Two design alternatives that were judged to have satisfied the constraints (or bounds) of the design problem were then evaluated according to the established criteria in Chapter 5. The optimum design was chosen and a prototype was fabricated. This prototype revealed problems with the design, so development work was initiated on the other alternative design. Time constraints prevented further development but the design foundations which were established and the final iteration of the design process did allow a number of conclusions to be presented in Chapter 6 along with some ideas for further work and progress.

2 Background Literature

2.1 Clinical Background

Surgical procedures involving the spine must pay close attention to its complex anatomy because any implants, such as spinal rods, must essentially fit in and be fixed within the spinal structure. Deformities of the spinal curvature present a pathology that can affect the function of the spine. Some of these deformities are caused by underlying disease, but others are classified as idiopathic (having unknown causes). The two most common and well recognized spinal deformities are kyphosis and scoliosis. Both of these deformities can be treated for using a variety of surgical and non-surgical techniques. Spinal implants are typically used to treat severe cases of scoliosis and kyphosis, where the deformity poses a threat or hindrance to quality of life. Implants are installed using surgical tools which are designed to work within the constraints of spinal surgery. Thus, spinal anatomy and curvature pathology are important consideration in tool design. For example, tools such as in situ spinal implant rod cutters must fit and function within a confined space near the spinal column.

2.2 Spine Anatomy

The primary functions of the spine are to transmit loads from connected structures to the pelvis, provide support and facilitate mobility to the body (Boos & Aebi 2008) and to protect the spinal cord. The spine is grouped into four distinct regions of function: cervical, thoracic, lumbar and sacral. As explained by Patel et al. (2014), the overall structure consists of 24 independent vertebral bodies, each separated by intervertebral discs.

The cervical spine consists of seven independent vertebral bodies while the thoracic has twelve, the lumbar has five and the sacral region has one large body consisting of five fused vertebral bodies along with a small flexible tailbone (coccyx) section. (Figure 2.1). The top two vertebrae, atlas (C1) and axis (C2) do not have a disc between them (Patel et al 2014). Instead, there are synovial joints that permit guided relative sliding of the vertebra and load transmission (whereas the discs only have their own deformation to permit relative motion of the vertebra and to react to load transmission). There are also synovial joints between C1 and the skull.

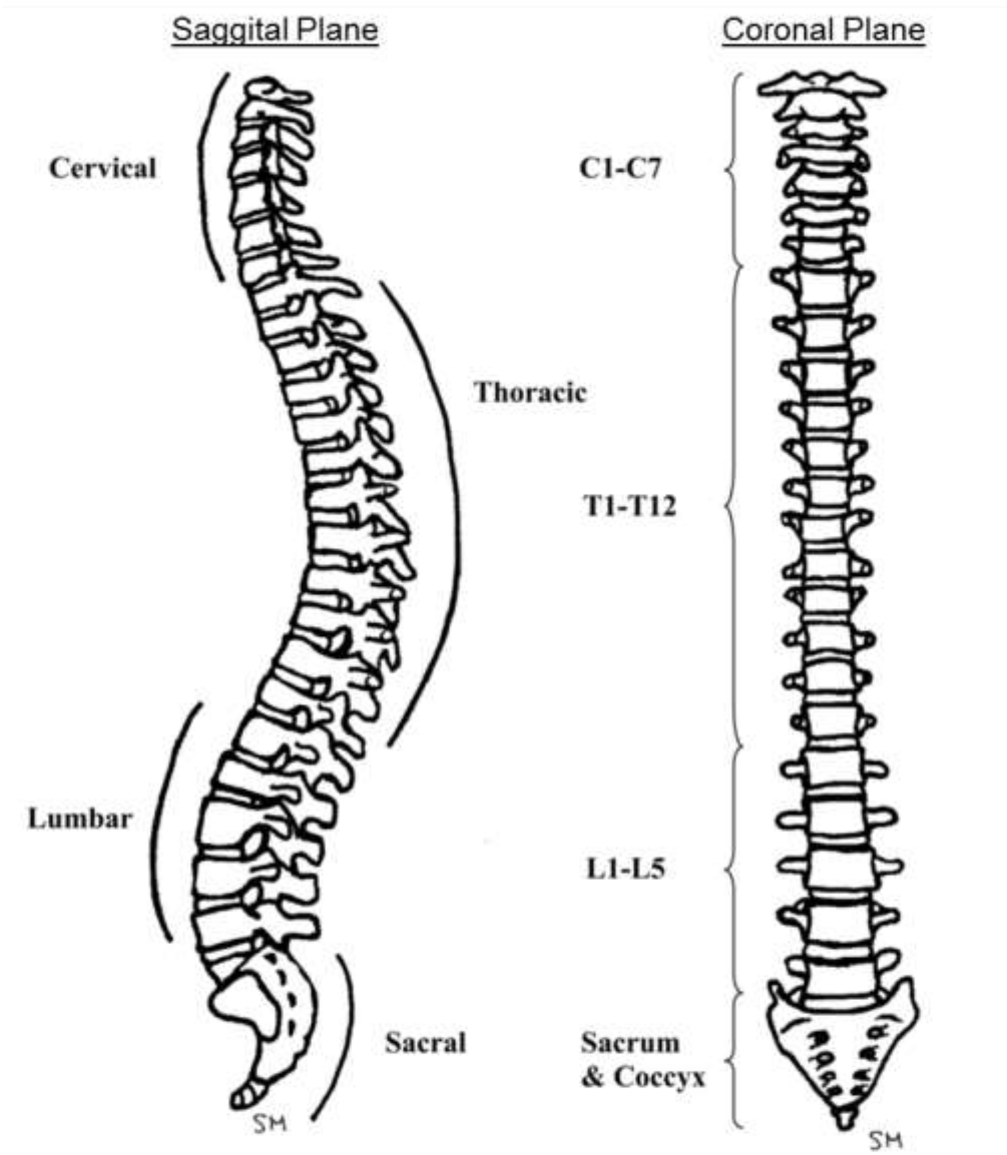


Figure 2.1 The neutral position of the spinal column curves with natural lordosis (inward curvature) and kyphosis (outward curvature) in the sagittal plane, while it is straight in the coronal plane (McLachlin 2008). *This image is used under the fair dealing exception.*

All independent vertebral bodies (except for C1 and C2, as mentioned previously) consist of similar anatomy but their shapes and sizes vary in the different regions of the vertebral column. These variations allow different motions to occur along the spine while transmitting loads are as explained by Patel. In general, the vertebral bodies become progressively larger from the upper to the lower regions of the spine. Cervical and thoracic vertebrae transmit vertical loads through their discs and through the articulation of connecting synovial joints (called facet joints). These synovial facet joints also transmit lateral loads (almost exclusively in the lumbar spine) and thus because of their distance from the neutral axis of the spine they transmit torsional moments (Figure 2.2). The facet joints vary in orientation when viewed from the sagittal plane to achieve this complex load carriage. The more horizontally oriented facet joints in the upper spine enable a greater degree of rotational motion than the more vertically oriented facet joints in the lower spine. Accordingly, the highest degree of rotational motion in the spine occurs in the cervical region (Patel et al 2014).

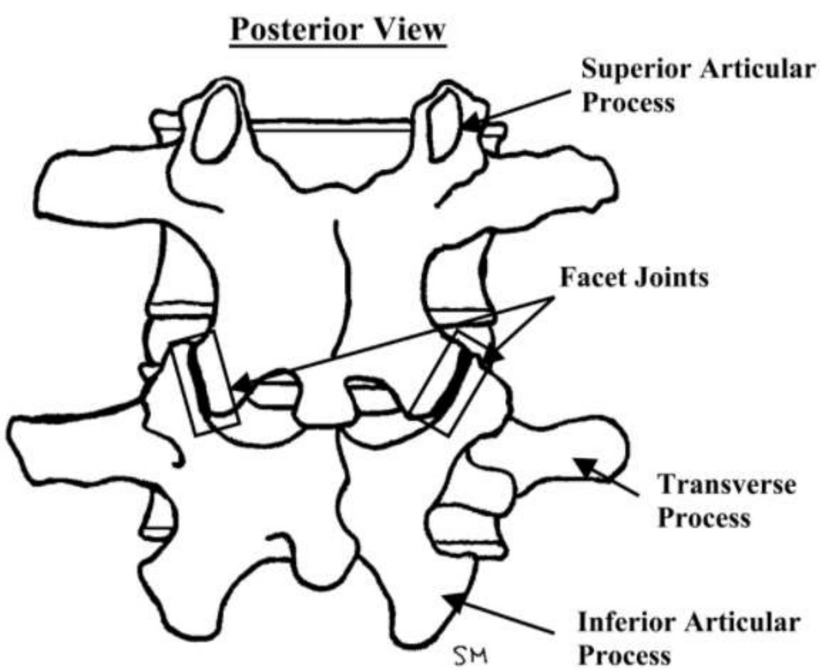


Figure 2.2 Thoracic vertebra shown illustrating their alignment and connectivity to each other (McLachlin 2008). *This image is used under the fair dealing exception.*

As explained in Boos & Aebi, the vertebral material composition consists of a compliant inner trabecular bone, which is shielded by a dense stiffer cortical bone shell. With the exception of the space between C1 and C2, intervertebral discs exist between each vertebral body. These discs, composed of a fluid-filled nucleus and circumferential collagen layers provides shock absorption loading reducing peak stresses on the vertebra caused by impact loading. The discs transmit compressive, bending and torsion loading along the spinal column. If the discs' degenerate, load distribution is no longer uniform across the discs. This causes abnormal local deformation, high local stresses and compression of adjacent nerves or nerves within the vertebral bone (Boos & Aebi 2014).

Force transmission and motion guidance within the spine structure is also dependent on the ligaments that connect vertebral bodies together (Patel et al. 2014). Various intersegmental ligaments are affixed to multiple vertebrae providing resistance to flexion motion of the spinal. These ligaments connect adjoining spinous processes together, and assist in maintaining upright posture. Also, the synovial facet joints are surrounded by the capsular ligaments which prevent distraction and guide motion.

In addition to the ligaments, the musculature of the back insert into the vertebrae of the spinal column. The spinal column plays a significant role in supporting anatomical extremities, helping to stabilize the body and transmit loads (Boos & Aebi 2014). Besides connection to the extremities, the muscles form a thick protective soft tissue barrier on top of the spinal column.

The fundamental motion segment of the spine is the vertebra-disc-vertebra unit that allows for simultaneous flexion, extension, bending and rotation. However, as previously mentioned, vertebrae C1 and C2 and the skull (sometimes referred to as C0) have synovial joints between them rather than discs. Their relative motion is responsible for the majority of rotational motion of the spine. This motion segment rotates axially approximately 5 - 8 times the amount of rotation when compared to the other cervical motion segments (Patel et al 2014). The entire cervical region of the spine is the most mobile, with twice as much flexion/extension as the lumbar region and five times as much as the thoracic region (Patel et al 2014). Lateral bending occurs in all motion segments and is quite similar, in the range of 5 – 10 degrees. Patel also said that overall the majority of spinal motion is flexion and extension with a high degree of rotation occurring at the atlas-axis motion segment. The spinal column experiences several types of loading: axial compression, shear, bending and torsion. During lifting activities, the lumbar spine can experience very high loads (5000 – 8000N) which approach the failure loads that a single vertebra can handle (Boos & Aebi 2014), with the most likely location of failure at the vertebral endplate (Grant et al. 2002).

2.2.1 Spine Pathology

Scoliosis and kyphosis are two significant spinal deformity diseases. If severe and/or progressive enough, they can be corrected using rod-type implants. Scoliosis is abnormal curvature of the spine occurring in the coronal plane (Figure 2.3). In order to be considered a "scoliotic" deformity, the coronal spinal column curvature as measured by the Cobb angle (Figure 2.4) must exceed 10° (Boos & Aebi 2014). This coronal plane curvature is also combined with vertebral body rotation about the long axis of the spine (Boos & Aebi 2014).

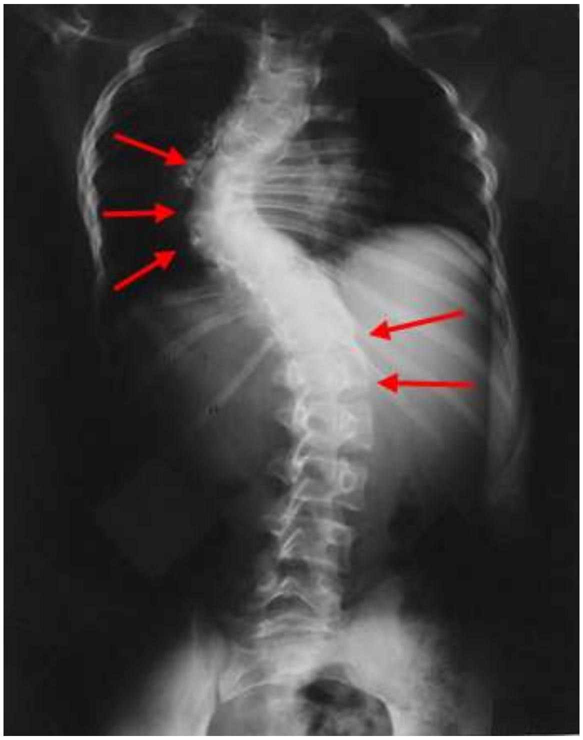


Figure 2.3 X-ray of scoliotic spine with red arrows showing abnormal curvature of the spinal column in the sagittal plane (Gkiokas et. al. 2006). *This image is used under the fair dealing exception.*

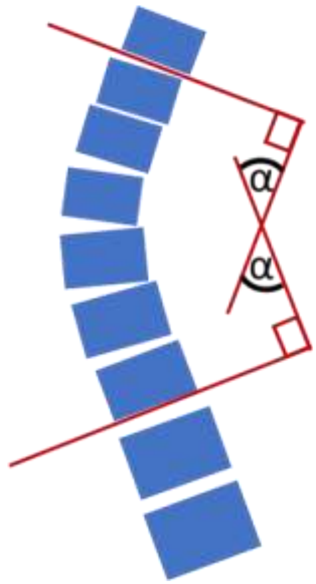


Figure 2.4 Schematic showing how the Cobb angle α is determined. The Cobb angle is used to quantify the degree of scoliotic curvature of the spine.

Scoliotic deformities can be classified into four different types: idiopathic, neuromuscular, congenital, and degenerative (Boos & Aebi 2014). Idiopathic scoliosis is the most common in adolescents between the ages of 10 – 18 years (Spine Centre n.d.), and typically occurs in the thoracic spine region. In some cases, it may be caused by an imbalance of growth in both the anterior and posterior sides of the vertebral bodies possibly with genetics and connective tissue diseases being involved (Guo et al 2003). Large amounts of vertebral rotation and curvature in the coronal plane can cause nerve impingement and pain, as well as rib cage compression of internal organs.

Neuromuscular scoliosis is associated with an existing underlying nerve or muscular condition some of which include: tumors, spinal cord injury and cerebral palsy (Boston Children's Hospital n.d.). These diseases cause the muscular system to become weak and therefore the spine cannot be supported, causing curvatures. Congenital scoliosis is the presence of coronal plane curvature caused by abnormal structural vertebral defects that are present at birth (AAOS 2010).

Degenerative scoliosis is caused by intervertebral disc degeneration. A progressive structural degeneration of the disc leads to asymmetric loading on the spinal column which ultimately leads to a progressive deformity of the spine, particularly in the thoracic and lumbar spine regions (thoracolumbar), which can cause immense pain (Boos & Aebi 2014).

Kyphosis deformity differs from scoliosis deformity in that the spine is curved abnormally forwards in the sagittal plane (Figure 2.5) compared with the natural healthy spine shown in a previous section (Figure 2.1). Kyphosis can occur at any age, but older people are more likely to have kyphosis as a result of age-related osteoporotic weakening of the vertebral bodies which leads to cracks and local compression failures (Mayo Clinic 2014). The smaller vertebrae in the cervical and upper thoracic region fail first and this causes the progressive forward rounding of the upper spine that is known as kyphosis.

Figure 2.5 Kyphotic spine, excessive forward rounding shown. (Betts et al 2016) *This image is used under the fair dealing exception.*

As with scoliosis, various other types of kyphosis exist. For example, there is juvenile kyphosis (or Scheuermann's disease) which occurs in humans aged 13 to 16 (Medscape n.d.). This disease affects the thoracic or thoracolumbar region of the spine such that extreme kyphosis (hyperkyphosis) occurs. The exact pathology behind juvenile kyphosis is not known, but there has been some research to suggest that underweight and tall children are at higher risk (Oded et al 2004). Another type of kyphosis is congenital kyphosis which is an abnormal forwards curvature of the spine present at birth. This type of kyphosis is uncommon but can be quite catastrophic and may result in the spinal cord being crushed. For this particular type of kyphosis, surgical treatments with implants are always necessary (Winter 1977).

When looking for similarities in the development of abnormal spinal curvatures (scoliosis and kyphosis), it is important to note that the natural ageing process has a degenerative effect on the spinal column. In comparison to the other musculoskeletal tissues in the body the spinal column degenerates much sooner in life (Boos & Aebi 2014). Intervertebral discs, vertebrae endplate cartilage, and facet joints degenerate with time along with a decrease in blood supply which affects delivery of nutrition. This degeneration of the spine results in a decrease in spine articulation and the ability of the spine to support and stabilize the body. Vertebral body structure strength, musculature and ligaments also degenerate though a variety of mechanisms, often accelerated by aging. Consequently, both scoliosis and kyphosis can often be attributed to aging.

2.2.2 Surgical Treatments and Implant Design

Surgical treatment of abnormal spinal curvature involves the installation of spinal rods to mechanically realign the spinal column. These metallic rods span the least the length of the deformity and are attached to the spine using screws which are driven into the pedicles of each vertebral body (Figure 2.6).

Figure 2.6 Pedicle screws driven into the vertebral body (Spine-Health n.d.) *This image is used under the fair dealing exception.*

Rods are bent into a corrective shape prior to installation. Then, they are attached to the installed screws via channels and caps (Figure 2.7). The wide screw thread pitch and deep threads grab onto the vertebral body bone, acting as anchors for the rods and allows the rod to apply corrective force to each vertebral body.

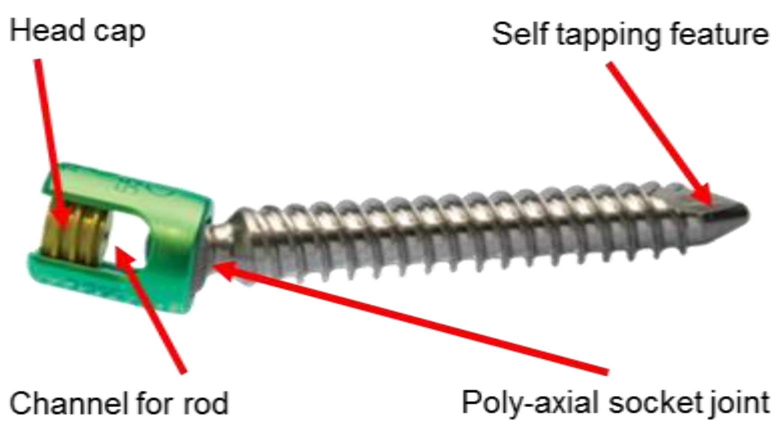


Figure 2.7 Example of a pedicle screw (Zimmer Spine | Sequoia Pedicle Screw Systems n.d.) *This image is used under the fair dealing exception.*

The intended result of the surgery is to correct spinal deformity by forcing the spine to assume the corrective shape of these rods. As a result of the installation of the rods, the normal motion of the attached vertebrae cannot occur and thus overall motion of the spine is reduced. Although this is somewhat undesirable, the alternative progression of the abnormal curvature is more undesirable.

Most surgeries for the abnormal spinal curvatures (resulting from scoliosis and kyphosis) involve cutting the back skin and muscles open along the area of intended fusion and performing a posterior release by resecting the spinal ligaments and facet capsules (Patel et al 2014). This posterior release reduces resistance to alignment and clears the spine for the implant placement. The screws are placed into pedicles (Figure 2.11) and the rods are bent into the correct shape and placed in the screws. As the rods are placed, the spine becomes aligned to the corrected position. The implant rods and anchoring screws immobilize the spine over their region of placement and carry the loads imposed during subsequent patient activities of normal living. There are also minimally invasive surgery (MIS) techniques that use such instrumentation but the screws are placed percutaneously so long open cuts along the back are not required (Ozgur et al 2009). A long rod is then placed percutaneously through a small stab wound (Foley et al. 2001). Achieving the required correction can be challenging but MIS reduces overall trauma to the patient and can still correct spinal curvature (Figure 2.8). In any case, long rods are still used.

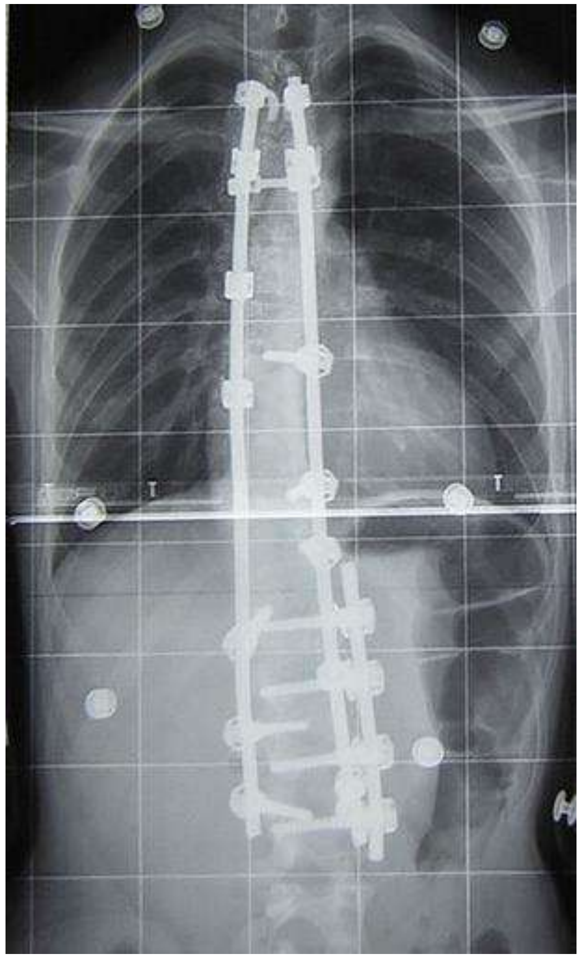


Figure 2.8 Post-surgical x-ray showing spinal instrumentation straightening an adult spine with scoliosis (Silverjonny 2006) *This image is used under the fair dealing exception.*

Modern spinal implants owe much to Paul Harrington who designed the first internally stabilizing spinal system consisting of a combination hooks and rods in the 1950's (Figure 2.9). Mohan and Das (2003) explain that prior to Harrington rods, spine vertebrae were fused without implants and held in place with external casts which was both ineffective and inconvenient for patients. However, there were a few successful attempts at wiring the spinous processes together. Even though Harrington rods were a major improvement over the old ways, patients often lost natural curvature in the lumbar spine region with Harrington rods according to Mohan and Das.

Figure 2.9 Harrington Rods (Medical Apparatus n.d.) *This image is used under the fair dealing exception.*

Since Harrington there were several variations of the rod implant systems, and in the 1980's the Cotrell-Dubousset instrumentation system (CD System) was introduced combining both hooks and screws to anchor rods into the spine. The most recent implants do not employ hooks but rely on pedicle screws alone for fixation as explained by Mohan and Das. They go on to say that modern pedicle screws have polyaxial heads (Figure 2.12) which help with rod placement in highly deformed cases. Modern systems of rods and screws allow for an extremely high degree of implant customization to best suit the patient anatomy and correction severity. They can correct curvature, de-rotate and distract the spine thus providing full three dimensional corrections.

The rods are usually made from titanium alloy or cobalt chromium alloy (Figure 2.10) and sometimes from stainless steel. When used in bulk these materials are "biocompatible" meaning that they do not elicit a significant adverse tissue reaction when used in the human body (Medical Dictionary n.d.). Typically, the rods range from 2 to 6.35 mm in diameter and the lengths are cut in the operating theatre using a bench top device. Occasionally, the rods have to be cut again during surgery when after bending and attachment to the pedicle screws, if it turns out that the rod is a little too long (University of Wisconsin-Madison College of Engineering 2016) This is discussed in more detail later in this thesis.

Figure 2.10 Image of the spinal rods used to correct scoliosis and kyphosis deformities (Yoshihara 2013) *Shown with permission from the Spine Journal*

Screw designs vary greatly including variable thread pitches, polyaxial screw heads and self-tapping features (Figure 2.7). Rod screws are typically available in 5 mm increment lengths for different vertebral body sizing. Once screws are screwed into the vertebra, rods are bent and placed into the screw channels which then have their head caps tightened down, sometimes rod links are used to connect the rods together, increasing rigidity of the overall implant (Figure 2.11). This makes it difficult to get the rod just the right length and occasionally it turns out to be too long, as previously noted, and must be cut in situ.

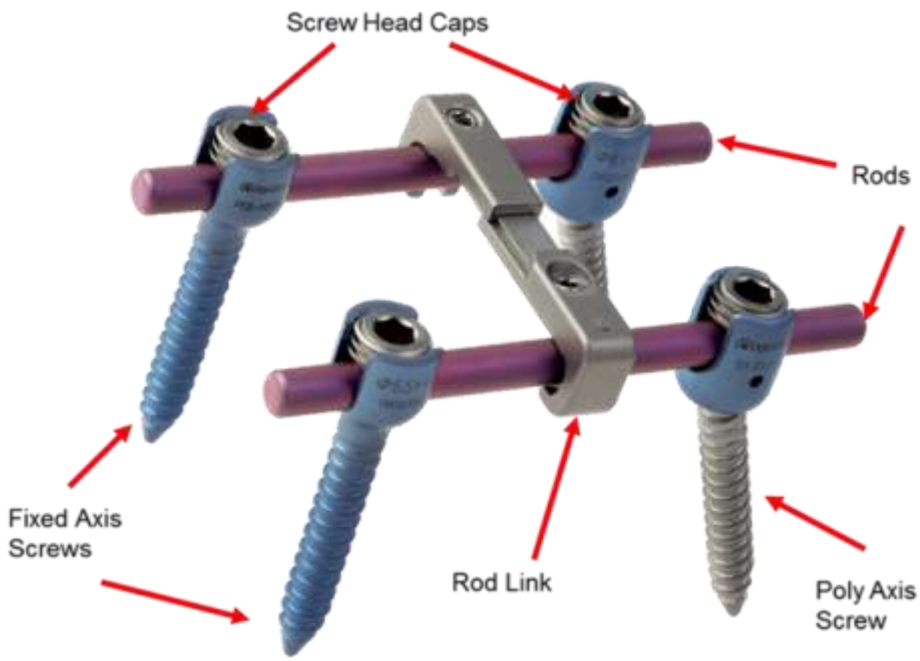


Figure 2.11 Typical modern rod assembly showing multiple screw types and a rod link (IMTech n.d.) *This image is used under the fair dealing exception.*

Sometimes a second surgery is performed and the original rod is partially replaced or extended in length. This is the case with revision surgeries to replace stiff sections of the rod which have pulled the pedicle screws out from the bone (Hoppe 2016). When extension is required special connectors are used (Figure 2.12) These connectors vary in style, but they all join a new section of spinal rod, to an existing section

Figure 2.12 Typical rod connector used in revision surgery (DePuy Expedium 4.5 System n.d.) *This image is used under the fair dealing exception.*

Modern implant systems allow surgeons to choose from many features and components so systems can be customized to better suit patient needs. A typical assembly of these components can involve different styles of screws, rod links, rod materials and rod extensions all in a variety of sizes and lengths (Figure 2.13)

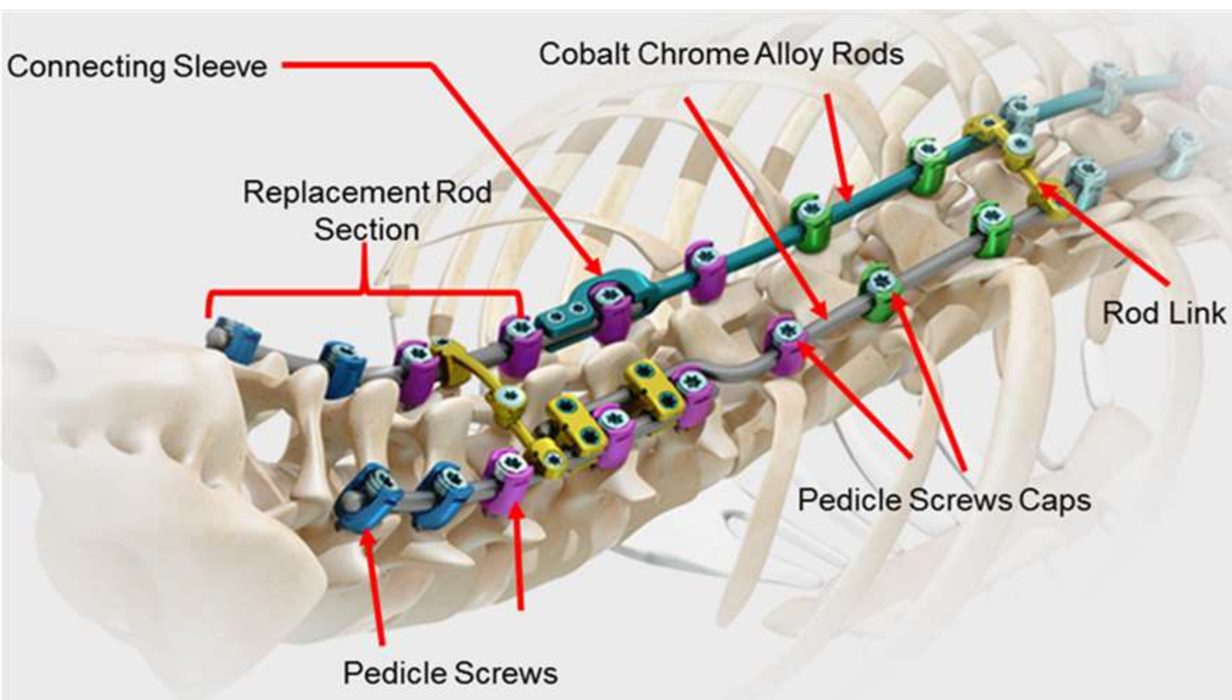


Figure 2.13 Typical modern implant system installed in the spine (Astra Revision Spine System n.d.) *This image is used under the fair dealing exception.*

2.2.3 Clinical Problem Statement

Having discussed the physiology, treatment and instrumentation of the spine, the complexities of designing an *in-situ* rod cutter can be better appreciated. The complex anatomy of the spine is difficult for surgeons to navigate, as many anatomical components play a vital role in the stability and quality of life of their patients. Spinal rods must be strong enough to be able to not only straighten the spine from deformity, but also support loading of the muscles attached to the spinal anatomy. It is difficult to manipulate and size these rods to straighten the spine because of the complex curvatures in the spine. When fully implanted, it becomes quite difficult to gain access around the rod due to the limited space available, thus care must be taken to not damage the surrounding tissues or traumatize the spine when further manipulating the rod *in-situ.* A lot of possibilities exist for implanting rods of different size, material and accompanying implants, which also restrict the amount of maneuverability in the exposed spine. Because of all these variables, an *in-situ* rod cutter design has these aforementioned clinical problems to address.

2.3 Engineering Background

Examination of the types of rod materials and the design of currently used rod cutting instruments helps to establish the engineering characteristics of the challenges a clinician faces.

2.3.1 Rod Material Properties

Currently, cobalt chrome (CoCr), titanium (Ti) and austenitic stainless steel (SS) alloys are used in the manufacture of surgical spinal rods. Although having aforementioned in Section 1.1 that cobalt chrome alloy rods are the most commonly used rods, there has been growing interest in Ti rods for their compatibility with magnetic resonance imaging machines (Yoshihara 2013). Each rod material must be fabricated in accordance with the material properties specified by the American Society for Testing and Materials (ASTM) in order to be considered adequate for implantation (Table 2.1).

Table 2.1 Material properties of common alloys used to fabricate spinal rods

Rod Alloy	Designation	ASTM Specification	Ultimate Tensile Strength (MPa)
Stainless Steel	316L	F139-12	860
Cobalt Chrome	Co-28Cr-6Mo	F75-12	960
Titanium	Ti-6Al-4V	F136-13	825

These ASTM standards only provide the minimum requirements for medical implants, and manufacturers are likely to modify the mechanical properties of these allows in a proprietary manner. Thus, the mechanical properties of the spinal rods must be determined with extensive materials testing, which was not performed in this work since the design aspects did not require. It was noted that the minimum requirement for ultimate tensile strengths are somewhat similar, suggesting all spinal rods alloys are designed meet a similar minimum strength regardless of the alloy used.

2.3.2 Existing Cutting Tool Designs

The design and performance of spinal rod cutting tools are not described much in academic literature. The complexities and nuances of spinal rod cutters are primarily left up to industry. Rod cutting systems can be classified into either a handheld or tabletop. Both handheld and tabletop variations provide a means of cutting rods of varying diameters and materials through some form of mechanism. Currently, all spinal rod cutters apply either shear or compression forces through blades to perform the required task. Abrasive cutting, melting, vaporizing or chemical methods are not used to cut rods. Additionally, all rod cutting is performed manually by the surgeon in the operating room.

Tabletop rod cutters (Figure 2.14) are typically levers where the load and fulcrum points are close together and the effort force is much farther away. Rods are placed through aligned bore holes in two components that have diameters just larger than the rod diameter and have centres at a small radial distance from the fulcrum axis. The lever arm is attached to one component and acts to displace the bore hole that holds the rod thus applying a shear force to cut it (Lenox 1999). The entire tool is mounted on a tabletop such that the lower lever arm is supported by a table and bodyweight can be used to the operator's advantage when pressing down on the top lever. The use of the tabletop rod cutter is restricted to the ex-situ cutting of spinal rods. As previously described, this means that the rod length must be determined based on the measurements, experience and judgement of a surgeon, before implantation and before rod bending is performed. If a surgeon needs to revise their estimate of the rod length, they must do so before any significant bending of the rod occurs, because the rod will not feed through the tabletop cutter if it is not straight.

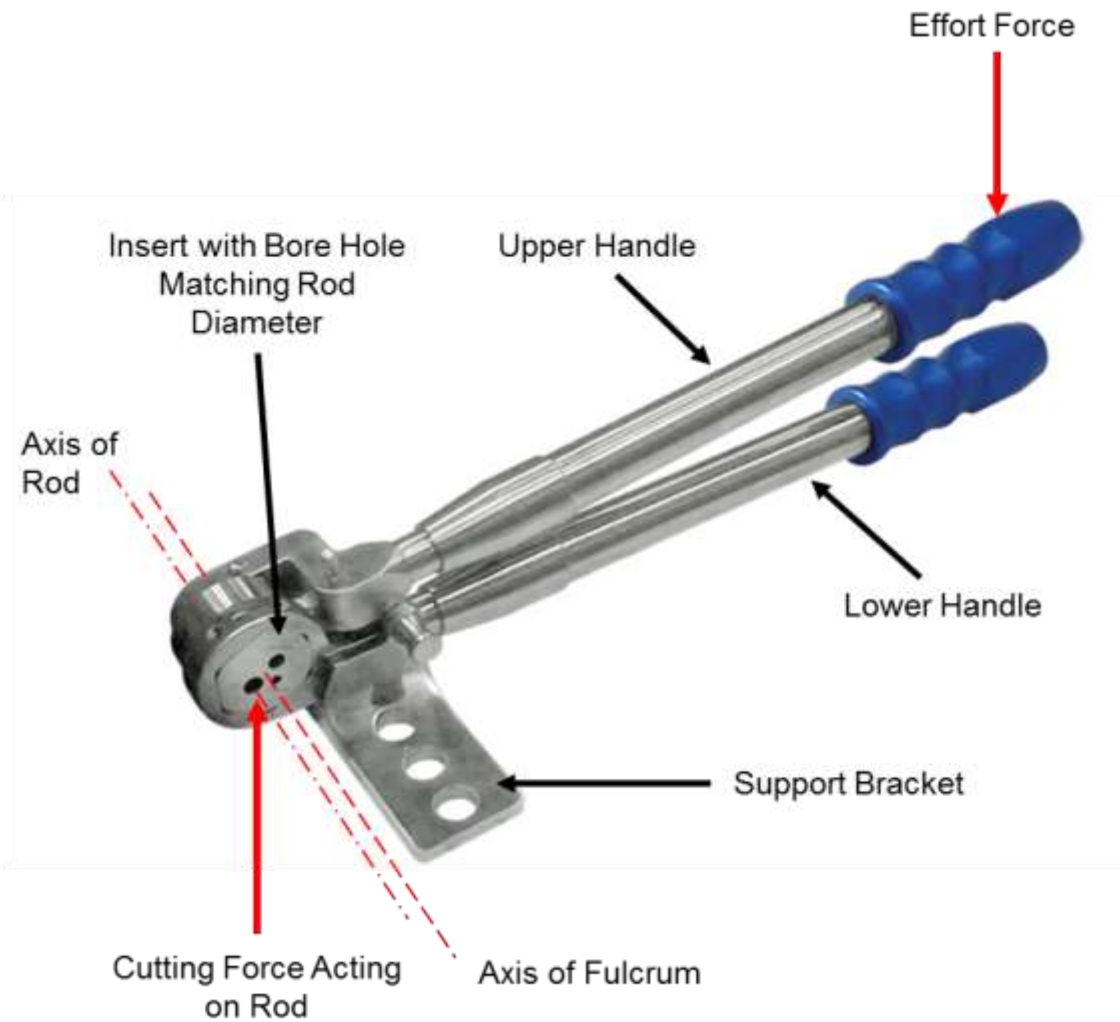


Figure 2.14 Bradshaw Medical tabletop rod cutter (Bradshaw Medical OEM Orthopedic and Spinal Instruments n.d.) *This image is used under the fair dealing exception.*

As an alternative to tabletop rod cutters, handheld rod cutting tools exist. Within the range of these handheld bolt cutters, there are two fundamental design variations. The first variation is similar to the tabletop design, but in miniaturized format. Neither lever arm is designed to be supported by a table, so they are both are operated by the surgeon. A modern version of this involves a ratcheting mechanism (Figure 2.15) to assist in the cutting process by keeping the displacement associated with the effort force on the rod thus giving creep deformation time to occur. The surgeon then “pumps” the levers re-asserting the maximum effort force. One of the levers is held fixed in space relative to the other, while the lever attached to the ratcheting mechanism is displaced by the effort force. When the effort force is released, the ratcheting lever arm is sprung back to its original position by a small leaf spring.

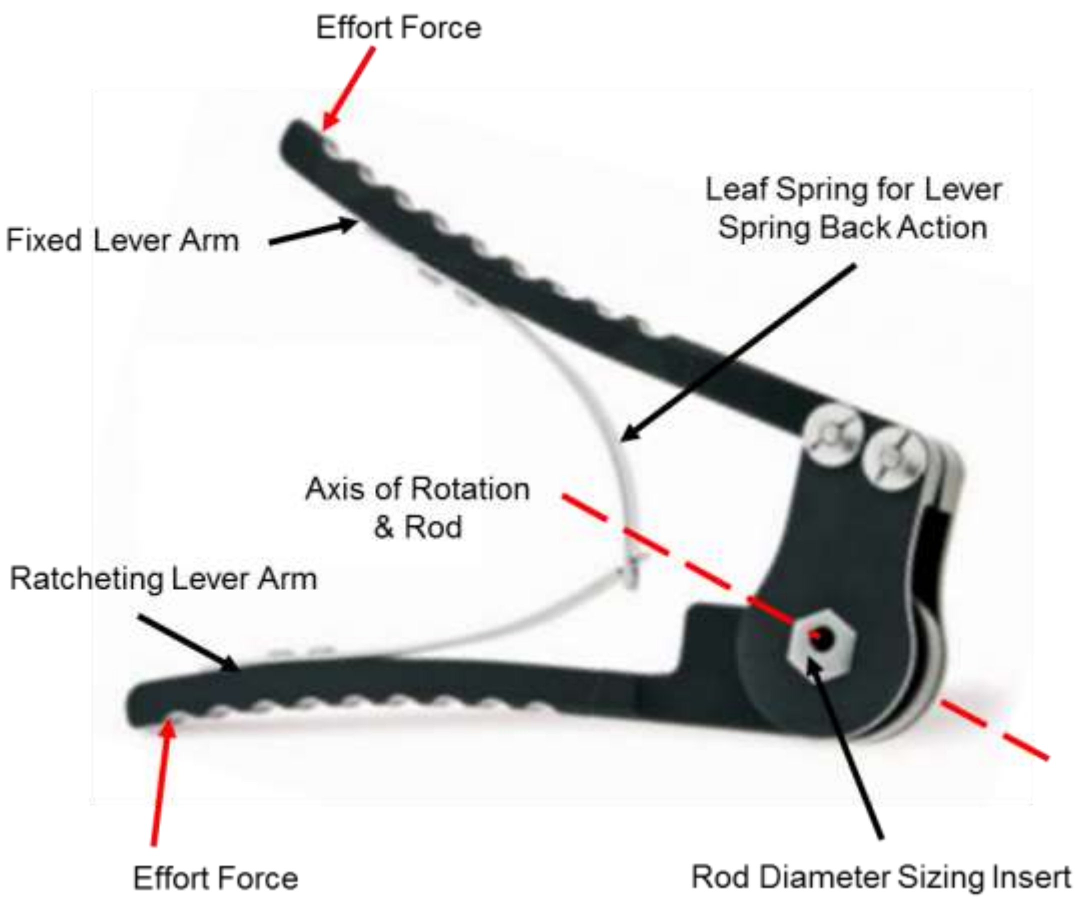


Figure 2.15 A Holmed racheting hand-held rod cutter. (Holmed n.d.) *This image is used under the fair dealing exception.*

This variation of hand held rod cannot not be used *in-situ* as it requires that the spinal rod is passed though the cutting cylinder through hole. Clearances between implanted rods and the surrounding anatomy do not allow for room to place this handheld cutter into the dissected back.

The second design variation is essentially identical to the previously described bolt-cutter (in Chapter 3). The effort force is applied to the lever arms to close a jaw lever which cuts through the spinal rod by applying a large compressive stress (Figure 4.6). There are two sets of levers that act together to multiply the mechanical advantage of each lever together. As discussed in Chapter 3, the jaw blades have small lands on their cutting face, with a taper on either side to “wedge” the blade into the rod and separate the material (Figure 2.17). These lands and jaws are aligned with each other and thus apply direct compressive stress rather than shear stress. This variation of handheld rod cutters can be used for in-situ cutting, but the surgical incision must be spread enough to allow the jaws to be inserted around the implanted spinal rod. This design is the only current solution for in-situ rod cutting and it has significant usage problems, as described in the next section. Consequently, the surgeons try as best they can to cut rods to the required length before implantation. However, there are numerous occasions on which in-situ rod cutting cannot be avoided, in particular during revision surgeries.

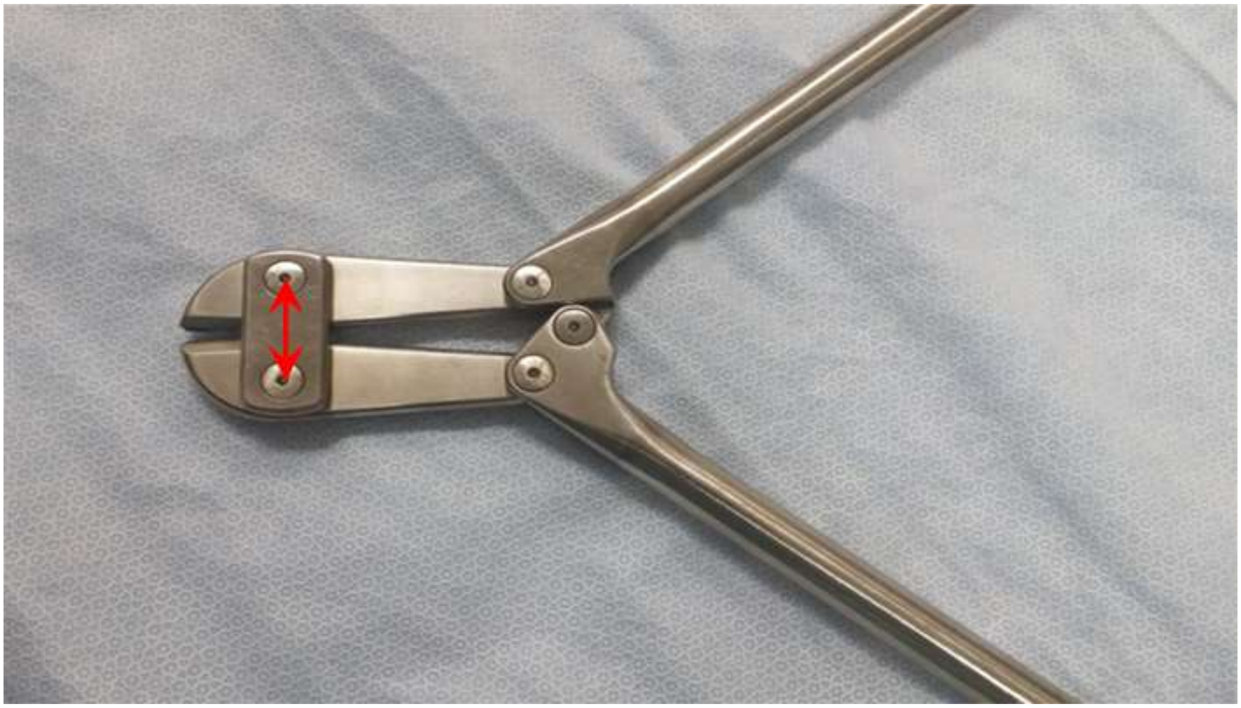


Figure 2.16 Handheld spinal rod cutters for in-situ cutting

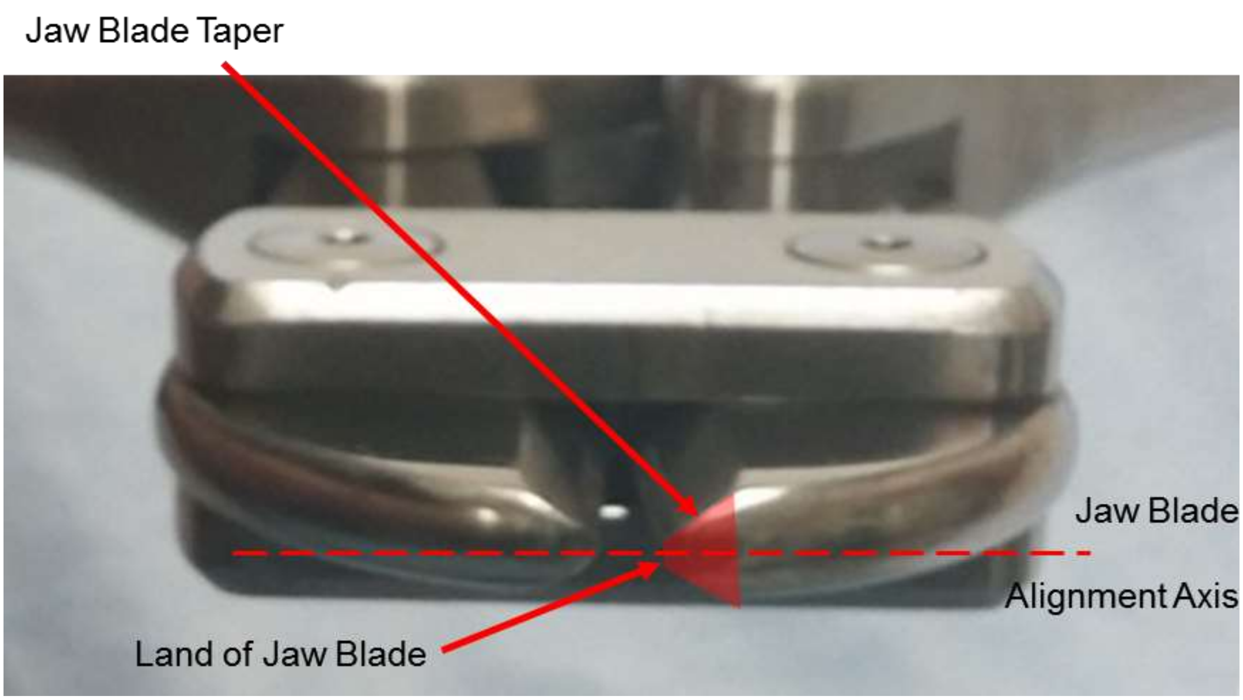


Figure 2.17 Cutting jaw geometry of in-situ rod cutters.

2.3.3 Engineering Problem Statement

Regardless of alloy, all spinal rods are designed to meet a similar minimum medical specification as specified by the ASTM. These material properties are selected to provide the support necessary for correcting and loading the spine. While work has been done on determining bending stiffness (Guidici 2017) and fatigue characteristics of these rods, little exists on the shearing and bolt cutting techniques which are used by these tools. The current tools for cutting rods employ long levers, using mechanical advantage to provide the required forces at their cutting zones. These tools are bulky and heavy, lacking nimbleness. All of them are manually operated, and only one style of design is capable of *in-situ* rod cutting. There is not a lot of literature available on how these tools operate, or the forces involved with cutting these spinal rods, so before any design of a new *in-situ* rod cutter occurs, work must be done to better understand these challenges and nuances of cutting spinal rods.

3 Experimental Analysis of Spinal Rod Cutting Forces

The experimental work presented here provides an idea of the nuances of rod cutting, and develops an understanding of the requirements for designing a new cutting tool. A bolt cutting technique was investigated that was very similar to the existing in-situ rod cutting technique. A shear cutting technique was chosen for exploration as the author took inspiration from existing shear cutting devices for pipes, while an impact cutting technique was investigated to determine if cutting with an impact force could reduce the force required to cut a rod. These three techniques were selected as they were thought of to be the most feasible options for cutting spinal rods in-situ. Other techniques, such as abrasive cutting, were rejected because the resulting debris would have to be kept away from the patient and this would be very difficult. The following experiments shed light on the feasibility of these cutting techniques as well as the forces required to cut spinal rods. The observations and experimental results are also used to help form constraints and criteria for the design process.

3.1 Manual Experimental Approach

Initially, two quite different techniques for cutting rods were chosen for examination. A bolt-cutting technique was selected since handheld bolt cutting tools are already used in the operating theatre. A pipe cutting technique developed for copper tube cutting was also selected because it provided a more gradual, lower force alternative to direct shearing. Surgically retrieved rods of varying materials and size were cut using both techniques and examinations of the resulting cut rod ends were performed. Since it was costly to purchase new rods, this experiment proceeded with a representative selection of retrieved rods of various materials and diameters. Most of the rods used in the experimentation were left over pieces from a primary surgery. The two cutting techniques were qualitatively assessed by examining the cut surfaces.

3.1.1 Materials and Methods

Four groups of rods were used (Table 3.1). They were made from medical grade alloys and, as previously mentioned, they were either retrieved components or extra sections left over from primary surgeries performed at Victoria Hospital (London, ON).

Table 3.1 Summary of rods used

Rod Material	**Symbol**	**Diameter [mm]**
Stainless Steel (316L)	SS	4.50
Titanium (Ti 6Al 4V)	Ti	3.50
Nickel-Cobalt (MP 35N)	MP35N	4.75
Cobalt-Chromium (Co 28Cr 6Mo)	CoCr	6.35

The bolt-cutting technique is manually performed using a hand-held bolt cutter (Mastercraft 24" Heavy Duty Bolt Cutter, Canadian Tire) with a cutting head that had been made from a proprietary chromium-vanadium steel alloy with a specified hardness of 55 Rockwell C (Figure 3.1). This bolt cutter was very similar to those used in surgery (Figure 3.2) with about the same jaw geometry and hardness of the cutting edges but the materials were not surgical grade alloys and would tend to corrode upon repeated autoclave sterilization.

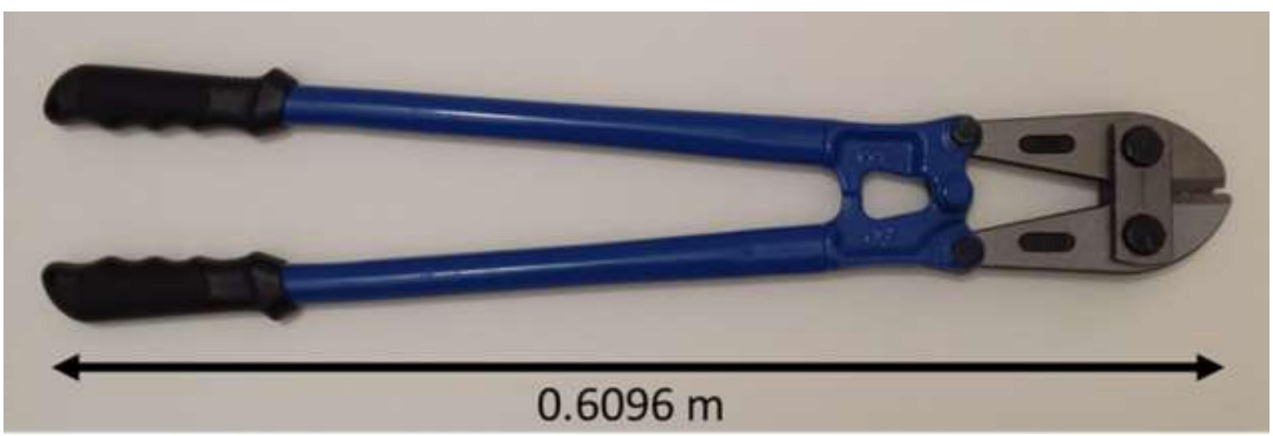


Figure 3.1 Mastercraft 24" Heavy Duty Bolt cutter

Figure 3.2 Surgical rod cutters used at Victoria Hospital, London, ON

The jaw configuration of the Mastercraft bolt cutters is the same as the surgical bolt cutters (Figure 3.3), both are configured as centre-cut blades. Centre-cut blade edges are tapered on both sides, and have small lands at the end of the taper, which align with the opposite blade. For example, the blades of the Mastercraft bolt cutter had a taper with an included angle of about 60o and a land width of about 1 mm.

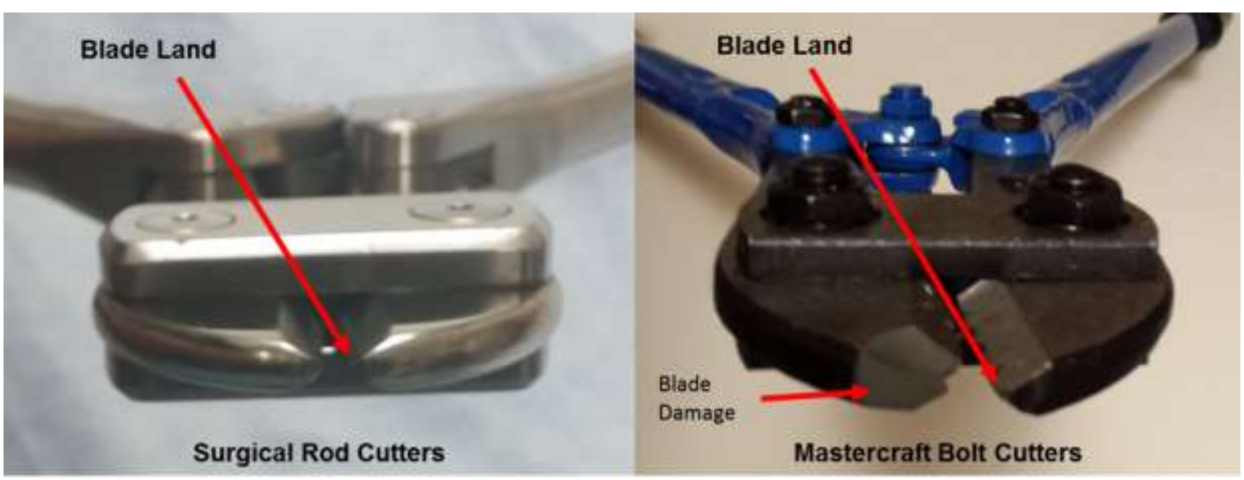


Figure 3.3 The similar blade configuration of the Mastercraft bolt cutters (right) and the surgical rod cutters (left).

The Mastercraft bolt cutter was chosen for this preliminary experiment because it was cheap and readily available. Rods were placed between the cutting jaws of the bolt cutter, held in place using a minimal clamping force, and the lever arms were vertically oriented to mimic the position used in surgery. The lever arms were closed manually with a swift and constant motion, using bicep flexion and the rod was sheared.

The quite different pipe-cutting technique was also manually performed using a commercially available product (Mastercraft 1/8 to 1-1/8-in. Tube Cutter) that was purchased from Canadian Tire. It had a c-clamp shape with two support rollers that were squeezed towards a cutting roller using the lead screw mechanism (Figure 3.4).

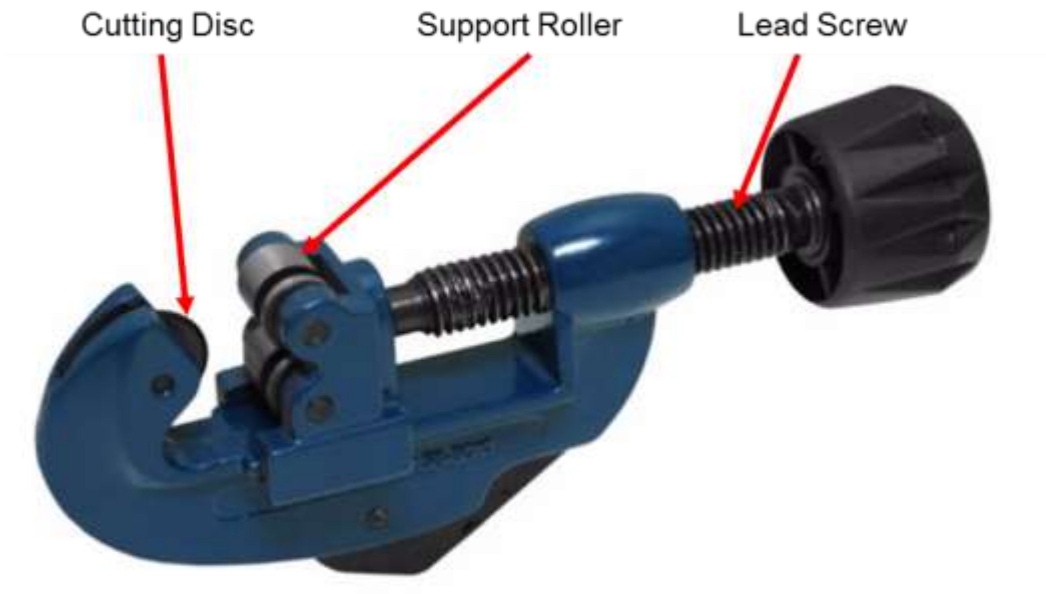


Figure 3.4 Pipe cutting tool (Canadian Tire Mastercraft 1/8 to 1-1/8-in. Tube Cutter. (n.d.)
This image is used under the fair dealing exception.

The cutting disc material was a tool steel but the detailed specifications were not known. The pipe cutter was loaded with a retrieved rod, and the lead screw was rotated until the rod contacted the upper cutting disc. The entire pipe cutter was rotated around 180 degrees. The cutter was then reversed 360 degrees to ensure that the scoring of cutting wheel was aligned. Failure to do this resulted in the cutting disc contact moving along the rod (Figure 3.5), thus creating a misaligned screw shaped scoring which prevented efficient cutting. The lead screw was then tightened and the pipe cutter was again rotated. The tightening and rotation were repeated until the rod was cut.

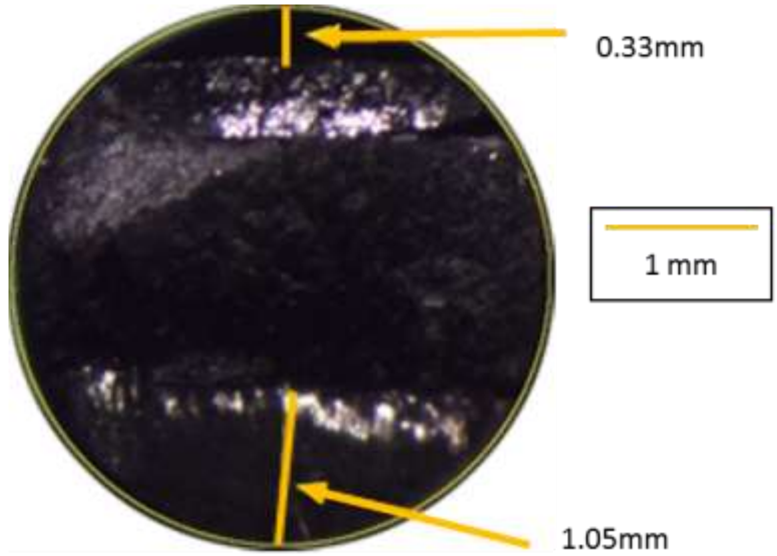
Figure 3.5 Example of cutting disc contact moving along the rod

Each rod was cut three times using both of the techniques described. Pictures of the resulting cut rod surfaces are taken using a stereo microscope. The deformation types present during the cutting operations were characterized and then measured using a free open source software package (ImageJ downloaded from https://imagej.nih.gov/ij/)

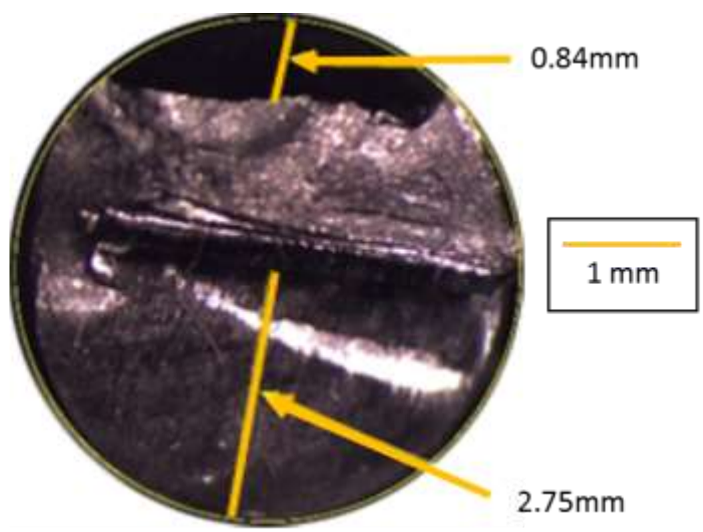
3.1.2 Results

Examination of the cut surfaces from the bolt-cutting technique showed two different types of deformation occur during the shearing process. An outer region of slow plastic deformation (SPD) was observed in the cross-sectional areas caused by the initial contact of the bolt blades. Towards the center of the cross-sectional area, the surface was scalloped which suggested a rapid propagation of a crack culminating in rod fracture. These surface areas were both present in each rod type and were examined for one of the fracture surfaces. The percentages of the total cross sectional area that showed SPD were calculated using elementary planar geometry formulae (Figure 3.6).

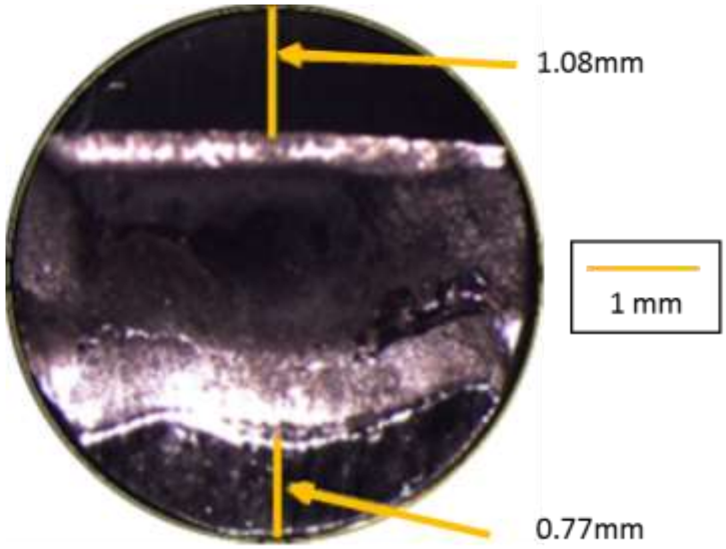
Ti, SPD 30%



SS, SPD 78%



MP35N, SPD 27%



CoCr, SPD 16%

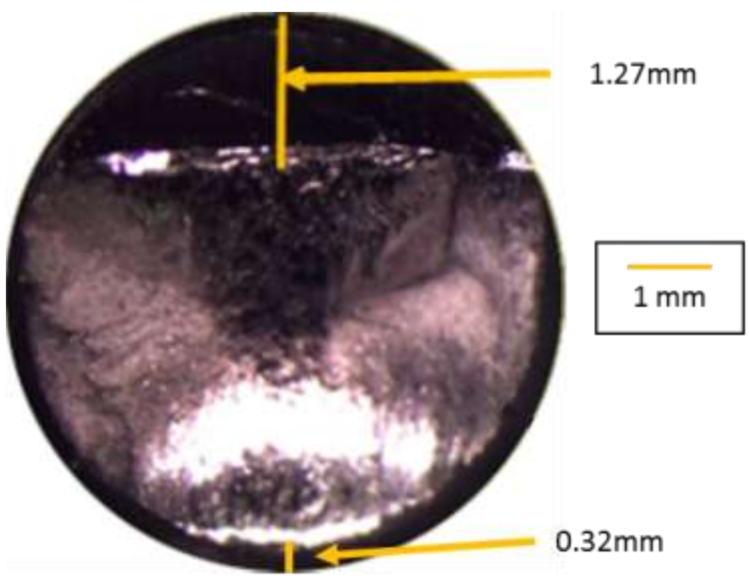
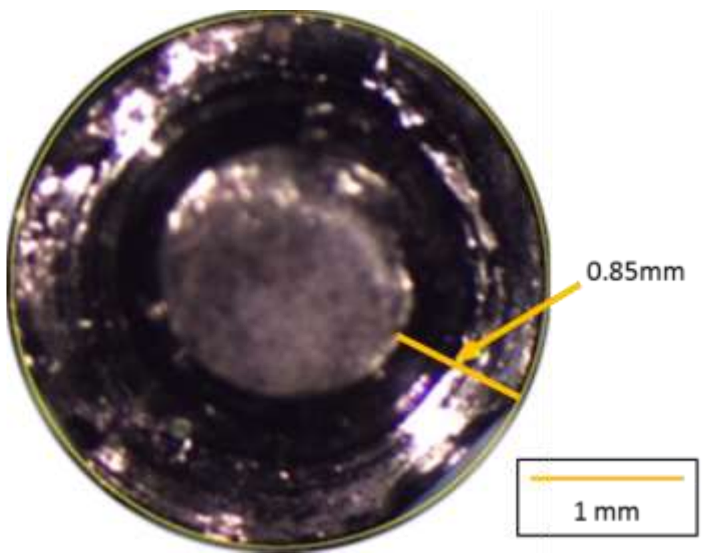


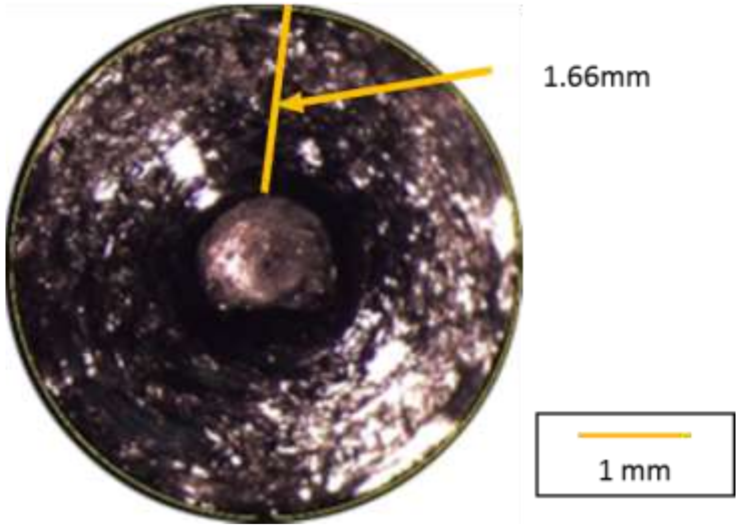
Figure 3.6 Optical microscopy images of “cut” surfaces using the bolt-cutting technique

Cross sections examined from the pipe-cutting method showed progressive shearing in an annular area, with some signs of plastic deformation occurring. The central regions of the cross sections had very similar rapid crack propagation appearances as had occurred for the bolt-cutting technique. Areas were calculated in similar manner to the specimens subjected to the bolt-cutting technique (Figure 3.7). However, only three of the four groups of rods were cut successfully. For the CoCr rods, the cutting disc itself deformed and was unable to penetrate the surface and thus they could not be cut.

Ti, SPD 74%



SS, SPD 93%



MP35N, SPD 93%

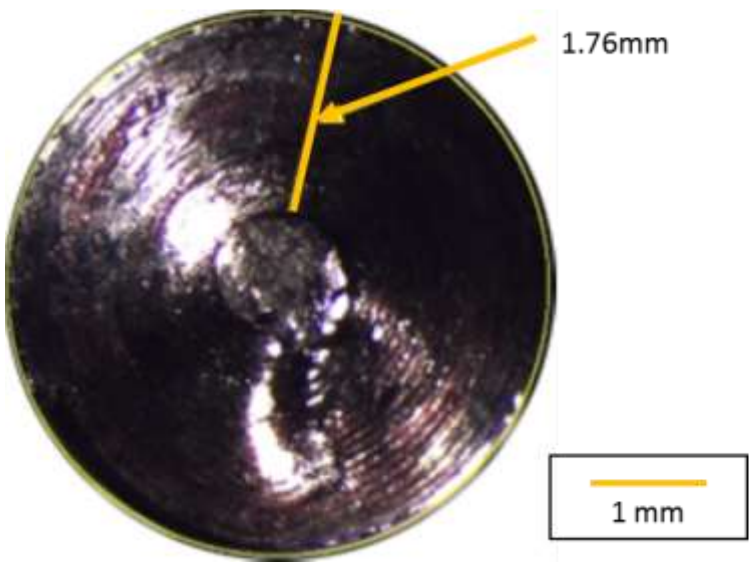


Figure 3.7 Optical images of cut surfaces using the pipe-cutter technique

3.1.3 Discussion

These experiments, while preliminary in nature, provided valuable insight into the types of deformation that occurred using both of the cutting techniques. In the case of bolt-cutting technique, it was evident that the bolt cutting blades did not plastically deform the entire cross sectional area in a uniform manner. Instead the fracture surfaces suggest that the rods underwent an initial slow plastic deformation which reduced their cross-sectional area. The contact zone between the blade and the rod might then have initiated a crack which propagated quickly over the remaining cross-section. Alternatively, the plastic zones created by the initial indentation of the bolt cutter blades might have interacted and the hydrostatic pressure was sufficient to cause a rapid fracture of the remaining cross-section. In any case, the high speed of propagation in the central region was suggested by the scalloped surface with large zones of similar planar orientation.

This also suggested that the forces were highest during the initial compression of the rod between the blades in the bolt-cutter technique. Operation of the bolt cutters supported this idea because a large initial force had to be applied and cutting/fracture did not occur at first. Then, the handles closed quite rapidly and the unconstrained cut end of the rod was projected away from the bolt cutter. These qualitative observations were consistent with the characteristics of the fracture surfaces, as previously discussed. Operation of the bolt-cutting technique required the application of considerable force, making it evident that either a very strong person or multiple people would be needed to operate the currently used handheld rod cutters for in-situ rod cutting.

It was also noted that in order to cut the NiCo, CoCr and SS rods using the bolt-cutting technique, one of the bolt cutter handles had to be braced against the floor so that the operator’s body weight could be applied. During cutting of the CoCr rod, a small chunk of the cutting edge of the bolt cutter was removed by a fracture. The rod had slipped away from centre of the cutting blade surfaces and had moved to the tip region where there was the least amount of supporting blade material. The blade itself also experienced plastic deformation from cutting the CoCr rod (Figure 3.3 & 3.8). However, bolt cutter blades made from higher hardness alloys do exist and could probably cut the CoCr rods without sustaining damage themselves.

The bolt cutter required a large space to operate the handles but this only had to be on one side of the rod. Thus, such a cutting method could be used for an in-situ spinal rod cutter. In fact, it has been used, with some difficulties, as discussed in the introductory chapter of the present thesis.

Figure 3.8 Damaged blades of the bolt cutter after cutting the CoCr rod

The pipe-cutting technique was compromised because the device had been designed for copper pipe rather than much harder, non-tubular spinal rods. However, while tedious in nature, shearing the rods using this technique was successful for Ti, SS and NiCo alloy rods. However, the cutting disc was destroyed when attempting to shear the CoCr rod. In similar manner to the bolt-cutting technique, at a certain stage, when the cross-sectional area was reduced by the incremental cutting, a crack rapidly propagated from the contact point to complete the cutting. Here the idea of interacting plastic zones was also feasible in that plastically deformed rod material would occur below the cutting disc and interact with the zone created when the disc was moving over the opposite side of the rod. However, less force was required to operate the pipe cutter and so the plastic zone under the cutter-rod contact would be reduced. Thus, the idea of a crack propagating from the contact point itself looked more feasible.

The pipe-cutting technique took considerable time (several minutes) to complete the cutting and it would need considerable space around the rod to operate (a radius from the rod centerline of at least 150 mm) a six-inch radius of the rod. It was hypothesized that a pipe-cutting tool with a harder cutting wheel material would be able to cut the CoCr rods. Furthermore, a compact gearing system might be designed to drive the rotations and thus perhaps allow an in-situ spinal rod cutter to be developed with this type of cutting. However, it would be a difficult design exercise.

3.1.4 Indications of Direction

The bolt cutting technique proved successful for all rod cutting operations as expected, but there was a small failure of the bolt cutting blades. This suggested that a minimal amount of blade thickness was required for the high cutting forces experienced. Additionally, the uncontrolled projection of the rod during the cutting process indicated that safety precautions which have to be taken during in-situ rod cutting. Both ends of the rod would have to be constrained and transferring forces to the spinal column would have to be avoided. To avoid damage to the bolt cutter blades, they would have to be made from much harder materials. Results and observations from using this technique indicated that an initial plastic deformation occurs in the rod followed by a subsequent drop in required applied force and a rapid crack propagation to complete the cutting of the rod.

The pipe-cutting technique could not be used for in-situ rod cutting unless a mechanism was developed that could work within the space available around the rod in-situ. It might be worth investigating such a mechanism because even though the pipe cutting technique took a lot of time, the amount of force required was very low and the resulting surface was flatter than the surfaces generated from the bolt-cutting technique.

3.2 Automated Experimental Approach

3.2.1 Bolt Cutting

The design of an improved spinal rod cutting tool for use in-situ requires some estimate of the forces needed to cut the rods. In this experiment, forces were applied to spinal rods using a manual bolt cutter mounted in a materials testing machine. This bolt cutter was very similar in geometry, particularly blade geometry and blade material hardness, to those currently in use for cutting spinal rods in-situ. Thus, although the bolt cutter was not intended for use in spinal surgery, the forces it would apply to spinal rods were deemed to very similar.

3.2.1.1 Apparatus, Materials and Methods

A Hit Bolt Cutter (Figure 3.9) with center cut blades was selected to cut the rods. The centre cut blades meant that they were opposed to each other in orientation (Figure 3.10).

Figure 3.9 Hit Bolt Cutter (24-inch, Tool No. BC 600-H) made by Toho Koki Co., Ltd., Yamatokoriyama, Nara 639-1042, Japan www.hittools.co.jp/ap/products/en/i/00000000278 *This image is used under the fair dealing exception.*

Figure 3.10 Centre cut orientation of bolt cutter jaws in the closed position as shown at www.lawson-his.co.uk/faithfull-faibcj36n-bolt-cutter-jaws-c-p158024 *This image is used under the fair dealing exception.*

The bolt cutter was modified to fit into a materials testing machine (Instron 6508, www.instron.us) in order to apply compressive forces to its handles (Figure 3.11). To attach the bolt cutter to the Instron, its hollow handles were cut down in length and a 4140 steel cylinder was inserted into the bolt cutter handles using size M8 bolts. The steel cylinder was modified to form a pin joint. Then, a flat plate “gripper adapter” was fabricated and attached to the pin joint to allow the grips of the Instron to engage (Figure 3.12). The gripper adapter included a “support” ledge that prevented vertical slip between the adapter and the grips of the Instron when transferring compressive forces. In this way,

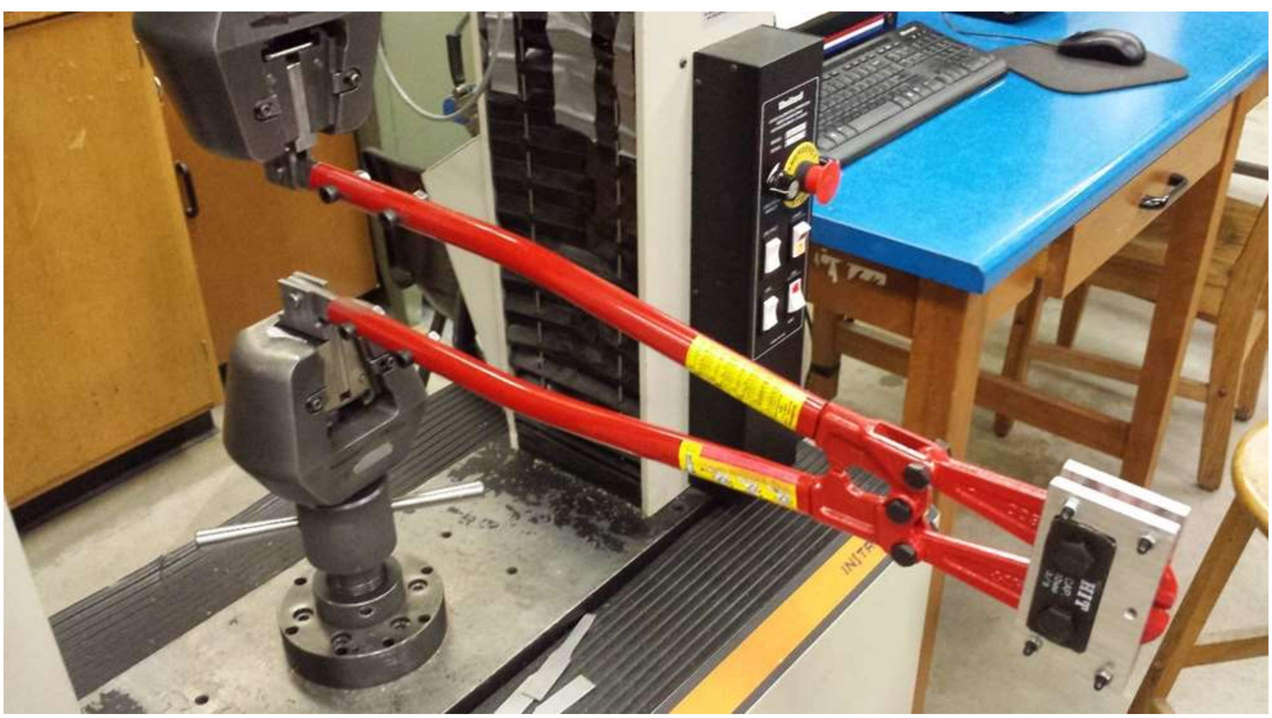


Figure 3.11 Experimental setup for measuring forces required to cut rods using HIT bolt cutter

the bolt cutter was connected to the Instron materials testing machine so that it could apply forces to the bolt cutter handles.

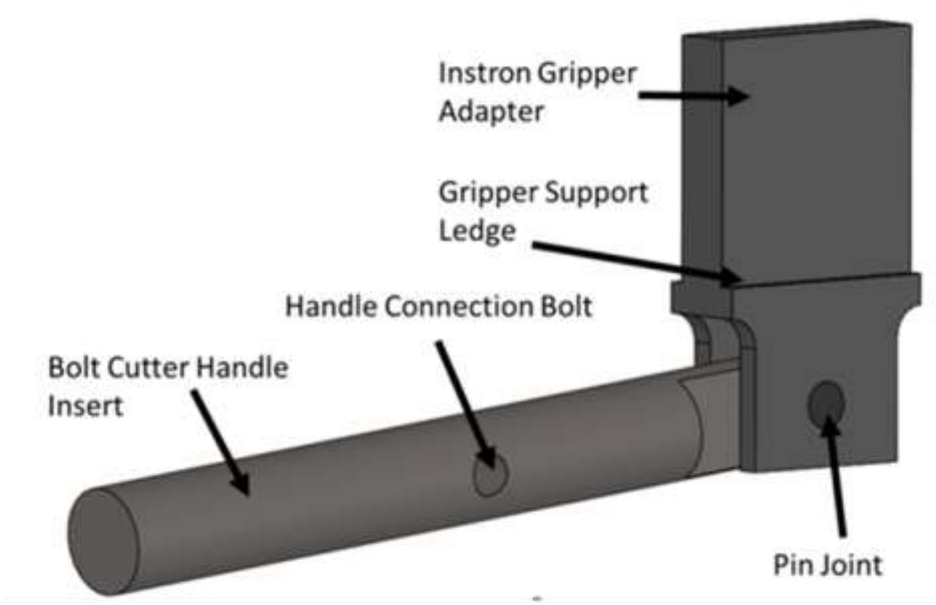


Figure 3.12 3D rendering of the custom-made Instron attachment fixture

The cylinders of the attachment fixture (Figure 3.12) were sized to fit snugly inside the bolt cutter handles and they went far enough into the handles of the bolt cutter to minimize contact stresses between the handle walls and the cylinder. The pin joint between the cylinder and grippers allowed rotation of the handle with respect to the Instron grips in a vertical plane of motion.

Also, a “rod holder” was constructed and attached to the jaws of the bolt cutter to allow the rods to be held in place during cutting. This holder was made from aluminum and allowed rods of varying diameters to be placed and held between the bolt cutter blades at the same location for each experimental run. The overall assembly was then mounted into the Instron machine as shown in Figure 3.11 and compressive loading was applied to the handles through the attachment fixture.

Rods were chosen for testing to represent those used currently in spinal orthopaedics (Table 3.2) as described by Yoshihara (2013) and Slivka et al (2013). However, it was difficult to obtain medical grade alloy spinal rods in all the diameters. Fortunately, some cobalt chromium (CoCr) rods with diameters of 6.35 mm were available from Victoria

Hospital (London, ON) but the stainless steel (SS) and titanium alloy (Ti) rods were purchased from a supplier (McMaster-Carr, www.mcmaster.com). The stainless steel 316L alloy and the Grade 5 titanium alloy were selected since they are commonly used alloys for medical applications. The MP35N alloy rods that were used in Section 3.1 were not included in the present testing because it was difficult to obtain and was not used in Victoria Hospital (London, ON) or in Sunnybrook Hospital (Toronto, ON).

It was assumed that all rods of the same diameter and material were the same. Thus, in many tests the same rod sample was cut multiple times and despite being the same diameter and same material, the peak compression forces applied to the rod at cutting showed variation. While more testing could have been done to more fully understand the cutting process, it was hoped that the current testing would be sufficient to identify a peak cutting force that would be more than enough to cut all types of rods.

Table 3.2 Rods Used

Material	**Symbol**	**Diameter [mm]**	**No. tests**
Stainless steel (316L)	SS	5.35	3
Cobalt chromium (Co 28Cr 6Mo)	CoCr	5.50	4
		6.35	3
Titanium (Ti 6Al 4V)	Ti	3.18	4
		3.50	4
		4.76	4
		6.35	4

The test protocol consisted of placing the spinal rods into the rod holder with the bolt cutter jaws fully open. The Instron machine was moved down manually until the bolt cutter blades made initial contact with the rod. This was verified by reading a small increase of force on the Instron readout. The crosshead of the Instron was moved up a small amount so that there was minimal blade contact force acting on the rod. Then, the force transducer and position were set to a reading of zero. The Instron software (Bluehill) was used to apply compressive loading by instructing the crosshead to move down at 50 mm/ which was judged to be similar to that used in manual operation. When cutting of the rod was verified by the separation of the rod into two pieces, the Instron was stopped manually. The forces applied to the handles were recorded automatically throughout the testing and the peak force was identified.

3.2.1.2 Results and Analysis

The peak force on the bolt cutter handles increased with increasing diameter regardless of material (Table 3.3).

Table 3.3 Peak force on handles required to cut the rods

Material	Diameter [mm]	Peak force on handles [N]
SS	5.35	336.05 345.07 339.09
CoCr	5.50	269.38 312.84 301.95 293.71
	6.35	396.44 380.95 363.40

Material	Diameter [mm]	Peak force on handles [N]
Ti	3.18	108.20 103.40 97.32 101.83
	3.50	114.48 102.61 114.19 117.33
	4.76	249.47 250.55 219.55 217.59
	6.35	363.95 360.62 357.38 346.10

The peak force imposed by the blades on the rods was calculated by multiplying the force on the bolt cutter handles by the mechanical advantage the bolt cutters provided. The bolt cutter consisted of a "handle" lever and a "jaw" lever, each with its own pivot point (Table 3.3). The lengths of these levers were used to calculate the force applied by the bolt cutter blades to the rod just before cutting (Equation 3.1Equation 3.1).

Figure 3.13 Dimensions of bolt cutters used.

Equation 3.1

$$(F_p)_B = \frac{450}{15} * \frac{65}{25}(F_P)_H \rightarrow \left(F_p\right)_B = 78.0(F_p)_H$$

where:

$(F_p)_H$ = peak force applied at the handles

$(F_p)_B$ = peak compression force applied to the rod by the blades

It was convenient to also calculate a peak nominal shear stress (Equation 3.2) to explore the influence of rod diameter. This was considered a nominal peak shear stress because it was calculated from the peak compression force applied to the rod by the blades.

Equation 3.2

$$(\tau_p)_{nom} = \frac{(F_p)_B}{\frac{\pi d^2}{4}}$$

where:

$(\tau_p)_{nom}$ = peak nominal shear stress

d = rod diameter

Both the peak forces (Figure 3.14) and the peak nominal shear stresses (Figure 3.15) were plotted for all the rod specimens and least squares lines were fit to all of the data.

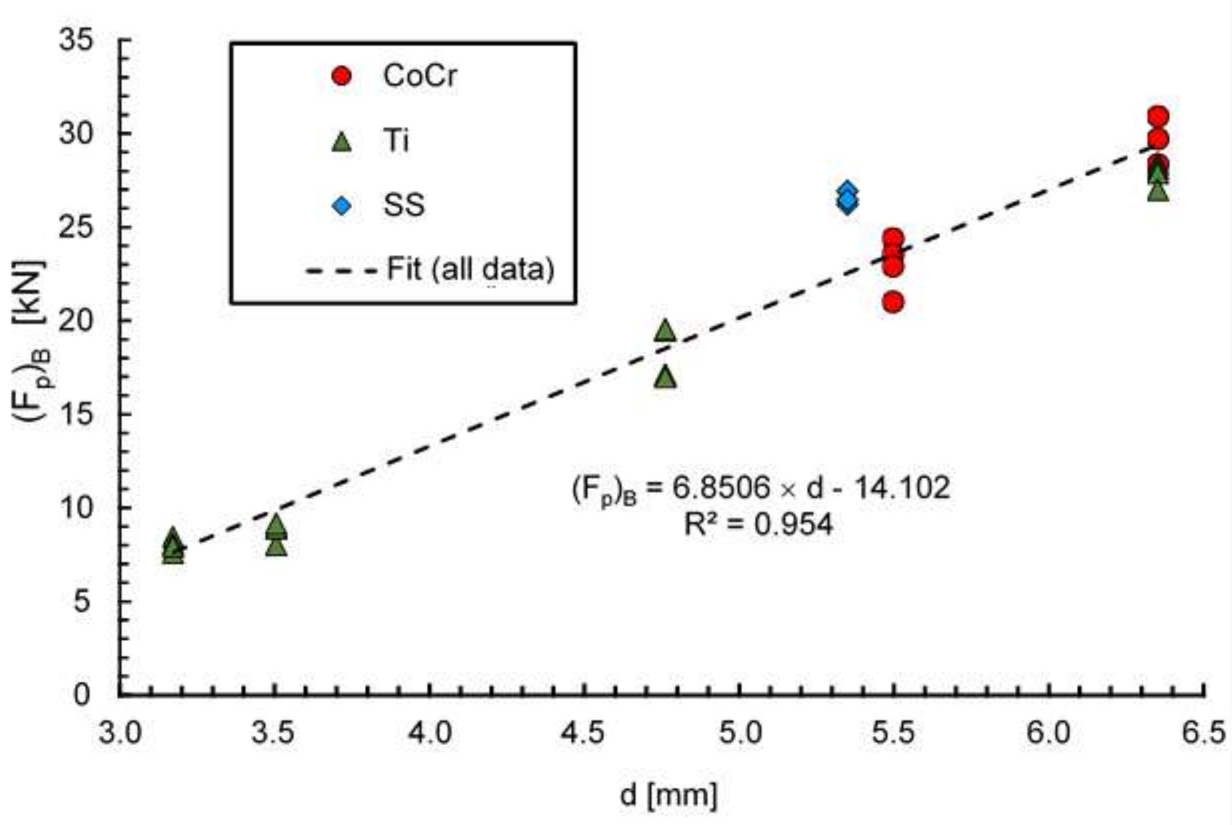


Figure 3.14 Peak compression force on rod using a bolt-cutter

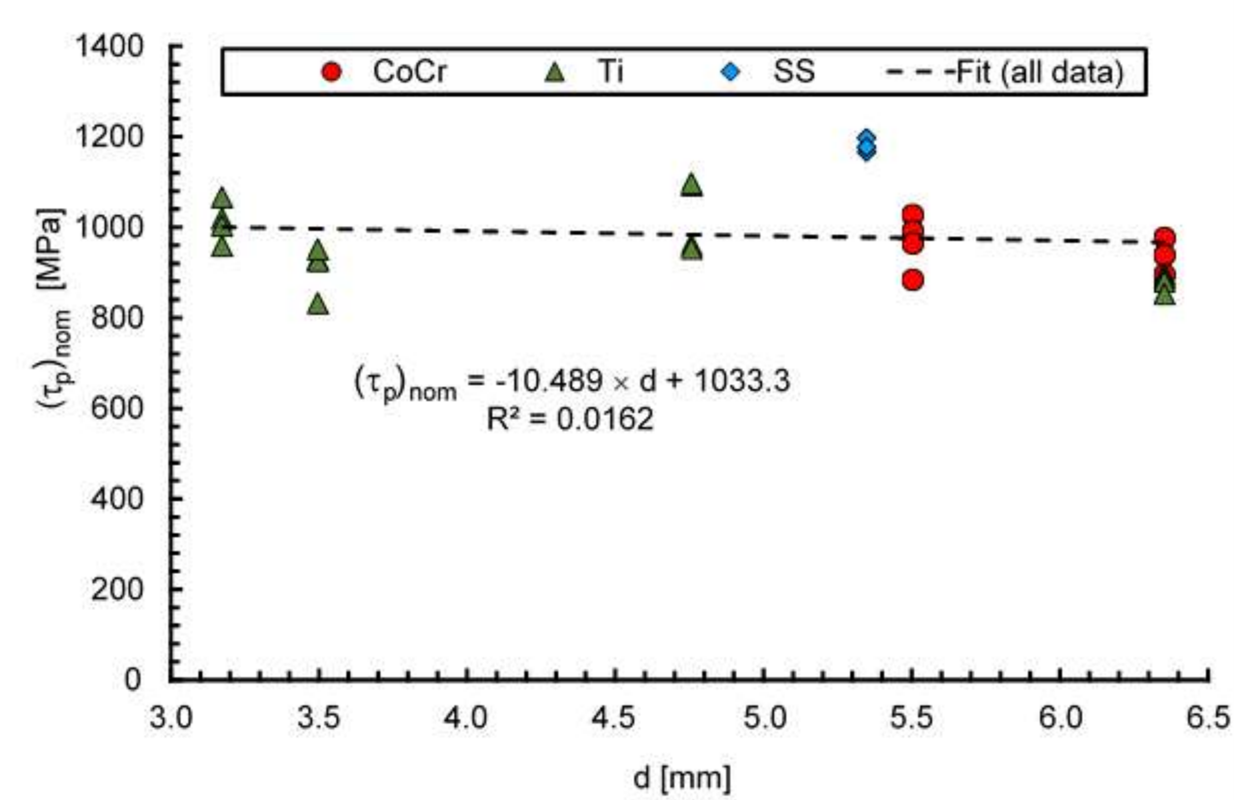


Figure 3.15 Peak nominal shear stress on rods

The larger average peak compression forces and their corresponding standard deviations were needed to determine a required force that would be sufficient to cut any rod as explained in the next section. Thus, these larger values were identified in Table 3.4.

Table 3.4 Peak forces for the bolt cutting technique with the largest diameter rods of each material.

Material	**Diameter [mm]**	**$(F_p)_B$ [kN]**					
		Individual tests				Average	Standard deviation
CoCr	6.35	30.92	29.71	28.35	-	29.66	1.289
Ti	6.35	28.39	28.13	27.88	27.00	27.85	0.605
SS	5.35	26.21	26.92	26.45	-	26.53	0.358

3.2.1.3 Discussion

For the three rod materials tested, as rod diameters increased so did the peak force required to cut the rod using the bolt cutter (Figure 3.14). This indicated that rod diameters were a significant factor when determining the required force to cut the rods. However, material did not seem to play a large role. The lack of effect of material was probably a result of the various alloys being mechanically worked and heat treated to have about the same strength. This idea was supported by the lack of correlation of peak nominal shear stress (which would be expected to be related to material strength) with rod diameter (Figure 3.15). However, the peak nominal shear stress did show considerable scatter and thus other material-related factors probably had some influences.

From the viewpoint of designing an in-situ spinal rod cutter, it was considered important to be able to develop a large enough cutting force on the rod to ensure that any spinal rod of any material and any diameter could be cut. Therefore, it was decided that an in-situ spinal rod cutter, that used bolt cutting techniques, should be designed to generate a cutting force equal to the largest value for a calculation consisting of the average peak cutting force plus six times the standard deviation. This force value should provide an adequate cutting force. As shown in Table 3.3, the rods with the largest diameters had the highest average peak compression forces. In Table 3.4, it was seen that the CoCr rods had the largest average peak compression force and also the largest standard deviation. Thus, the required peak compression force for an in-situ spinal rod cutter that used bolt-cutting techniques was estimated as 29.66 + 6 x 1.29 = 37.40 kN.

After cutting all of the rods, the cutting blades were inspected for damage and deformation. There was minimal deformation to the cutting blades as shown in Figure 3.16. This supported the feasibility of using bolt-cutting techniques for the in-situ cutter provided a cutting force of at least 37.40 kN could be easily generated.

Figure 3.16 Close up view of damage to the cutting blades on the bolt cutters

3.2.2 Shear Cutting

Shear cutting of cobalt chromium alloy spinal rods was explored as a possible concept for developing an in-situ spinal rod cutter. Three shear cutters were made for this investigation, each with a different geometry. Cutting forces were obtained from testing using the Instron test machine (Model 6508) that was described in **Error! Reference source not found.**.

3.2.2.1 Materials

Three CoCr spinal rods that each had a diameter of 6.35 mm were tested in the shear cutters. These rods were the left over segments from various spinal surgeries and were supplied by Dr. Parham Rasoulinejad (Victoria Hospital, London, ON). These left over segments were cut from the original rod length using a standard “bench top” cutter.

In the present investigation, shear cutters were made that had two hardened plates with one sliding over the other to create a plane for shearing (Figure 3.17). The three size variations of this design were made by changing the dimensions (t_h, w and D). The dimensions that were used (Table 3.5) resulted in quite different lower blade components as shown in Figure 3.18 This variation is sizing was selected to get an idea of the minimum cutting blade thickness t_h which is required to successfully cut the spinal rods.

Table 3.5 Shear cutter dimensions

Cutter	w **(**mm)	t_h (mm)	D (mm)
1	19.05	12.70	12.70
2	12.70	6.35	6.50
3	12.70	3.18	6.50

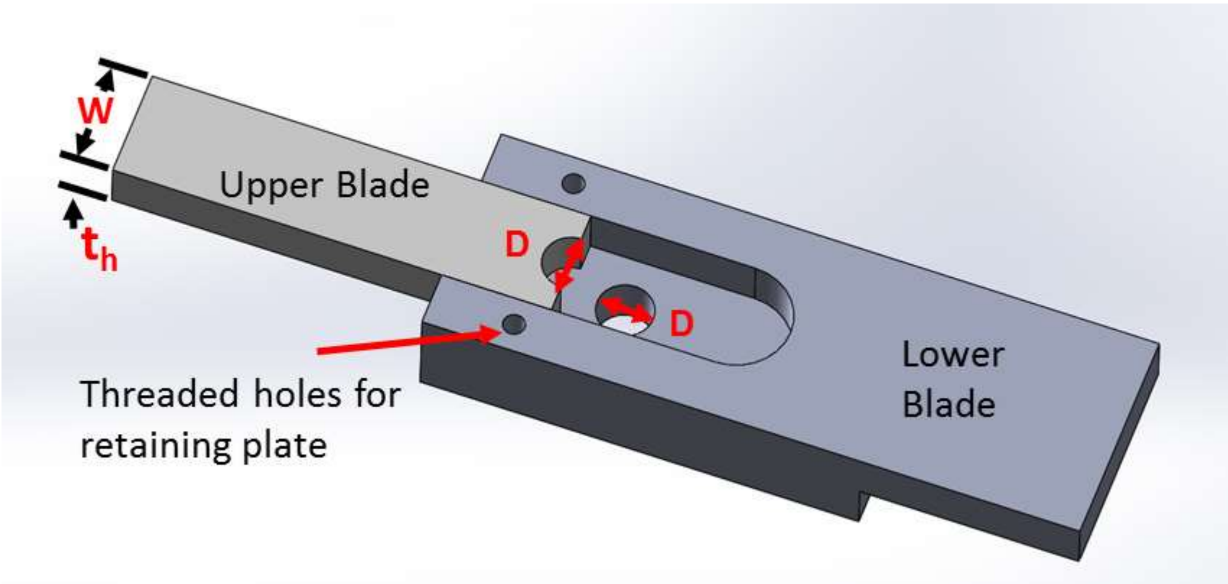


Figure 3.17 3D rendering of shear cutter

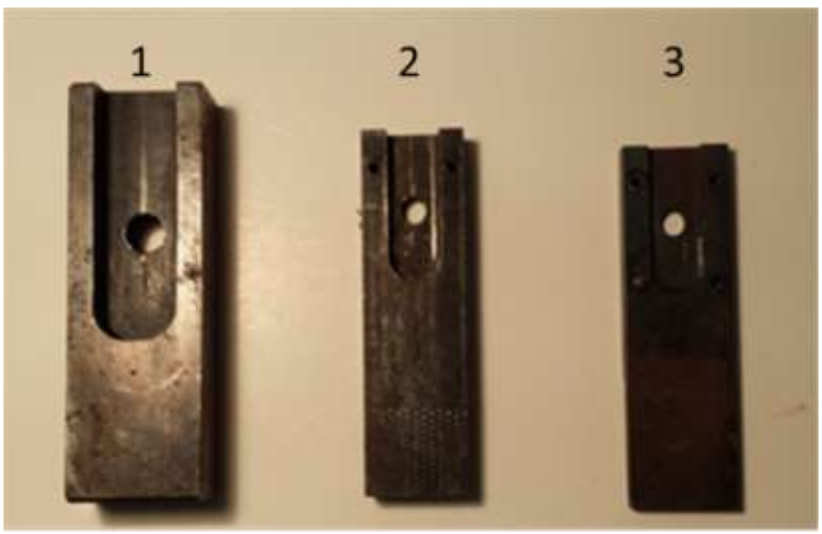


Figure 3.18 Lower blades of the shear cutters

The cutters were fabricated using standard machining techniques with care to keep the metals cool thus avoiding any phase transformations which could have resulted in localized stress concentrations of the materials. The circular edges which contact the rods were cut using a final end mill pass of 0.001” (0.0254 mm) to develop a clean and sharp edge. The cutters were made from AISI 4140 carbon steel alloy which had an elastic modulus of 190-210 GPa and a Rockwell C hardness (HRC) of 13 (AZO Materials 2017). This material was easy to machine and could be heat treated subsequently to a much higher hardness. The present cutters were hardened to 55 HRC by using the heat treating schedule specified in Table 3.6. A Rockwell C hardness test was performed after the heat treatment to ensure that the hardness was within ±1 HRC.

Table 3.6 Heat treatment schedule developed from Heat Treating Data Book (SECO/Warwick 2011)

Process Steps	**Temperature (°C)**	**Notes**
Annealing	1200-1250	Soak for 3 hours to ensure uniform temperature
Quench	21	Air quench acceptable here since cross section small
Temper	200	30 minutes to achieve 55 ± 1 HRC
Cooling	21	Air cooled

3.2.2.2 Apparatus and Methods

During a test, the cutter was mounted in an Instron test machine and a CoCr spinal rod was placed through the hole in the lower blade of diameter as shown in Figure 3.19. A 'T' shaped plate was used to push the upper blade down along the lower blade channel. The lower jaw of the Instron was fixed, while the upper jaw could move downward. A force plate was placed above the upper jaw. After the force plate was zeroed, the upper jaw was manually jogged downward so that the upper blade touched the rod and the lightly held it in place. The Instron controls were then set to the zero-extension position and programmed to push the upper blade downwards at a constant speed of 50 mm/min while the force was recorded. Once the rod was sheared into two pieces, the Instron was manually stopped.

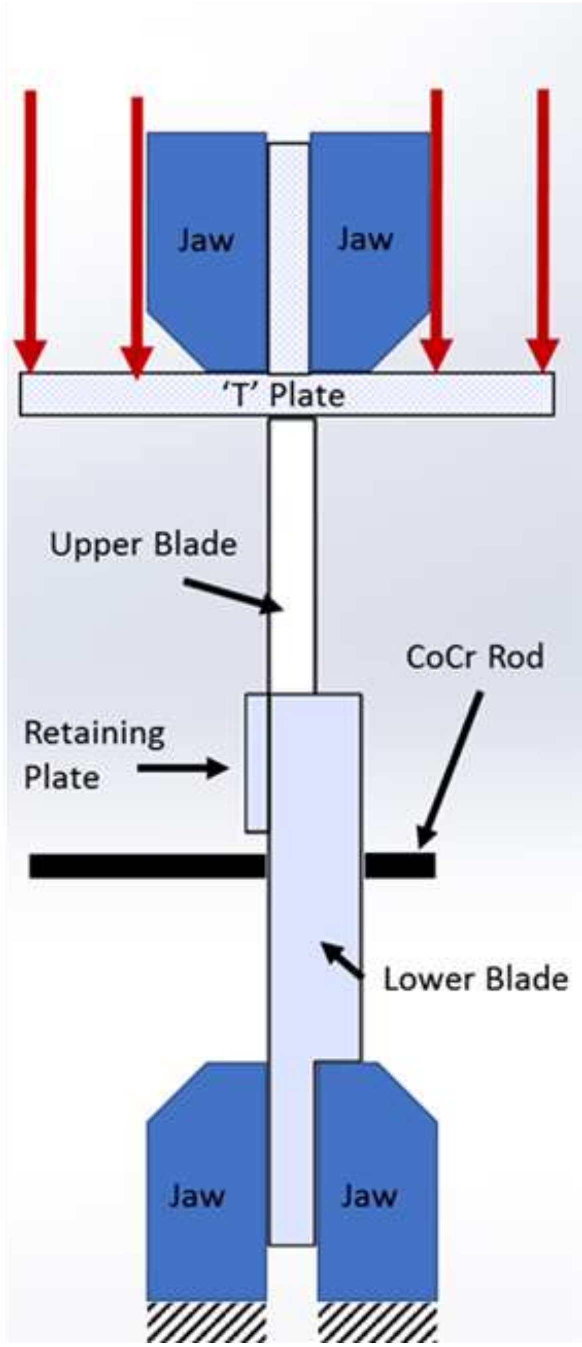


Figure 3.19 Schematic showing the experimental cutter mounted in the Instron. The red arrows indicate the direction of motion of the upper jaw.

3.2.2.3 *Results and Analysis*

The Instron software package produced force-displacement curves (Figure 3.20). An initial region of zero load occurred as the slack between the 'T' plate and jaws was taken up.

Each cutter was assigned one of the three retrieved CoCr rods to cut three pieces from each rod. Only six cuts were made, three on Cutter 1 and three on Cutter 2, versus the intended total of 9 cuts to be made. This is because Cutter 3 deformed under the loading and could not shear the rod. Peak shear forces were considered to be statistically significantly lower ($p<0.05$) for Cutter 1 according to a two-tailed t-test for unequal variances (performed using Microsoft Excel 2010, Version: 14.0.7184.5000 32-bit) but the actual amount lower was considered to be small (Table 3.7).

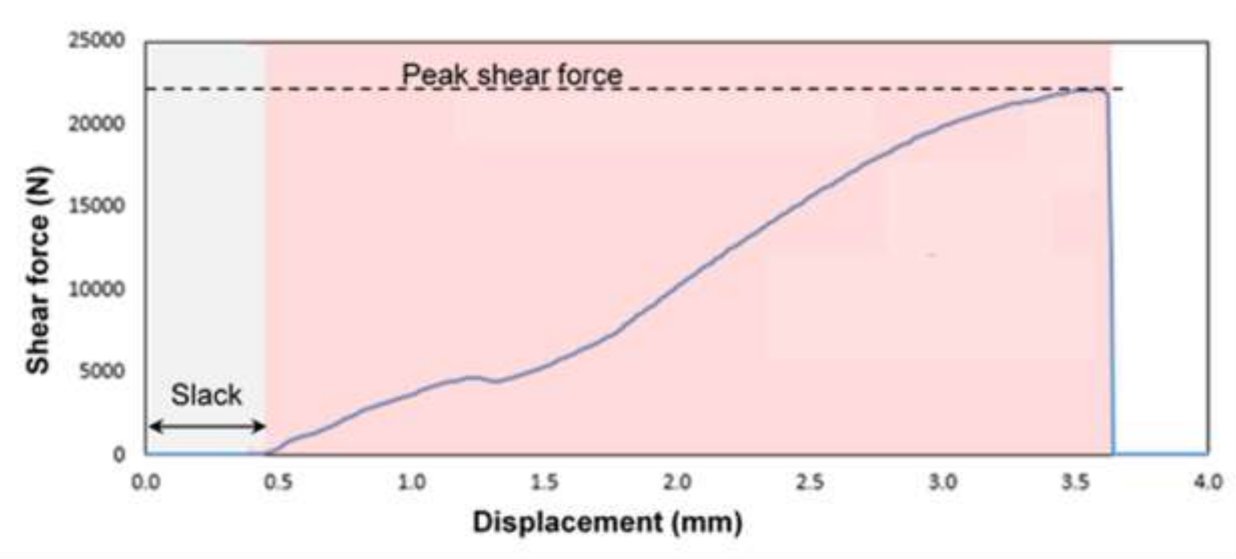


Figure 3.20 Typical force-displacement curve

Table 3.7 Peak forces for the shear cutting technique

Cutter	Peak Shear Forces (kN)				
	Individual tests			Average	Standard Deviation
1	22.12	23.41	24.21	23.24	1.052
2	24.98	25.92	27.35	26.08	1.190
3	-	-	-	-	-

Some visual observations were made. Pictures were taken of the ends of the cut rods. The cut surfaces were very consistent, typically with cut surfaces perpendicular to the long axis of the rod (Figure 3.21). The damage to the cutter surfaces was also examined. Very little visual damage was observed for the cutting edge (Figure 3.22).

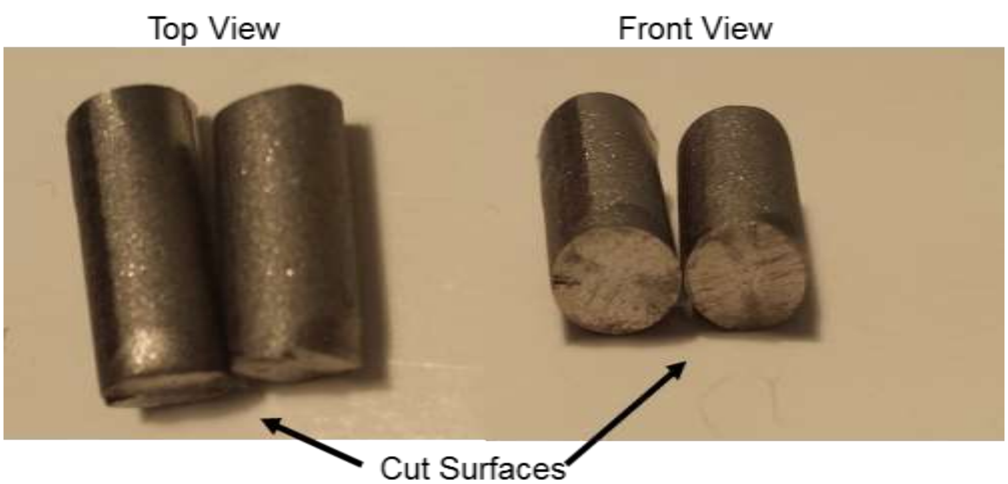


Figure 3.21 Typical cut surfaces of CoCr rods, using the shear cutters

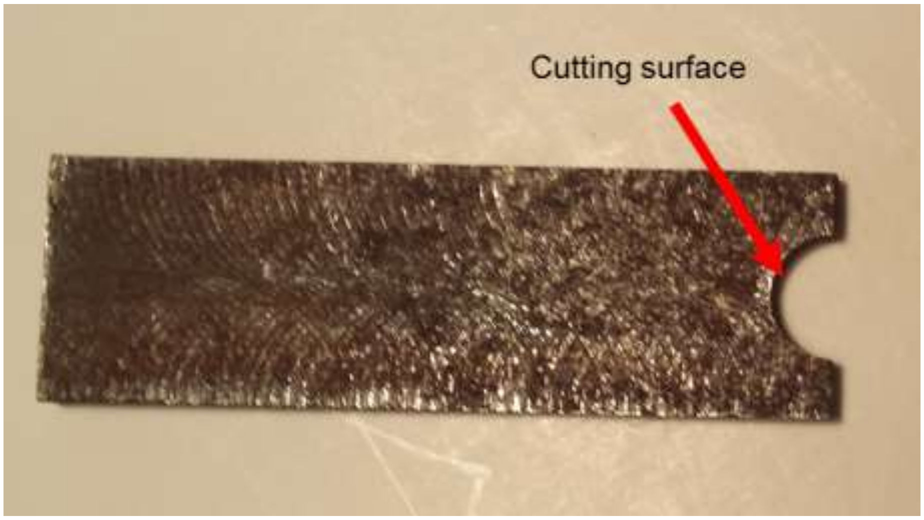


Figure 3.22 Cutting surface of the upper blade of experimental cutter 2

3.2.2.4 Discussion

The 3.18 mm thick upper blade of Cutter 3 buckled during experimentation, while the thicker upper blades of Cutters 1 and 2 stayed intact. So an upper blade thickness of 6.35 mm was adequate for a shear cutter made from 4140 steel alloy.

The average peak shear forces for the two cutters were statistically significantly different but the actual magnitude of the difference was quite small. It was considered likely that the lower average peak force for cutter 1 was a result of a stiffer cutting surface due to its larger width, thickness and smaller area of contact because of the larger D value.

For the 6.35 mm CoCr rods, the average peak force for the shear-cutting technique (23.24 kN) was considered to be statistically significantly lower (p=0.003) than the average peak compression force for the bolt-cutting technique (29.66 kN) found in the previous Section 3.2 (according to a two-tailed t-test for unequal variances performed using Microsoft Excel 2010, Version: 14.0.7184.5000 32-bit). A required peak shear force could be identified in the same manner as was used in Section 3.2 for the required peak compression force. Doing this gave a required peak shear force of 23.24 + 6 x 1.052 = 29.55 kN which was substantially lower than the required peak compression force of 37.40 kN. Also, the cut surfaces were very smooth which would be beneficial for rod section replacements as discussed in more detail in Chapter 4. This suggested that the shear cutting technique might be better than the bolt cutting technique for an in-situ rod spinal rod cutter.

3.2.3 Impact Cutting

The idea of cutting rods using a high velocity impact cutting tool was considered to be worth investigating because it might reduce the force required. This would mean that the power input requirements would be reduced and the size of the overall tool could be smaller, making it more convenient for the surgeon to use.

To explore whether impact cutting could actually reduce the amount of force needed to cut a spinal rod, a preliminary investigation was conducted. The energy needed to cut the rods was measured with a pendulum impact test using a Charpy test machine (Figure 3.23), and the fracture surfaces of the rods were visually inspected to determine whether a suitably smooth and flat. Only CoCr spinal rods were tested.

3.2.3.1 Materials and Methods

Six cobalt chromium rod specimens were tested. Three had a diameter of 6.35 mm and the other three had a diameter of 6.00 mm. A slitting saw was used to make a small notch in the center of each rod (Figure 3.24). Coolant was applied and the cutting action was interrupted frequently to reduce the heating of the rods during the slitting operation and thus avoid widespread microstructural changes to the cobalt chromium alloy.

Figure 3.23 Charpy tester, Satec Systems Inc. (Grove City, Pa) Model SI-1K3

Figure 3.24 Test Specimen

Since the diameter and shape of the specimens could not be changed, the geometry of the specimens did not correspond to the geometry as specified by the American Society for Testing and Materials (ASTM) standards (A370-17). The standard specimen was not as long (55 mm), had a square cross-section and a V-shaped notch (2 mm in depth) with a 0.25 mm radius at the apex of the V-shape. If a spinal rod was to be cut in-situ using impact, it was likely that only a shallow notch could be cut in it. Heat, debris generation, and limited access to the rod would prevent the cutting of a deep notch.

To simulate this in an approximate way, the notch depth was reduced to 0.5 mm (about 8% of the diameters of the rods).

A slitting saw with a 45 degree angle-symmetric blade was used to cut the V-shaped notch in the specimens. All of the specimens were aligned in a vice on a milling machine, to prevent rolling and shifting during cutting. Two cuts, each 1 mm in depth, were made in succession by a professional machinist, using an oil based machine coolant to minimize any possible heat generation localized at the V-shaped notch. All of the specimens were cut at the same time, as the two passes were made across their centers.

The specimens were mounted in the Charpy test machine, with the notch facing away from the impact wedge, as specified by the ASTM. Each sample was subject to a single impact. The impact energies were read from the dial on the Charpy test machine. The change in height of the pendulum of the Charpy test machine before and after impact was related to the energy loss and had been used to calibrate the dial indicator to give the readout in Joules. Initially the pendulum was released without a specimen in place to obtain the frictional energy losses and the dial was adjusted to compensate. Thus, the impact energies were recorded and the pieces were recovered for macroscopic visual examination.

3.2.3.2 Results

All 6 specimens were completely sheared and impact energies were recorded for each specimen (Table 3.8).

Table 3.8 Impact energy from the Charpy tests

Test No.	**Rod Diameter (mm)**	**Impact Energy (J)**
1	6.00	39.31
2		35.35
3		27.11
Average ± standard deviation		33.89 ± 6.21
4	6.35	40.67
5		37.96
6		36.60
Average ± standard deviation		36.60 ± 4.89

After the testing, the rod specimens were visually examined (Figure 3.25). The specimens had sustained plastic deformation that bent them in the axial direction near the fracture site. The fracture surfaces themselves were scalloped and the outer edges were sharp.

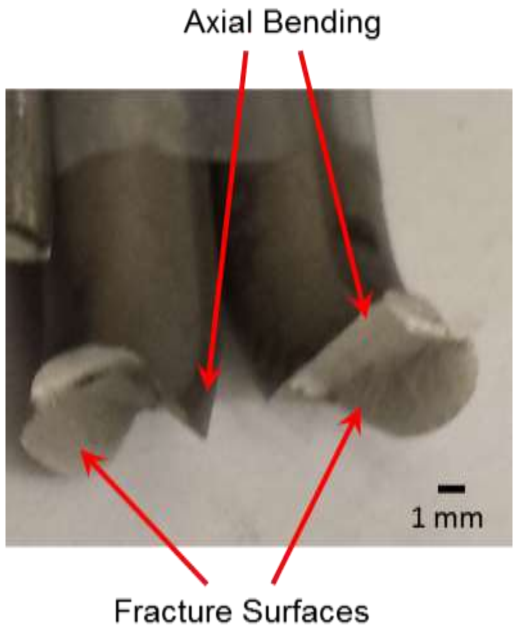


Figure 3.25 Typical specimens from the Charpy tests.

A very approximate estimate of the peak force was achieved using beam theory. For the Charpy test machine, the present rod specimens were simply supported beams with a span of 40 mm. Thus, the force imposed by the Charpy hammer (F_h), produced a moment (Mc) in Nm of Mc = 0.01 F_h for F_h in N acting at the centre of the rod specimen. For a rod diameter (d), the bending stress at the rod surface was $0.01xF_h/(0.09817xd^3)$ as given at www.atcpublications.com/Sample_pages_from_FDG.pdf. The cobalt chromium rod material had an estimated ultimate tensile stress (UTS) of 1.36 GPa as given at:

http://medicaldesign.com/print/materials/higher-performance-materials-dynamic-spine-market

While this UTS value might be low for the higher strain rates in the Charpy test, it was assumed that achieving it was sufficient to cause rod fracture and thus it was equated to the bending stress. This allowed F_h to be solved as 2.88 kN for the 6.00 mm diameter rods and 3.42 kN for the 6.35 mm rods.

An alternative method was also used to estimate the F_h required to fracture the rod specimens. This method was based directly on the Charpy test results. The elastic modulus of the cobalt chromium alloy was about 230 GPa and, as mentioned above, the span was 40 mm. For a rod diameter (d), beam deflection was 1.181x10-16xF_h/d^4 as given at www.atcpublications.com/Sample_pages_from_FDG.pdf. The energy measured by the Charpy test machine was considered to consist of the sum of the work to deflect the rod specimen elastically (1.181x10-16 F_h^2/d^4) and the work to push the crack through the diameter of the rod specimen which was $F_h$xd. Using the average impact energies from Table 3.8, this allowed a quadratic equation to be solved for F and gave 5.23 kN for the 6.00 mm diameter rod specimens and 5.43 kN for the 6.35 mm diameter rod specimens.

3.2.3.3 Discussion

A violent rebounding behavior of the Charpy pendulum was observed during the impact. This suggested that fracture did not occur immediately on the first impact. The axial bending of the rod specimen and perhaps the rebounding might have been caused by the Charpy hammer failing to strike the rod exactly opposite to the notch. As noted above, the fracture surfaces were scalloped and had sharp edges. However, whatever method is used to estimate the F_h needed to fracture the CoCr rods of 6.35 mm, it was considerably lower than that needed for the bolt-cutting or shear-cutting techniques.

3.2.4 Summary

The initial exploration of cutting techniques showed that the bolt-cutting technique was successful for all rod cutting operations but to avoid damage to the bolt cutter blades, they would have to be made from hard materials. Results and observations from using this technique indicated that an initial slow plastic deformation occurred in the rod followed by a rapid crack propagation to complete the cutting of the rod. The pipe-cutting technique required a lower force but it could not be used for in-situ rod cutting unless a mechanism was developed that could work within the space available around the rod.

Based on the tests performed, a peak compression force of 37.40 kN was estimated that would be sufficient for the bolt-cutter technique to achieve successful cutting any spinal rod that would be encountered in surgical practice. The blade material would have to be very hard to avoid progressive damage but as noted in Section 3.1, manual bolt-cutters have been used successfully for in-situ spinal rod cutting.

In a similar calculation to that performed on the results of the bolt-cutting technique, a peak shear force of 29.66 kN was estimated from the tests performed that would be sufficient for the shear-cutting technique to achieve successful cutting of any spinal rod that would be encountered in surgical practice. This value was considerably lower and suggested that shear-cutting might be a better technique than bolt-cutting for an in-situ spinal rod cutter. Also, the cut surfaces were smooth and perpendicular to the long axis of the rod. However, a mechanism would have to be designed that could apply shear-cutting to the rods in-situ where limited space was available.

An impact-cutting technique for spinal rods in-situ would require much less force (compared with bolt-cutting or shear-cutting techniques) but would produce a fracture surface with the potential to cause local tissue abrasion. More significantly, the surrounding spinal structures and cord would have to be shielded from high transient reaction forces that could damage them. Furthermore, a notch would probably have to be cut on the anterior surface of the in-situ rod and then precisely aligned with the impact hammer. This would be difficult. Thus, the idea of designing an in-situ spinal rod cutter using an impact-cutting technique was not encouraged.

4 Initiating the Design

The previous chapters describe efforts to develop enough knowledge to initiate a formal design process. Thus, the present chapter proceeds through a formal design process to the development of two alternative designs. This process is one of the many that are followed by design engineers. All such formal processes are intended to explain how a design is developed so that it can be understood and so that continued development can occur.

4.1 Needs Analysis

4.1.1 When Required

The first case in which rods may need to be cut in-situ is during the initial corrective surgery for scoliosis or kyphosis. In this procedure, rods are first cut ex-situ (during the operation but before the rod is placed in the patient) to an estimated final implant length. This is done by making a rough measurement of the required rod length by placing a flexible ruler along the spinal column once it is exposed in surgery in order to get a baseline measurement. It is difficult to determine the required length of the rods even with the flexible rulers as a guide, since the ruler cannot be positioned right at the neutral axis which is near the centre of the cross-section of the spinal column. As a result, the final corrective length of the spine and rods can only be estimated. To err on the side of caution, surgeons may have a tendency to estimate longer than necessary rod lengths which can result in the need to cut the rod down to a more appropriate length once spinal correction has been achieved. A rod that is too long can impinge on the surrounding tissue, while a rod that is too short will not achieve the desired spinal correction. If an in-situ rod cutter were developed that was easier to use, it would allow surgeons to cut the rods a little too long and then cut them down to the correct length in-situ without risking patient safety.

The second case of which the rod must be cut in-situ arises during revision surgery for either scoliosis or, more commonly, kyphosis. According to my surgeon co-supervisors, this is the most common usage case for an in-situ rod cutter. In particular, after the surgery, elderly patients may experience bone degradation (often due to osteoporosis that may have contributed to the original spinal deformity). This can lead to aseptic loosening of the pedicle screws. This loosening occurs from the correction forces applied by the rod pulling out the pedicle screws due to the poor bone stock. Further deformation of the spine will then occur because the screws can no longer hold it in a corrective shape. Thus, a revision surgery is performed to deal with this loosening of the pedicle screws. Sometimes, a replacement of the top section of spinal rod is performed to install a less stiff rod which reduces the pulling forces on pedicle screws as well as providing some degree of correction. So, the original rod must be cut and the new less stiff replacement rod must be connected to the existing rod. This is done using a connection sleeve (Figure 4.1) which can accommodate different rod diameters.

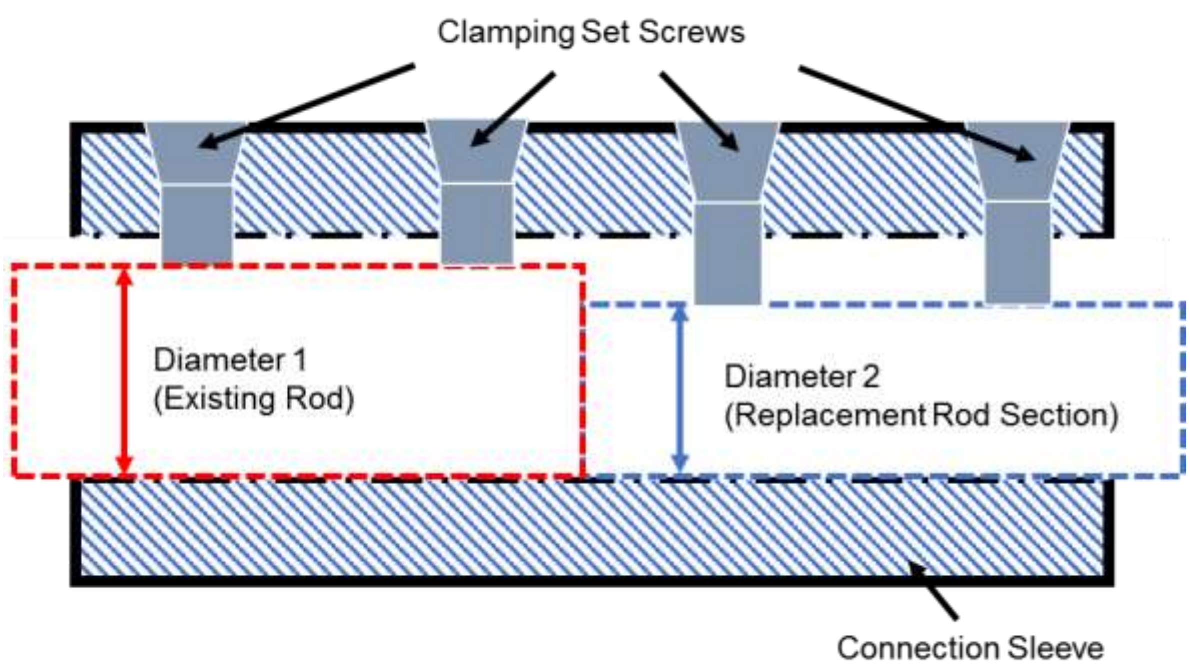


Figure 4.1 Depiction of connection sleeve used to connect a replacement rod section to the remaining section of the existing rod

In such procedures, both rod segment ends should align with each other and fit well into the connection sleeve. This maximizes the contact area between the rods ends as well as the rod contact with the sleeve, thus increasing the rigidity of the connection. According to my surgeon co-supervisors, deformation of the original rod near its cut edge could cause difficulties with inserting the rods into the connection sleeve, and sub-optimal contact with the sleeve wall as shown in Figure 4.2.

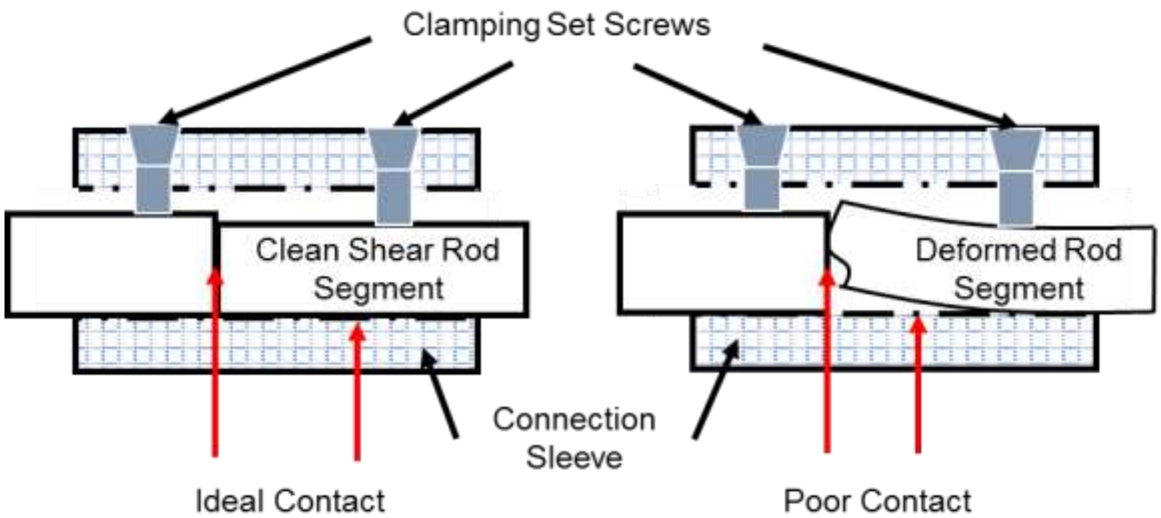


Figure 4.2 Comparison of contact between cut rod segments and the connection sleeve

4.1.2 Problems with the Use of the Current In-Situ Rod Cutters

The use of bolt cutters as in-situ rod cutters requires a great deal of input effort from the surgeon, especially when cutting cobalt chrome alloy rods of the maximum diameter (6.35 mm) are being cut. Both surgeon co-supervisors said that in order to operate the bolt cutter for in-situ cutting, it was common practice for another surgeon (or surgical assistant) to stand on the other side of the patient and then they would both use their body weight to help apply the effort force to the levers simultaneously. While some surgeons can operate this cutter on their own providing they are large and strong enough to do so, there are other issues which pose problems to the patient and the outcome of the cutting.

In addition to the physical strength required of surgeons to use this tool, the large size and heavy weight of the bolt cutters make it cumbersome to position and to maintain the position. If such a heavy tool slips and drops onto the patient, or any rapid changes in tool position occur while it is inside the patient either positioning it or during the actual rod cutting, forces may be applied to the spine causing damage. It is possible that the spinal cord could be damaged permanently.

Cutting rods with this tool also poses another problem, since a large amount of force is applied to the rods. In the final stages of cutting, a rapid crack propagation occurs and a rapid displacement of the rod ends may occur. Once again, a large enough force transient could occur to damage the spinal cord or the vertebral bodies.

4.2 Problem Definition

An improved in-situ rod cutter is clearly needed. In designing such a rod cutter, the actual method of cutting and the mechanism needed to apply the force to the rod are considered. The mechanism may also be designed to use pneumatic, electric or hydraulic power to assist in generating the effort force thus allowing the surgeon to concentrate on positioning the cutter and controlling unwanted shock forces associated with the final stages of the cutting.

4.3 Design Constraints

For the first iteration of the design process, all proposed alternative designs must satisfy certain constraints completely (often this must be re-visited and checked at later stages during the implementation of a design). These design constraints place bounds and limitations upon any proposed design alternatives. The constraints are determined based on some judgements made by the author and then applied absolutely. If design constraints are not specified in this way, very unfeasible design alternatives proliferate and slow the overall process of achieving an optimal (or at least "harmonic") design. The design constraints may be modified to some extent in subsequent iterations of the design process. For the current design problem, the constraints are specified in the following list

1. Space Available

The existing in-situ rod cutters are measured for size in their maximum required open position for cutting the large 6.35 mm rods. It was determined that the rods are located at a depth of about 60 mm from the posterior skin surface of the exposed spine. At the surface of the skin, the rod cutters are measured to be 80 mm in width in their open state. Just beneath the rod, at a depth of 66.35 mm the rod cutters are measured to be 35.35 mm wide in their open state. These measurements, forming a trapezoidal bounding box are close to the maximum space available for a rod cutting mechanism, since it is difficult to fit the existing cutters into place in-situ. A distance along the rod of about 25.4 mm is enough to allow the cutter to fit between two pedicle screws. The anterior distance between the rod and the spinal column is about 15 mm, which does not increase with smaller rod diameters due to the design of the pedicle screws. This anterior side of the spine must not be in contact with the rod cutter during cutting, so the cutting jaws must not protrude deeper than the rod by 15 mm. *The bounding box depicted by Figure 4.3 shows the maximum space available for the rod cutter.*

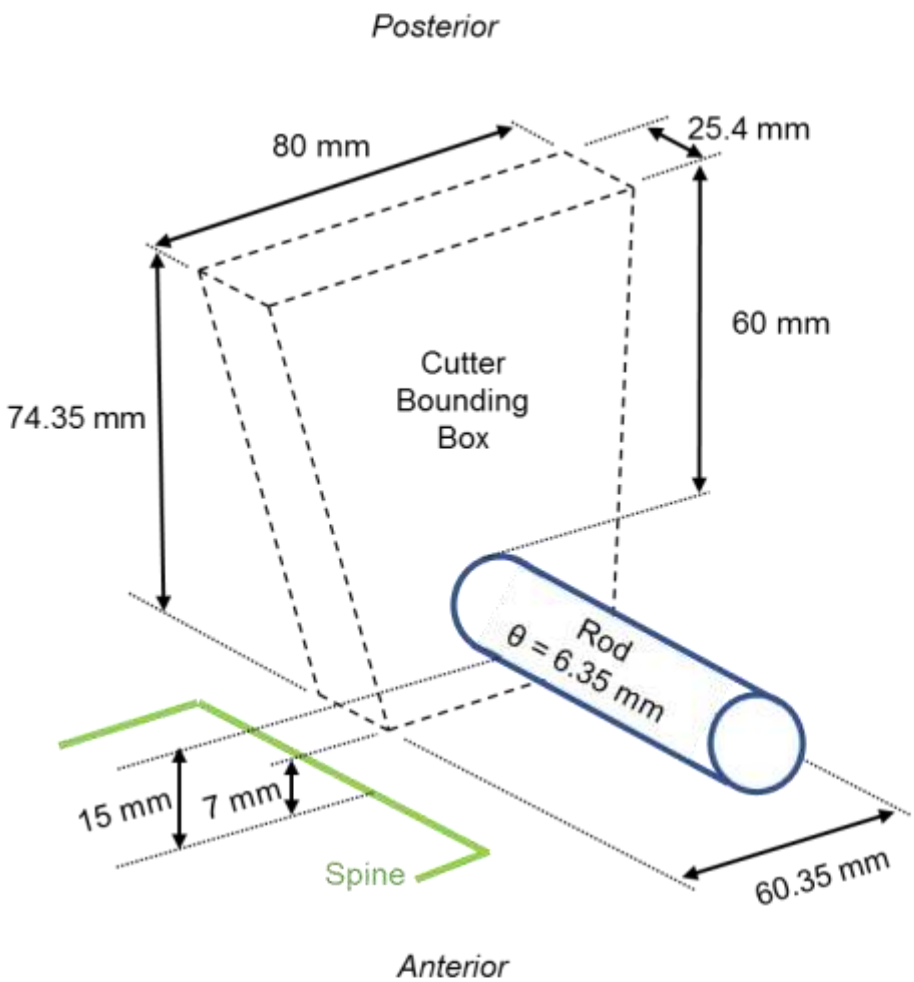


Figure 4.3 Dimensions of space available for fitting the in-situ cutter into the exposed spine.

2. Use of Mechanical Cutting

In Chapter 3, different types of cutting were investigated as options for in-situ rod cutting. The pipe cutting technique could not work due to the space constraints as there needs to be far more room around the rod on all sides than available. Other possible rod cutting techniques such as electrical discharge machining, sawing, water jet cutting, and laser cutting were all considered to pose significant risks to the patient. Any heat generation is dangerous as it can traumatize the spinal cord, while debris generation poses the risk of metalloids related illnesses to the patient. The high pressures involved with water jet cutting are difficult to control and could easily damage the spinal cord. *For these reasons, it was decided to restrict the cutting method to be mechanical (either shear or compression) with minimal debris and heat generation.*

3. Cutting Force Required

Experimental work in Chapter 3 determined the forces required to cut the rod in both shear and compression. The shear force was determined by cutting the rods using two cleaving jaws positioned next to each other to share a common cutting plane, while the compression force was determined using bolt cutters which pinched and compressed the rod with aligned jaws closing on opposite (lateral) sides of the rod. In Chapter 3, it was found that the 6.35 mm CoCr rods required the most force to cut, the average force to cut these rods in shear was found to be 23.24 ± 1.05 kN (avg ± SD) and 29.66 ± 1.29 kN in compression. To ensure that all alternative mechanism designs could cut 6.35 mm CoCr rods, a value of six times the standard deviation was added to the average value. *Thus, any mechanism design for shear cutting must provide a force of at least 29.6 kN on opposing lateral sides of the rod and any mechanism design for compression cutting must provide a force of at least 37.4 kN on opposing lateral sides of the rod.*

4. Power Source

The existing in-situ rod cutters are manually operated. There are several issues with manual operation which are undesirable in a rod cutter tool. Often two or three surgeons must be involved in the cutting process since it takes a large amount of strength to close the current in-situ rod cutter handles in order to cut the rod. This multiple surgeon approach leads to complications such as accurately holding the tool in place as well as having the surgeons match each other's input efforts to close the handles so the tool does not displace the central long axis of the rod too dramatically. This multiple surgeon approach is also an inconvenience as it requires that both surgeons are strong and coordinated enough to effectively operate the bolt cutters. This is quite difficult. A major concern with these manually cutters is the application of inadvertent forces on the spine at the instant of cutting. Since the final stage of the rod failure is a bit violent, surgeons must be prepared to control both their physical effort input and the rod cutter tool once the cut is complete. This is analogous to the feeling of pulling hard on a door which becomes suddenly unlocked. So, failure to control their physical efforts could result in the existing in-situ rod cutters pulling or pushing on the spinal column anatomy. It is strongly desirable that minimal strength be required by the surgeon to operate an in-situ rod cutter, thus it is necessary that a non-manual power source should be used to cut the rod. Hydraulic, pneumatic and electrical power sources could be used, but consideration must be made towards patient safety as well. In the case of hydraulics, large compressor equipment must be used to generate the hydraulic pressures. In addition, hydraulic oils are dangerous to human health and should not be in an operating theatre. Hospitals have 200 psi air lines available for pneumatics, and 120 and 240 v electrical lines for electrical equipment. *Thus, any alternative design must either use pneumatic pressure or electricity to power the mechanisms.*

5. Material Selection

Material selection is important in a clinical setting such as an operating theatre, as all equipment must be able to withstand sterilization. In the case of tools which go inside patients, an elevated temperature and pressure autoclave typically uses 2 atmospheres of pressure and about 135 ºC of superheated steam (3% humidity) to sterilize the tools. This process can greatly accelerate corrosion of materials, so materials should be selected to withstand corrosion. Typical metals used for surgical instruments (ASTM F899-12b) are 316L and 400 series stainless steels. Except for the blades, 316L stainless steel is often used. To avoid damage and failure of rod cutting blades, the hardness must be high enough to avoid plastic deformation and this can be achieved with 420 and 440 stainless steels. The existing in-situ bolt cutters are made from the above grades of stainless steel which satisfies these constraints. So, rather than consider an alternative material, *it was decided that any prototype designs should use 420 or 440 stainless steel for the blades and 316L stainless steel for the other parts of the mechanism.*

6. Limitations in the Scope of the Current Design Iteration

It was considered counter-productive to attempt to develop too many criteria because it would encumber the design process. The identification of the most important criteria would allow an iteration of the design process in which a prototype could be fabricated and tested. The experience gained in this first iteration would allow a second design iteration that would be much closer to optimal when judged according to the criteria (and much more certain that all of the constraints have been satisfied) when checked at the prototype stage. During subsequent design iterations, the issues identified below would have to be considered and would either remain as constraints or be developed into criteria.

Existing in-situ rod cutters do not have issues with fracture and fatigue problems, as the components are sized to withstand this. This design exercise does not consider detailed stress analysis and fatigue predictions, so similar sized components to that of the existing in-situ rod cutters must be used to minimize the chances of fatigue and fracture occurring in the designed mechanisms. In order to verify the lack of fatigue and fracture problems, prototype construction and testing would eventually be performed.

The cost, safety, ergonomics and marketing are aspects not considered in the present design exercise, but can be addressed once the designed rod cutters are prototyped and closer to the final stages of implementation. A large design improvement over the current in-situ rod cutters would increase the ease of sales to hospitals, and could justify a larger price point in relation to the current rod cutters. A large enough improvement on design could be achieved the above constraints were satisfied, as they address the major issues pointed out by surgeons using the current in-situ rod cutters. Safety issues, such as pinching parts as well as ergonomics and appearances can be implemented in future design iterations which would involve surgeon feedback and testing.

Ease of manufacture and sustainability are not considered in this design iteration. Ease of manufacture it is likely to be similar to other current surgical instrumentation. The objective of sustainability is to reduce the amount of non-renewable resources required to fabricate and produce a designed product. This considers material selection, worn out device disposal and carbon footprint of the manufacturer. It is not considered, and is likely to be similar to other surgical instrumentation.

4.4 Design Criteria

For this first iteration of the design process, the proposed alternative designs are judged exclusively on the specific desirable features identified as design criteria. These criteria are expressed as intentions in the creation of a solution to the design problem. Some criteria are more important than others thus weights are assigned to each criteria to reflect their importance. The extent to which alternatives designs satisfy these criteria is determined based on the authors experience and any experimental data values that are available. Often a design alternative is selected as optimal but upon building and testing a prototype, it is found that the performance is not as expected. Then a second design iteration is performed which may involve modifying the constraints or criteria or simply selecting the next best alternative design from the current first iteration. Then, a second prototype can be made and tested. If the designer’s judgement and skill levels are high, an optimal (or at least “harmonious”) design emerges without having an excessive number of iterations through the prototype and testing phases. For the current first design iteration, the criteria are specified in the following list.

1. Ease of Use (Weight 0.35)

It was pointed out that the existing in-situ rod cutting tool was cumbersome to use as it is large, bulky and difficult to position accurately. Surgeons will often require assistance of another surgeon to operate the existing tool because of this, and more care is required to operate such a large tool safely. A newly designed rod cutter should make it easier to cut rods than the existing in-situ rod cutting tool, should be operable by one surgeon only. Also, suspending a rod cutter at shoulder height, while holding on to handles (as for the currently used bolt cutter device), is tiresome and makes placement difficult. *Thus, a new* *tool should minimize the overall weight, without risking fatigue or fracture, and consider how the device should be held by the surgeon to achieve easy and accurate positioning.*

2. Minimize the Risk of High Transfer of Forces to the Patient (Weight 0.35)

A major concern with the operation of the existing in-situ bolt cutter is the risk of transfer of significant forces to the spinal cord, since trauma to the spinal cord can create permanent disability to the patient. The forces required to cut the largest and strongest rods (6.35 mm diameter CoCr) have been specified in the constraints. These forces have also been specified in the constraints to act on the lateral sides of the rod. *To minimize the risk of high transfer forces, the blades should be aligned to avoid high reaction forces and torques. Once the cutting occurs, high impulse forces might occur and designs should seek to minimize them.*

3. Shape of Cut Zone (Weight 0.2)

After rods are cut in-situ, the cut surface should be as close as possible to perpendicular to the long axis of the rod and have minimal bending or crushing of the rod (Figure 4.4).

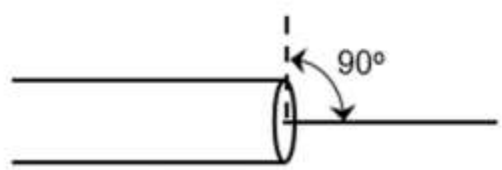


Figure 4.4 Ideal surface geometry of spinal rod after it has been cut

In Chapter 3, the end surfaces of rods were shown to vary with the different rod cutting techniques investigated. The quality of the surface is important to the use of rod extension clamps that join two rod ends together as discussed in greater detail in the aforementioned sections of this chapter. Additionally, a bent rod end could push against adjacent tissues, or it could interfere with the rod clamps which are used to adjust the rod's position and axial rotation once it has been implanted (Figure 4.5).

Figure 4.5 Holmed rod clamp (www.holmed.net), used to position, rotate and grip onto spinal rods. Gripper contact width W is in the neighborhood of 10 mm. The rod contacting this area should be as straight as possible to ensure adequate grip for adjusting the rod in-situ. *This image is used under the fair dealing exception.*

4. Mechanism Simplicity (Weight 0.1)

Simplicity of the mechanism design is important as the tool should be able to be disassembled and reassembled with some ease. The reason for this is that all operating room tools must be sterilized in an autoclave and thus, components with internal cavities and joints must be opened up for exposure to the autoclave environment. Autoclaving is done by specialized technicians at hospitals that must be trained to disassemble and reassemble any tools. Complexity in design can make this process difficult and longer, so it is advantageous to design a mechanism which is simple enough to be assembled easily and reliably.

4.5 The Shear Cutter Design

This design uses two blades (Figure 4.6) which approach either side of the rod by moving at an angle of 60 degrees. The piston acts by pushing downward on the piston linkage. This causes a force to be applied to the upper surface of the blades, pushing the downwards along the wall of the housing. As a result, a shear force is applied by the cutting surface of the blades to the opposing lateral sides of the rod. An internal “return” linkage is used to restore the blades to their starting position as the piston moves to its original position (Figure 4.7).

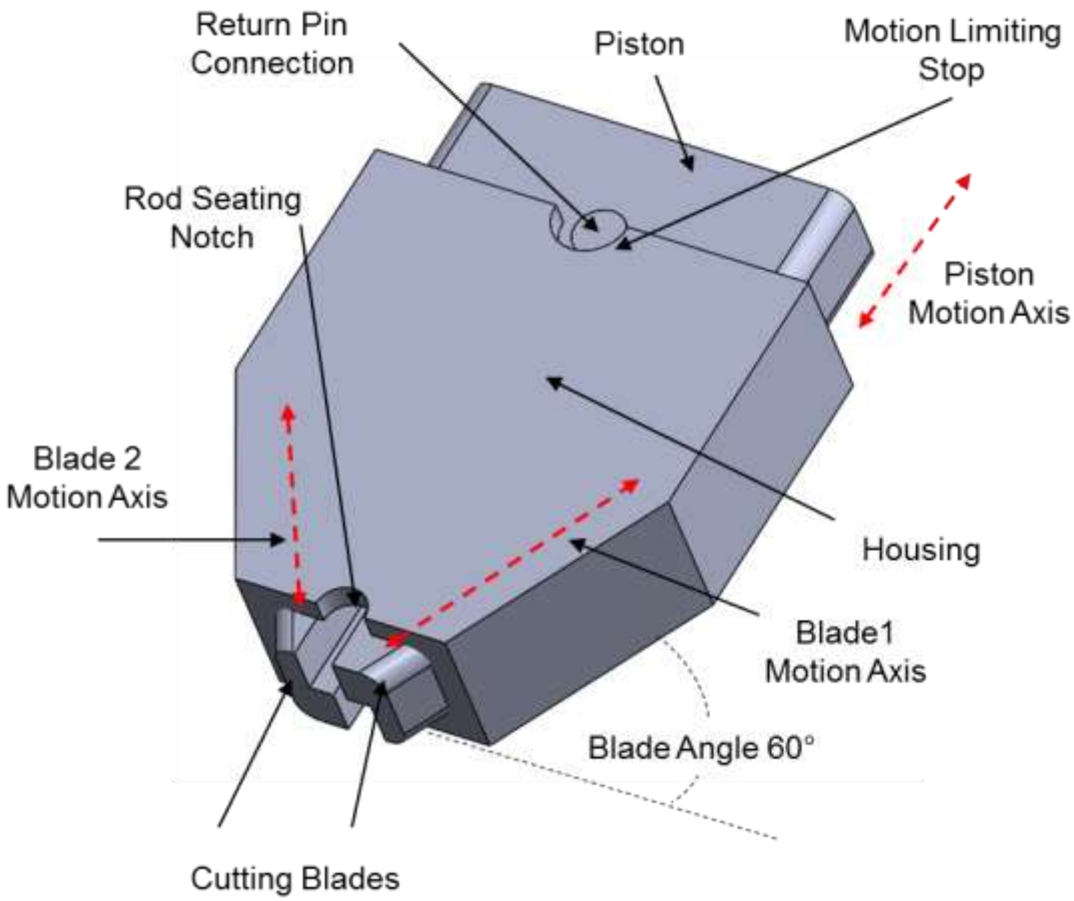


Figure 4.6 Shear-cutting design

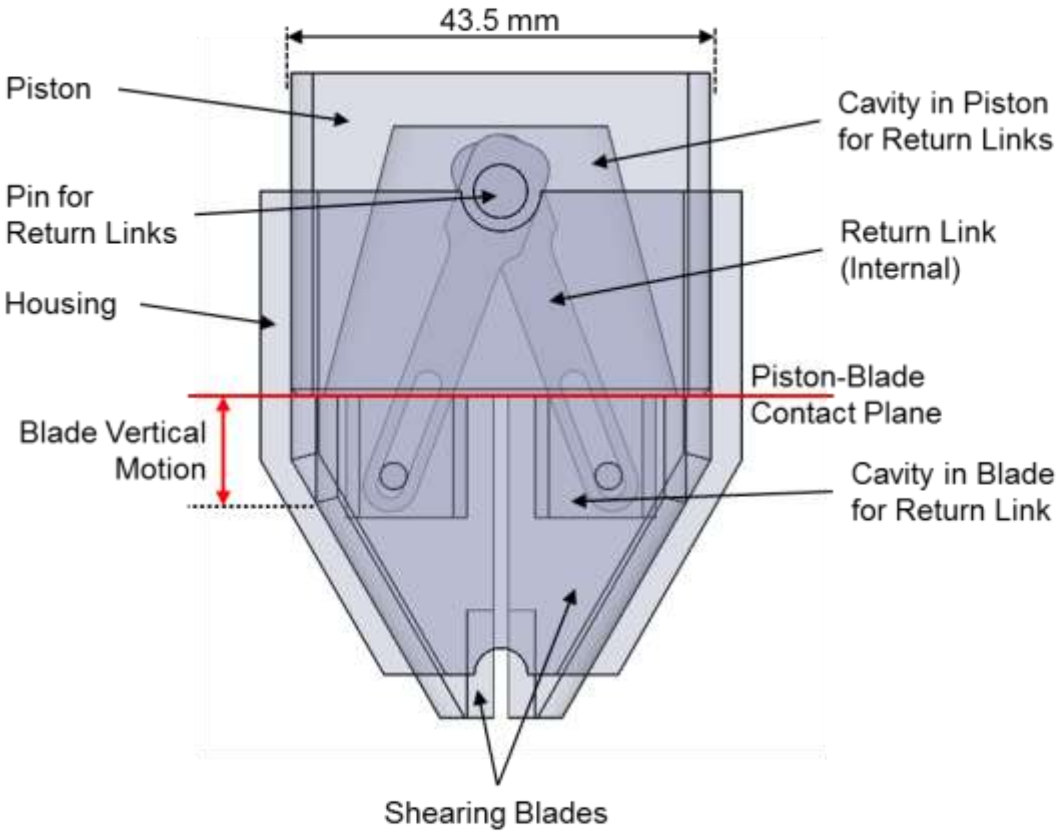


Figure 4.7 Schematic showing interior components and how they link together

The tips of the blades are designed to shear the rod on a single plane, while providing a relief zone for the rod to move to after shearing (Figure 4.8). The relief zone width was sized to accommodate the largest diameter surgical rod at 6.35 m. Since there are two blades, this width was 3.2 mm which is slightly larger than half of the rod diameter. The blade tip length h was set to 12.7 mm to ensure that forces did not act close to the edge of the blades.

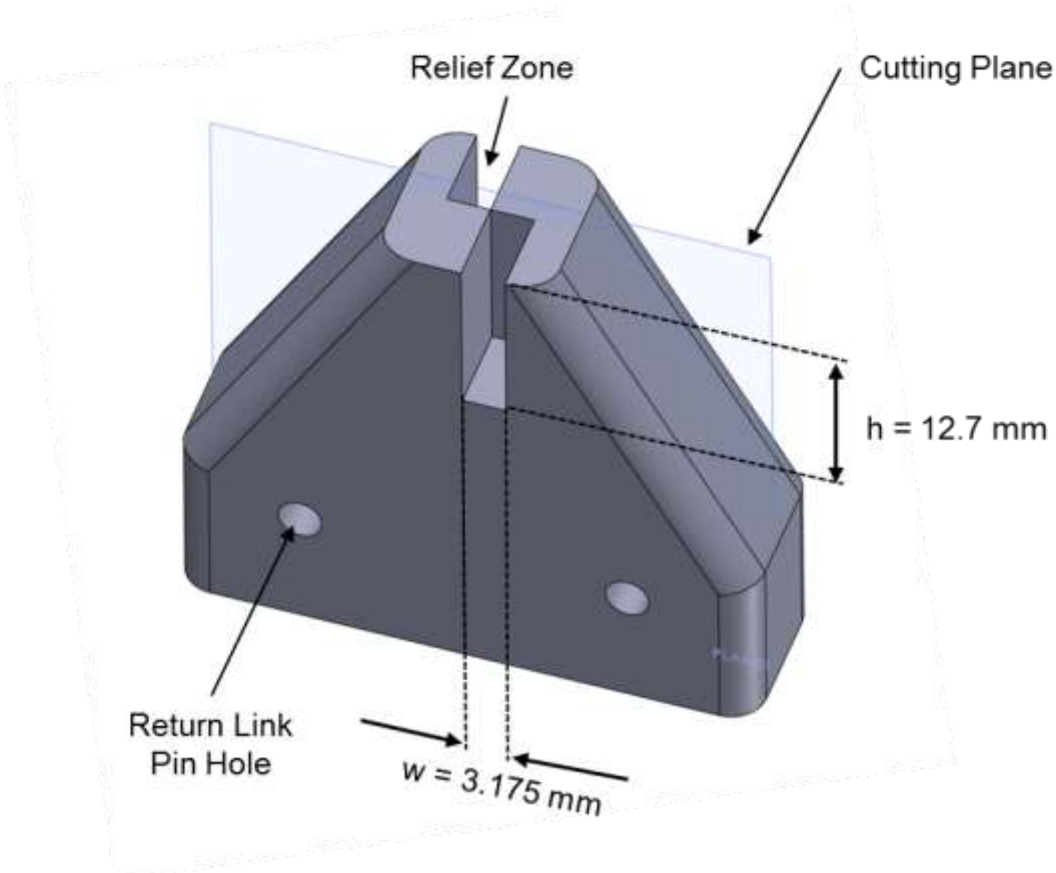


Figure 4.8 Cutting blade geometry shown in the blade closed position.

This design allowed shear cutting using forces (Constraint 2 - Use of Mechanical Cutting) applied to the opposing lateral sides of the rod (Constraint 3 - Cutting Force Required) and it fit into the space available (Constraint 1 - Space Available). The power source was a pneumatic cylinder (Constraint 4 - Power Source) that could be detached from the rest of the cutter mechanism and the material for the cutting blades would be 440 stainless steel while the rest of the mechanism would be made from 316L stainless steel (Constraint 5 - Material Selection). Components were sized using the existing in-situ rod cutters as a guide and thus should not have high stresses or fatigue problems (part of Constraint 6 - Limitations in the Scope of the Current Design Iteration).

The design was considered to be easy to use and should not introduce high transfer forces (Criteria 1 and 2). Based on the testing in Section 3.3, it was considered likely that the shape of the cut zone would be ideal (Criteria 3).

The cutting mechanism was quite simple (Criteria 4) but it had to be assumed that a large enough pneumatic cylinder could be specified to supply the required force. More detailed discussions of this alternative design are given in the next chapter where the optimal design is chosen.

4.6 Bolt Cutter Design

This design has the same bolt-cutting technique (Constraint 2 - Use of Mechanical Cutting) as the existing manual in-situ rod cutters (Figure 2.16 and Figure 2.17). The main feature of this design is the linkage that connects a pneumatic piston (Constraint 4 - Power Source) to the blades (Figure 4.9). This linkage provides considerable mechanical advantage and thus allows a large enough force to be applied to the opposite lateral sides of the rod (Constraint 3 - Cutting Force Required). The entire mechanism fits within the space allowed (Constraint 1 - Space Available).

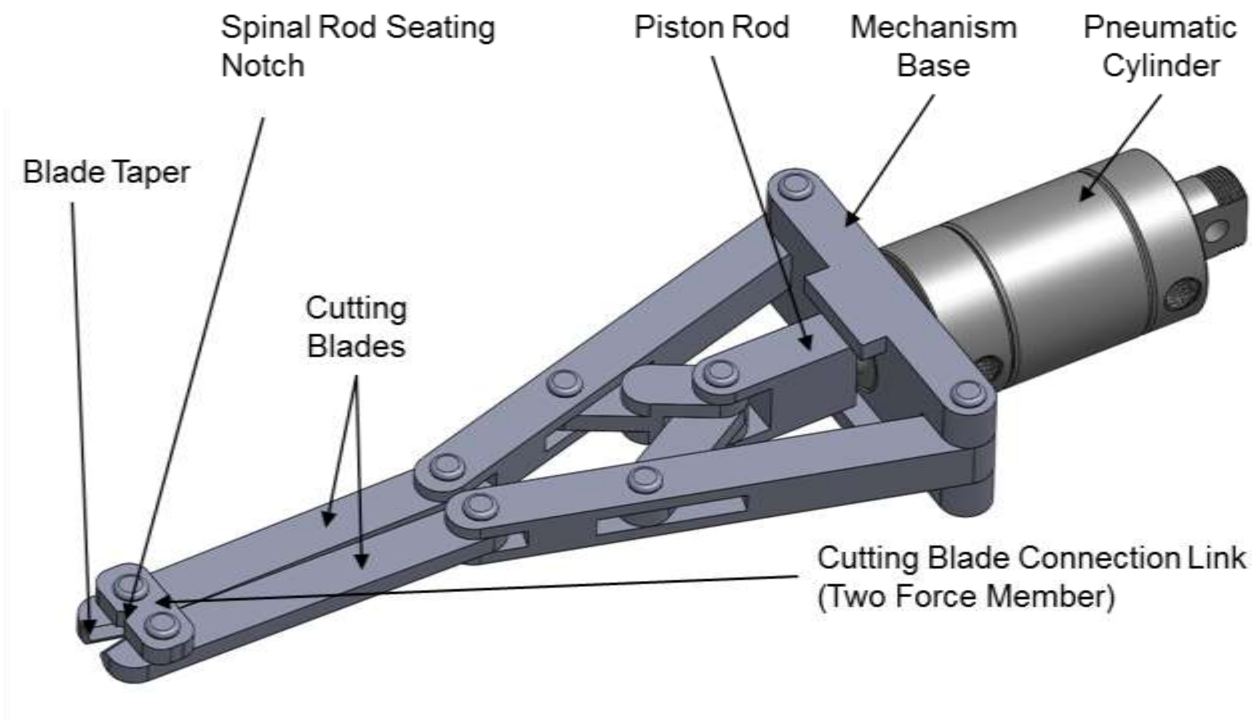


Figure 4.9 3D Rendering of bolt cutter design

The links were sized using the existing in-situ rod cutters as a guide (part of Constraint 6 - Limitations in the Scope of the Current Design Iteration), and all components were to be fabricated from stainless steel (Constraint 5 - Material Selection).

The pneumatic cylinder would be connected to the supply line in the operating theatre. During operation, the pneumatic cylinder would be pressurized and the mechanism would close the blades around a rod (Figure 4.10 and Figure 4.11). After cutting, the piston direction would be reversed, using the double action of the pneumatic cylinder, and the jaws would open to be ready for the next cutting action.

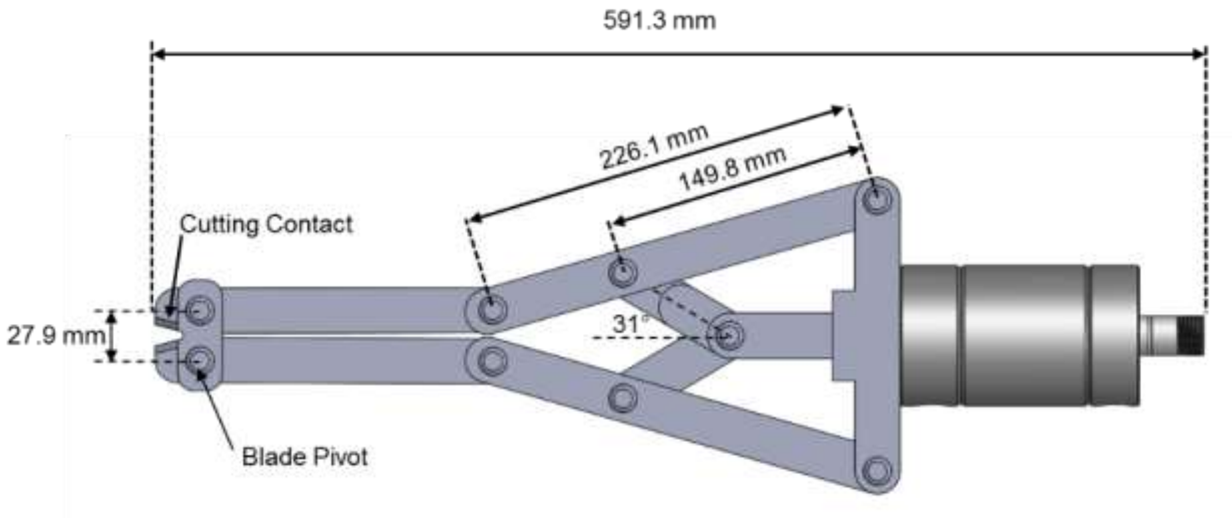


Figure 4.10 Bolt cutting design shown in its *opened* state, top view

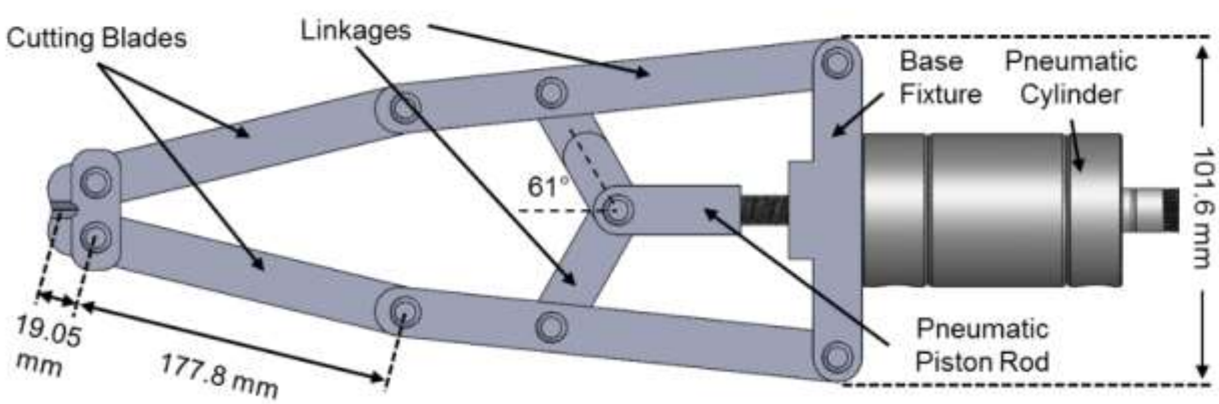


Figure 4.11 Bolt cutting design shown in its closed state, top view

This alternative design was considered to be easy to use and should not introduce high transfer forces (Criteria 1 and 2). Based on the testing in Section 3.3, it was considered likely that the shape of the cut zone would not be ideal and so Criteria 3 would not be well addressed. However, the cutting mechanism was quite simple (Criteria 4). More detailed discussions of this alternative design are given in the next chapter where the optimal design is chosen.

4.7 Design Matrix

Based on the criteria set forth in this chapter, the proposed design alternatives, the shear cutter design and bolt cutter design, were scored in these categories using the decision matrix shown in Table 4.1

Table 4.1 Decision matrix used to determine the optimal design

Criteria	**Weighting**	**Shear Cutter**	**Bolt Cutter**
1. Ease of Use	0.35	8	7
2. Force Transfer	0.35	8.5	8
3. Cut Zone Shape	0.20	10	7
4. Simplicity	0.10	6	5
	Total	8.4	7.2
	Shear Cutter is the optimal design		

The authors experience and judgement were used to determine the scores for each design. Both designs were considered easy to use, since they implement a pneumatic power source and are designed to be operated by only one surgeon. The weight of the designs would be quite high given the amount of bulk metal required to withstand the high forces of cutting. However, the bolt cutter has an additional linkage to achieve mechanical advantage which would increase its bulk. Thus, the shear cutter was given a score of 8 but the bolt cutter had a score of 7.

Both designs were developed to cut rods using opposing forces, with their cutting blades aligned on either side of the rod as required by Constraint 3 - Cutting Force Required. This lateral alignment of the blades should reduce transfer of forces to the spine, as the equal and opposite forces result in a net applied force of zero. However, since the stresses of the rod during cutting vary with the shear cutting and bolt cutting techniques, the two designs were scored differently for Criteria 2. This was because cutting along a shear plane would not produce the axial tension forces along the rod which would occur during the compressive loading in the bolt cutter design (Figure 4.12). During the final fracture of the rod, it was expected that a shock load would travel axially down the rod for the bolt cutting but the shock loading would be more localized for the shear cutting. Thus, the shear cutter had a score of 8.5 whereas the bolt cutter had a score of 8.

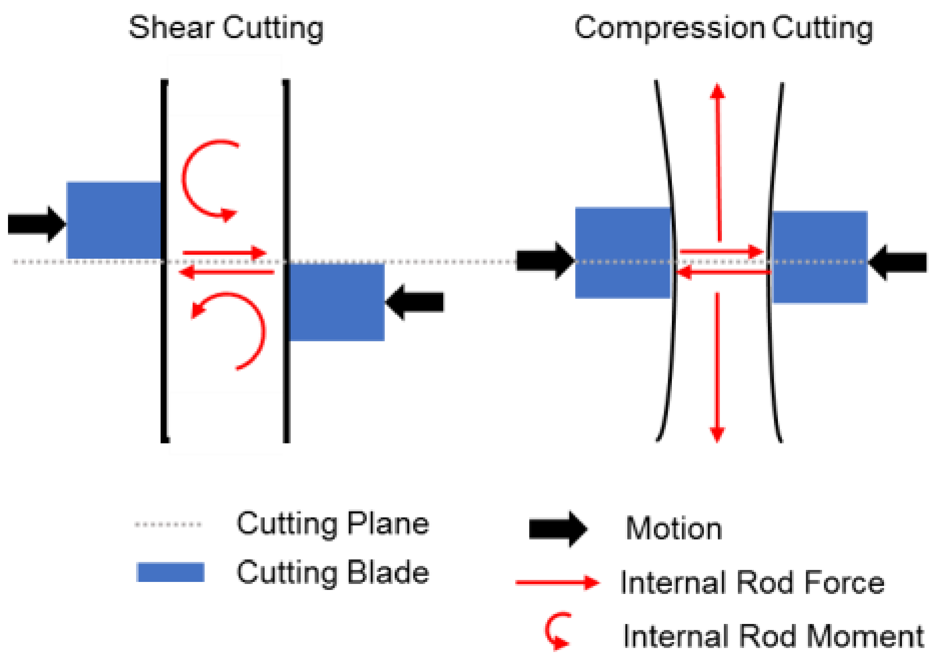


Figure 4.12 Simplistic description of the internal forces during shear and compression (bolt) cutting operations.

The cut zone shapes for both shear and bolt cutting were explored in Chapter 3. It became clear that shear cutting produces a significantly better shape of the cut zone Thus, for Criteria 3, the shear cutter had a score of 10 whereas the bolt cutter only had a score of 7.

Both designs were developed to have mechanism simplicity (Criteria 4), but the bolt cutter required more linkages to achieve a mechanical advantage. Thus, the bolt cutter scored lower than the shear cutter. Unfortunately, both designs would require some disassembly and reassembly of components for autoclaving purposes. This requires that the hospital sterilization staff must have additional training to perform the assembly, so neither design scored exceptionally high in this category.

Overall, the shear cutter had a score of 8.4/10, which was higher than the bolt cutter score of 7.2/10. The shear cutter design was selected for the next stages of design, in which implementing and testing the mechanisms of the design occurs.

5 Design Implementation, with Some Testing and Analysis

5.1 Shear Cutter Design

5.1.1 Testing of Prototype

Rather than further developing this design by choosing a pneumatic cylinder size and/or performing stress analysis, it was decided to build a prototype to see if rods could be successfully cut. Several simplifications to the shear cutter design were made to fabricate test an initial prototype. These simplifications not only reduced the manufacturing time, but also the cost. A specialized apparatus was constructed to interface the cutting mechanism with the Instron test machine that had been used in Section 3.2 (Figure 5.1). Further simplifications were made to the mechanism itself to accommodate the specialized apparatus. Thus, the Instron machine was used to apply force to the mechanism.

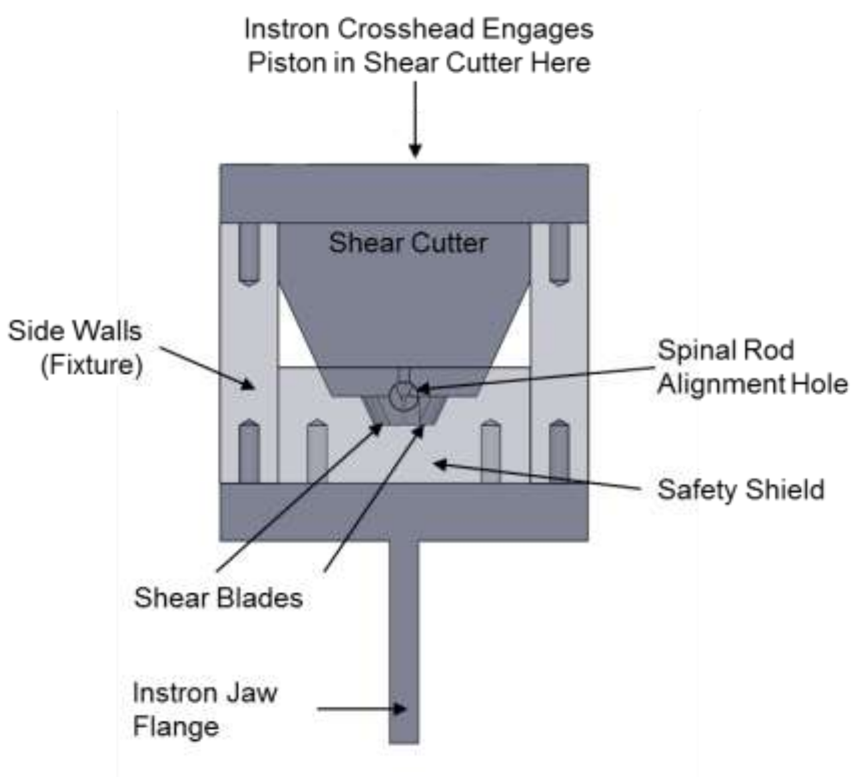


Figure 5.1 Front view of experimental cutting mechanism mounted in custom Instron fixture

In this less complex, experimental version of the shear cutter, linkages and pins were not included but the fundamental cutting mechanism was not changed (Figure 5.2). The operation of the simplified design was to be very similar to the original design with the blades being driven using a single piston to move them along the housing wall. In order prevent internal rotation of the blades, a central aligning post feature was added to the casing (Figure 5.2). Since smaller rods require that the blades travel a larger distance before contacting the rod, the blades cutting face length and the total blade displacement length had to be adjusted to prevent an over-extension of the blades into the spinal column when cutting these smaller diameter rods.

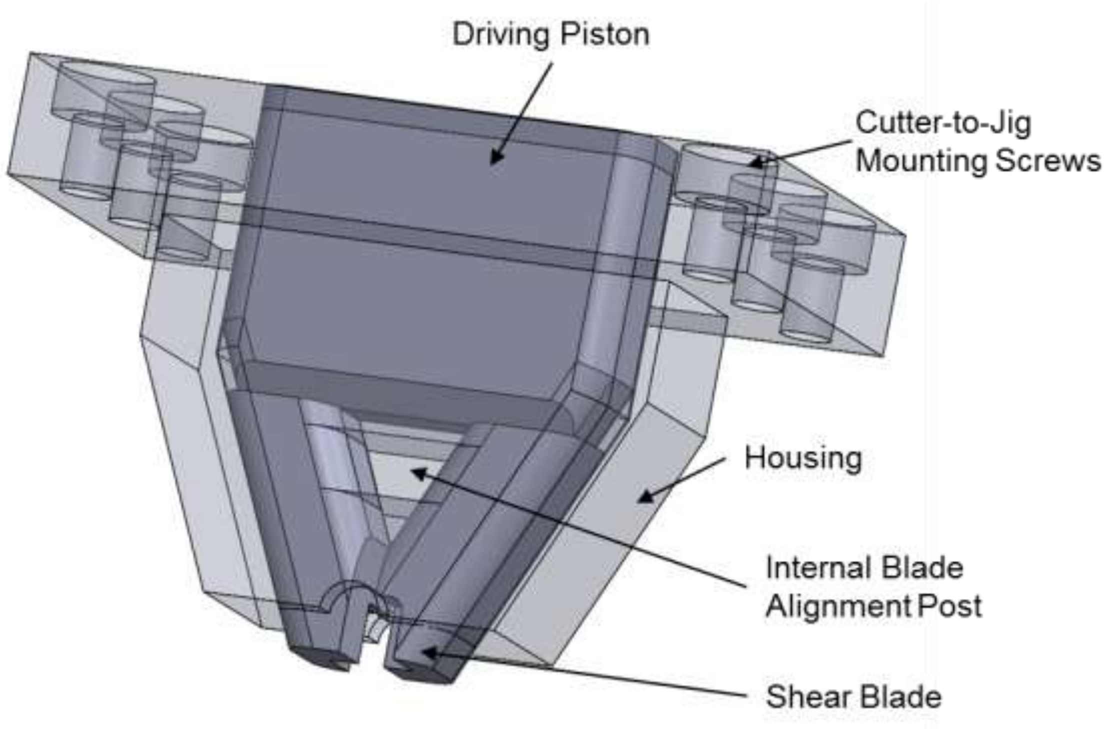


Figure 5.2 Assembly of experimental cutting mechanism

The shear cutting operation involved motion of the blades in the direction of force application (Figure 5.3). Initially, the tool was in the retracted starting position, where it was centered on top of the rod to be cut. During the cutting operation the input force was applied to the piston from the Instron crosshead, which pushes on the cutting blades. The cutting blades move downwards sliding against the housing wall, the ends contacting the lateral sides of the rod and thus squeezing it. As the mechanism reached the final position, the rod was sheared and the shear cutter could be manually returned to its starting position.

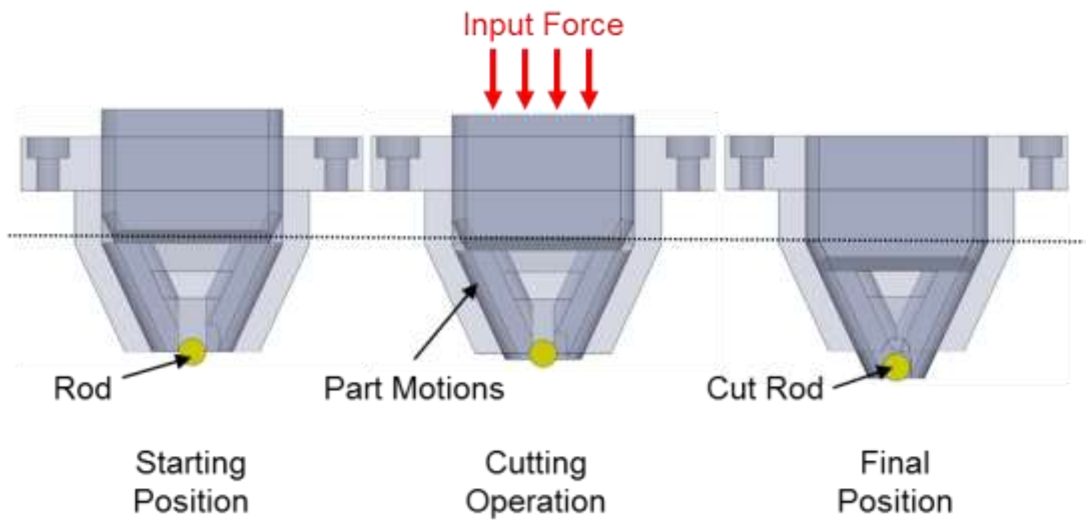


Figure 5.3 Cutting sequence of the mechanism

In order to cut the hard cobalt alloy rods, the cutting blades were manufactured from AISI O2 grade tool steel, rather than a stainless steel specified for the shear cutter design. This steel was hardened to 55 HRC so that damage to the cutting edge would be minimal. All other components were made from AISI 4140 grade steel which also differed from the stainless steel specified for the shear cutter design. These materials were easier to obtain and were expected to cut in a similar manner to the specified one.

5.1.2 Force Analysis

Although it was known that the forces would be quite high, the fracture described in the previous section was not expected. Therefore, to further investigate the shear cutter design a force analysis was performed. Forces were only considered in the vertical plane because it was assumed that the forces causing the twisting moment in the horizontal plane would not have a substantial effect on the forces in the vertical plane. However, it was recognized this twisting moment would cause reaction forces on the pedicle screws holding the rod that might have been detrimental to rod fixation after the cutting action. A free body diagram (Figure 5.4) was constructed to reflect the static forces acting on the cutting blade, when the shear cutter design was in the closed position. Dimensions used in this static analysis are shown in Figure 5.5, with the origin located at the lowest contact between the blade and the housing. With the goal of determining the mechanical advantage offered by the shear cutter design, several assumptions had to be made:

Assumptions:

- The blade is only in contact with the housing on the outer side, thus only one friction force is considered.
- The location of point C (Figure 5.4) is unknown, and must be determined
- The force applied from the piston to the top of the blade is concentrated at the outer edge of the blade
- The rod force is the maximum force required to cut the rod using a shear technique as determined in Chapter 3 (F_{NRod} = 29.25 kN)
- The coefficient of friction, μ = 0.30 is chosen since the housing is a mild steel in contact with a polished O2 blade steel.

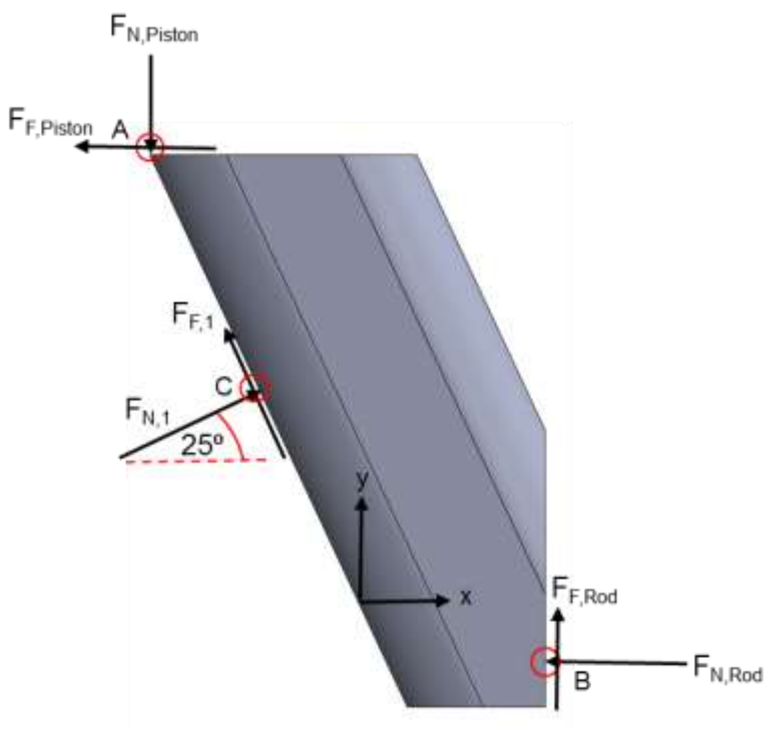


Figure 5.4 Free body diagram of the cutting blade in the closed position

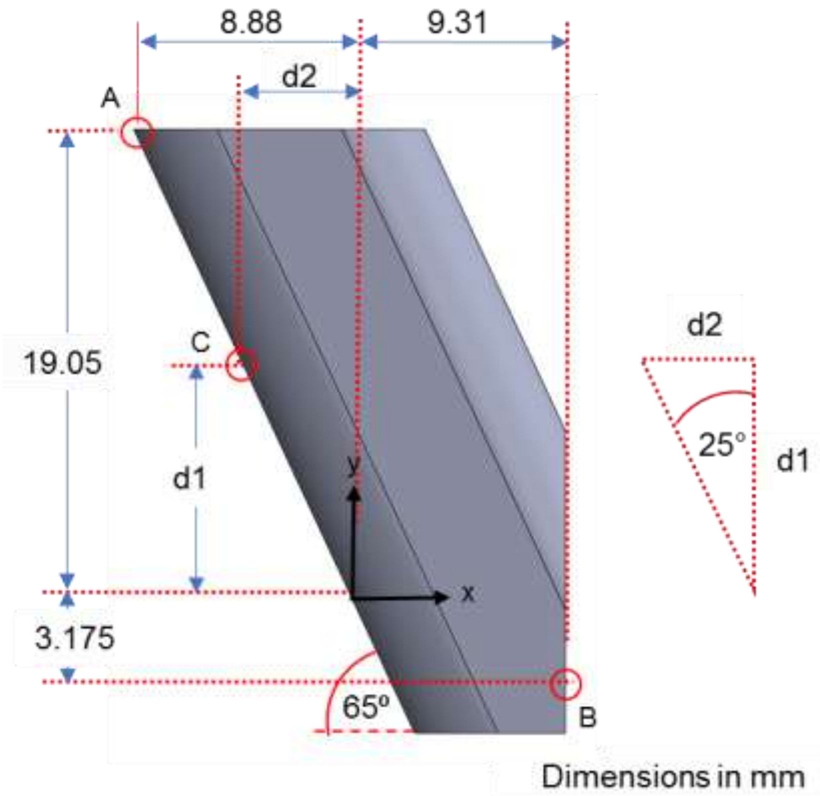


Figure 5.5 Dimensions necessary to perform analysis of forces shown in Figure 5.4

The equations summing the forces in the x and y directions provide enough information to determine the force acting on the piston $F_{N,Piston}$, and the normal force $F_{N,1}$.

$$\sum F_x = 0$$

Equation 5.1

$$-F_{N,Rod} + F_{N,1}(\cos 25 - \mu \cos 65) - \mu F_{N,Piston} = 0$$

$$\sum F_y = 0$$

Equation 5.2

$$\mu F_{N,Rod} + F_{N,1}(\sin 25 + \mu \sin 65) - F_{N,Piston} = 0$$

$$F_{N,Piston} = 48.03\ kN$$

$$F_{N,1} = 56.39\ kN$$

Thus the mechanical advantage of the system can now be determined by taking the ratio of the output shear force to the required input force on the piston:

$$MA = \frac{F_{N,Rod}}{2 * F_{N,Piston}} = \frac{29.55}{96.06} = 0.31$$

Since the mechanical advantage is less than 1, this indicates that the shear cutter design requires a greater input force than it outputs to cut the rod.

The location of the normal force from the blade contact with the case can now be determined:

$$\sum M_C = 0$$

Equation 5.3

$$F_{N,Piston}(8.88 - d2) + \mu F_{N,Piston}(19.05 - d1) - F_{N,1}(d1 + 3.175) + \ \pi F_{N,1}(d2 + 9.31) = \ 0$$

where:

$$d2 = d1 \tan 25$$

In Equation 5.3, all distances are in mm and all forces are in kN. Substituting in the known forces and solving for d1 and then d2 gives: $d1 = 11.08$

$$d2\ = 5.16$$

5.1.3 Discussion

The first prototype of the shear cutting design was fabricated and tested in the Instron. After one successful preliminary shearing of a 6.35 mm cobalt chromium alloy rod, one of the blades sustained a brittle fracture (Figure 5.6). The likely cause of the blade fracture was the misalignment of cutting blades when initially contacting the rod (Figure 5.7) that might have been caused by a shift in the housing alignment. However, the experimental version of the cutter did not have linkages to hold the blades in a parallel orientation. Instead, the blades were positioned manually prior to the cutting sequence and any small misalignment could have led to the failure. In addition, it was found that the less hardened metal housing deformed on the side of the broken blade and this suggested that the hardened blade ploughed into the softer housing thus preventing the intended sliding motion. Finally, the shear-cutting technique caused a moment to be applied to the rod and a reaction moment would be applied to the housing. This reaction moment might have caused housing deflection that increased the ploughing action.

Figure 5.6 Broken cutting blade which failed during experimentation

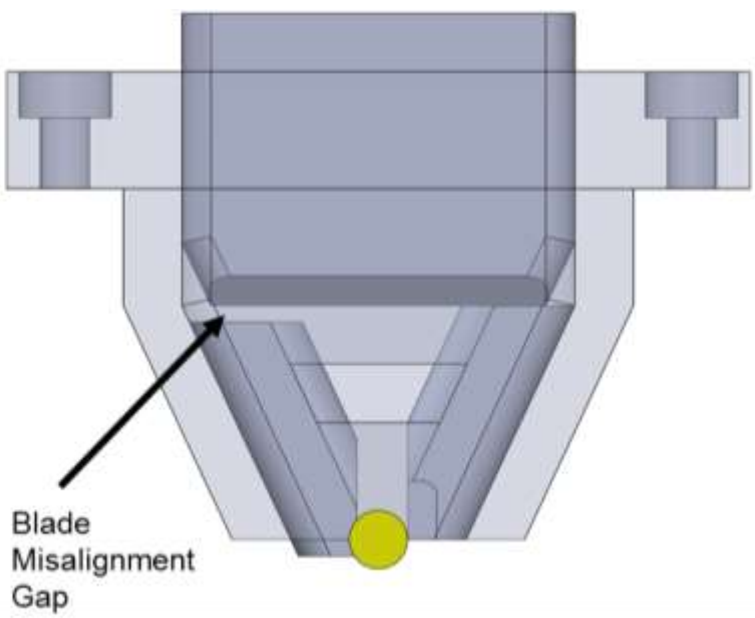


Figure 5.7 Depiction of how misalignment of the experimental tool blades may have occurred in the starting position

The functional problems with this shear-cutter mechanism were not the only issue with this design. Based on the aforementioned analysis of forces during cutting, it is clear that this mechanism does not provide any mechanical advantage to assist in shearing rods. The amount of input force gets reduced by two thirds thus, a pneumatic cylinder would have to be quite large to deliver such high forces to operate the cutter. It now seems clear that the force analysis, should have been performed earlier, it might have discouraged the development and testing of a prototype. For these reasons, the second design alternative was pursued instead of this shear cutter design.

5.2 Bolt Cutter Design

5.2.1 Force Analysis

An important feature of the bolt cutter was the linkage that was intended to give a mechanical advantage to the overall mechanism. This would allow the pneumatic cylinder to be small and thus improve the ease of use of the bolt cutter. In Section 3.2, a manual bolt cutter was analyzed to determine the mechanical advantage. The bolt cutter design alternative (Figure 5.8) was analyzed in somewhat similar but more rigorous manner to determine the mechanical advantage the mechanism provides. This information is then used to determine the sizing of the pneumatic cylinder powering the mechanism.

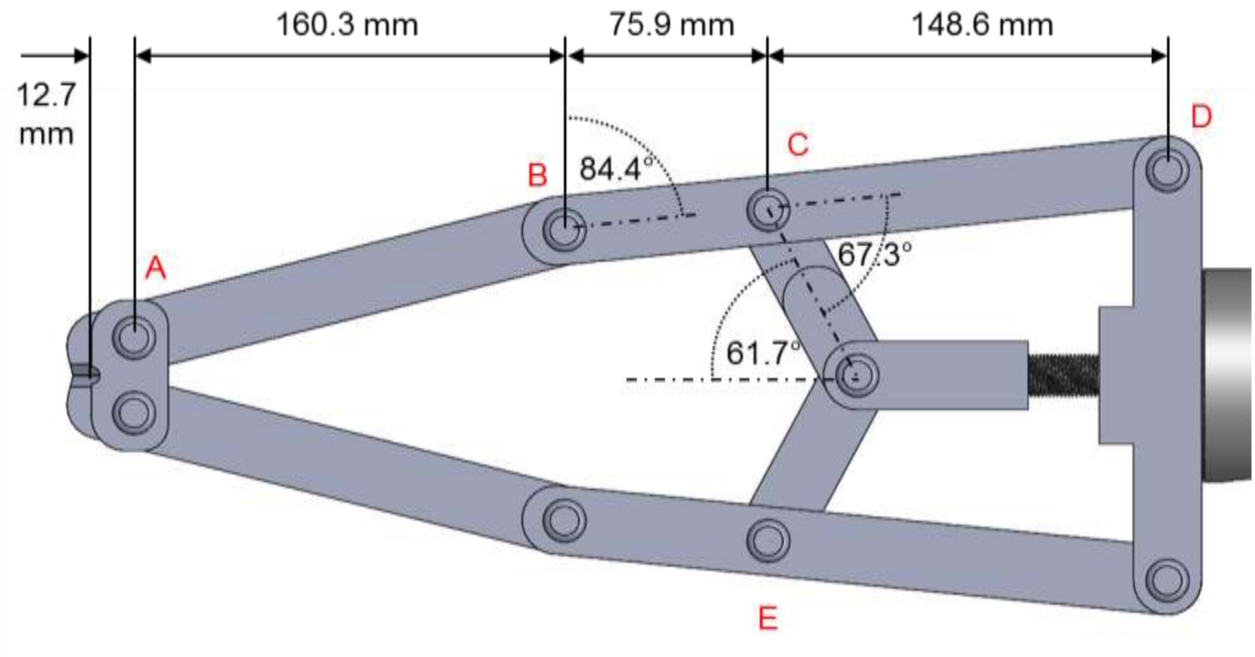


Figure 5.8 Drawing showing the dimensions necessary to calculate the mechanical advantage of the bolt cutter in its closed position

A free body diagram was generated for each of the segments needed to perform the calculation of mechanical advantage. Link AB is shown in Figure 5.9, and the static equilibrium equations are derived as follows.

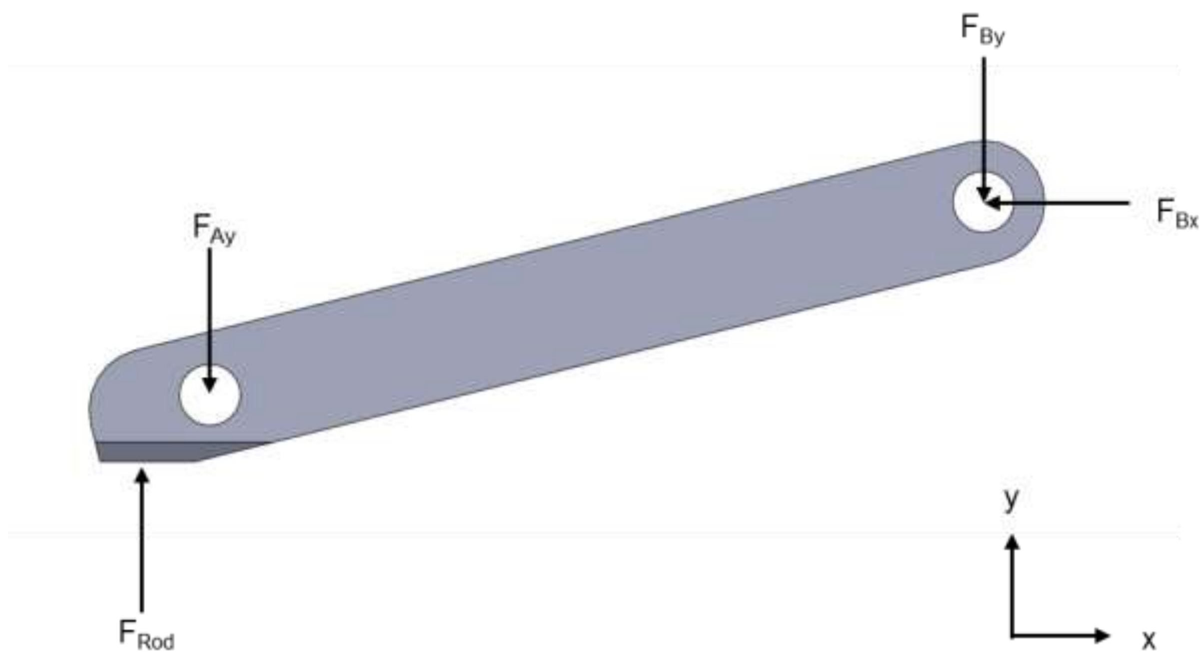


Figure 5.9 Free body diagram link AB (the cutting blade) in the closed position

Note that there is no force acting on point A in the x direction. Since the connecting member between the blades is a two force member in static equilibrium, there is no force acting in the x direction thus,

$$\sum F_x = 0$$

$$F_{B_x} = 0$$

The moment is then taken about point A which acts as the fulcrum in this lever:

$\sum M_A = 0$

$-12.7F_{Rod} - 160.3F_{B_y} = 0$

Equation 5.4

$$F_{B_y} = \frac{-12.7}{160.3}F_{Rod}$$

As shown above, the pin force in the y direction is known in terms of the rod force. The equations derived from the free body diagram of link BD (Figure 5.10) can now be solved for:

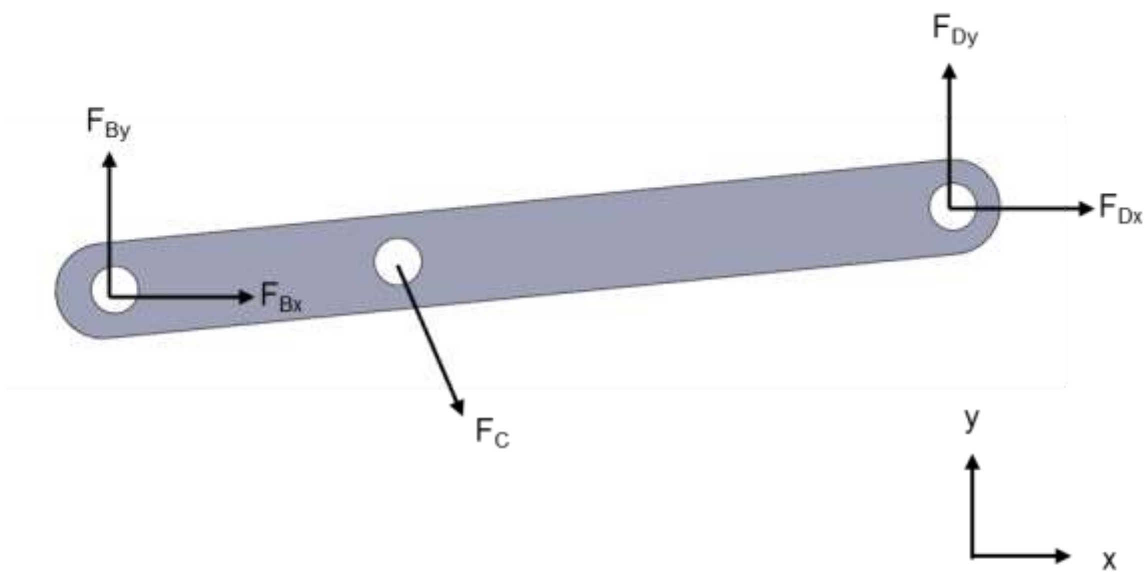


Figure 5.10 Free body diagram of link BD

The moment is taken about the fulcrum of this link, at point D:

$$\sum M_D = 0$$

$$148.6F_c \sin 61.7 - (148.6 + 75.9)F_{B_y} + 148.6F_c \cos 28.3 = 0$$

Equation 5.5

$$F_c = \frac{(148.6 + 75.9)F_{B_y}}{(148.6 \sin 61.7 + 148.6 \cos 28.3)}$$

Equation 5.4 and Equation 5.5:

Equation 5.6

$$F_c = -\frac{(148.6 + 75.9)}{(148.6 \sin 61.7 + 148.6 \cos 28.3)} * \frac{12.7}{160.3} F_{Rod}$$

Thus, F_C is now expressed in terms of F_{Rod} (Equation 5.6), and by inspecting the free body diagram of the piston link pin (Figure 5.11) it is obvious that F_{Piston} = 2*F_C*cos61.7

thus F_{Piston} can now be expressed in terms of F_{Rod} (Equation 5.7) to get the mechanical advantage.

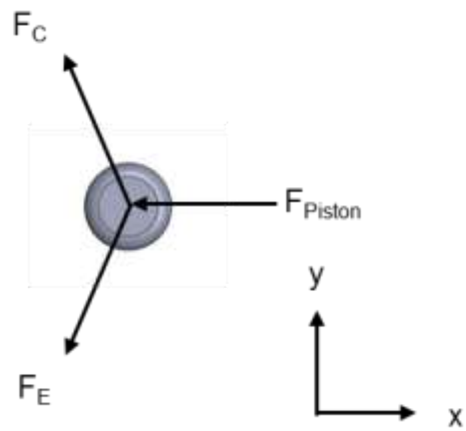


Figure 5.11 Free body diagram of the piston connecting pin

Equation 5.7

$$F_{Piston} = 2 * \left(\frac{(148.6 + 75.9)}{(148.6 \sin 61.7 + 148.6 \cos 28.3} * \frac{12.7}{160.3} F_{Rod} \right) \cos 61.7$$

Thus, the mechanical advantage is F_{Rod}/F_{Piston} = 8.17 or F_{Piston} is determined to be:

$$F_{Piston} = 0.1224 F_{Rod}$$

Knowing this relationship (mechanical advantage) between the F_{Rod} and F_{Piston}, and the required force, of 37.4 kN (F_{Rod}) to cut the rod using the bolt cutting technique, the piston diameter can be sized. The pneumatic lines in hospitals typically supply a pressure of 200 psi (1.38 MPa), thus, the minimum piston diameter could be determined as follows:

Equation 5.8

$$F_{Piston} = P_{guage} * A_{piston}$$

where:

$F_{Piston} = 37.4 * 0.1224 = 4.578\ kN$, (required force for the mechanism to be able to cut the rod)

$P_{guage} = 1.38\ MPa$, (supply pressure)

$A_{piston} = \pi(\frac{D}{2})^2$, (face area of the piston where D is the diameter

Therefore:

$$D = \sqrt{\frac{4 * F_{Piston}}{\pi P_{guage}}} = \sqrt{\frac{4 * 4578}{\pi * 1378.95 \ * 1000}} = 65\ mm \approx 2.6\ in$$

Since pneumatic cylinders were likely to be fabricated in standard Imperial sizes, a 3 inch (76.2 mm) diameter piston could be selected to ensure adequate force is provided to the mechanism.

5.2.2 Prototype Development

As in the development of the shear cutter design, simplifications were made to the design for purposes of initial prototyping. Inner links were removed from the design and replaced with a linear spreader, the linear guide was replaced with a simple link to hold the blades together, and finally the pneumatic fixture was replaced with a smaller unit which acted as a housing for the linear spreader (Figure 5.12).

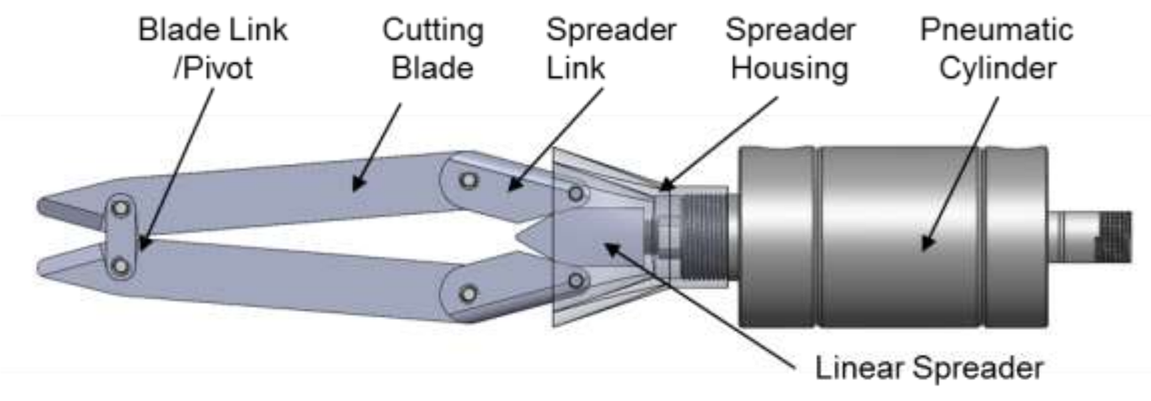


Figure 5.12 3D rendering of simplifications made to the original bolt cutter design, for initial prototyping.

These simplifications were made in order to demonstrate the concept of the pneumatic cylinder’s linear motion being transformed into an angular motion of the cutting blades. A 3D printed prototype of the design specified in Figure 5.12 was fabricated to demonstrate the motion capabilities of the linkages connected with the piston. The sequence of motions is captured in the three pictures (Figure 5.13, Figure 5.14 and Figure 5.15) which did not include the pneumatic cylinder.

Figure 5.13 3D printed “proof of motion” prototype in starting position

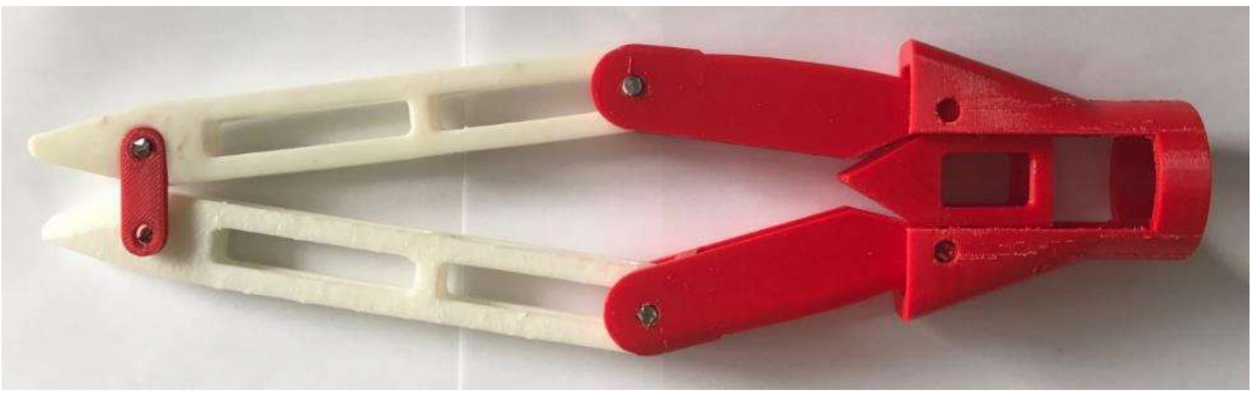


Figure 5.14 Proof of motion prototype, showing in the position of mid-cut

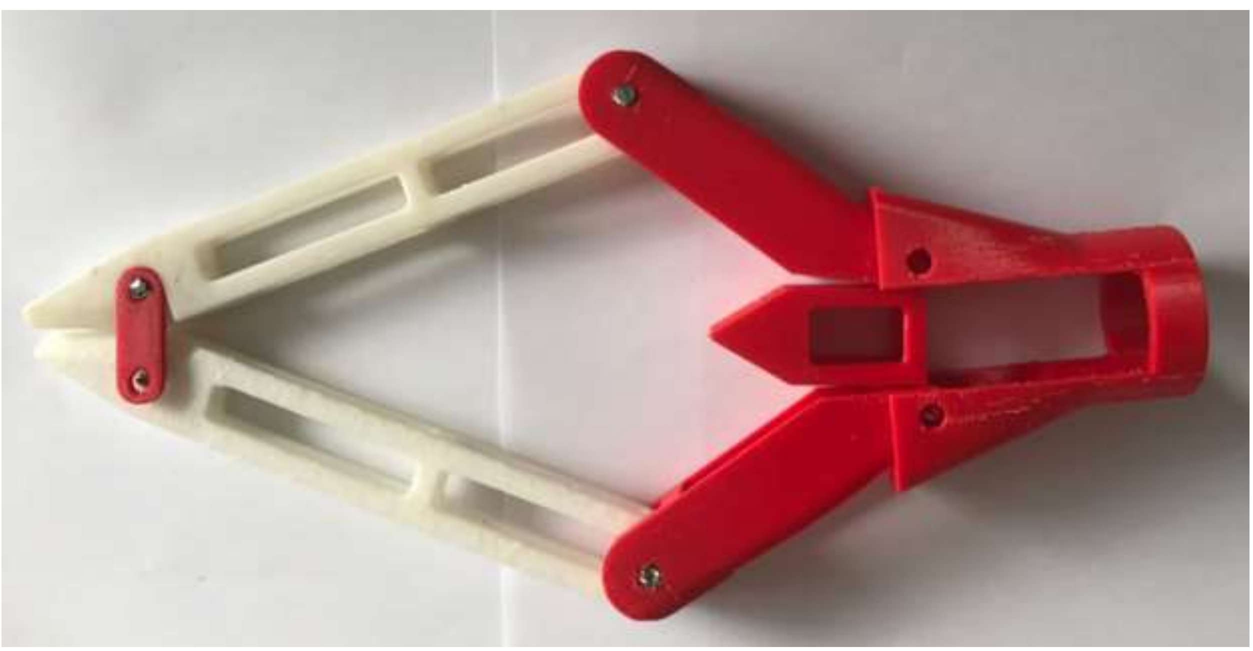


Figure 5.15 Proof of motion prototype shown in final position at the end of the cut.

The prototype demonstrated that the cutting blades would behave in a manner similar to the existing in-situ rod cutter, while requiring very little room to operate around the spinal rod. However, this simplified version did not attempt to demonstrate the mechanical advantage of the bolt cutter design. This would require precision manufacture of the components of the bolt cutter design using medical grade stainless steels or equivalent materials such that realistic forces could be applied.

Due to time constraints, no further work was done to develop this design. More analysis, prototype development and prototype testing would be needed to complete the implementation of this design.

5.3 Discussion

Both of the alternative designs were subjected to development as part of the implementation. The shear cutter design was originally chosen as optimum in competition with a bolt cutter design. After some simplifications, a prototype of the shear cutter design was fabricated and its ability to cut large diameter (6.35 mm) cobalt alloy rods was investigated. Unfortunately, after one successful cut was made, the prototype blades fractured. While some design modifications might have allowed the shear cutter to perform better, it was clear that it did not satisfy at least one of the constraints and had perhaps been over-rated in the criteria scoring. Focus was shifted to the bolt cutter design. This was a more conventional approach and its bolt-cutting technique did work for the existing manual in-situ bolt cutters. A mechanism connecting a pneumatic cylinder to the cutting blades was checked analytically for its mechanical advantage. A prototype was made from a polymeric material using 3D printing to demonstrate the mechanism motion. Unfortunately, there was not time for further development of this promising design.

6 Conclusions and Recommendations for Future Work

An engineering design process was applied to develop a new design for an *in-situ* spinal rod cutter. Experimental work was performed to determine the technical requirements of the design. Constraints and criteria were developed from a combination of surgeon experience, experimental results and engineering experience. Two alternative designs (shear cutter and bolt cutter) were presented and given scores based on the criteria established. The shear cutter design was initially chosen as the optimum one but it was abandoned after fracture problems in the prototype testing. The implementation of the bolt cutter design was initiated. The conclusions of this thesis are as follows:

1. Shear cutting and bolt cutting techniques successfully cut the titanium, stainless steel and cobalt chrome alloy rods, while the pipe cutting technique that was tested in Chapter 3 did not successfully cut the cobalt chrome alloy rods.

2. When employing the bolt-cutting technique, it was found in Chapter 3 that the force required to cut the rod increased with the rod diameter. However, the rod material seemed to have little effect on the required cutting force, probably because the rods all had similar similar yield strengths.

3. The cobalt chrome alloy rods, with maximum standardized diameter of 6.35 mm, required the most force to cut. In Chapter 3, the shear cutting technique gave an average cutting force of 26.08 ± 1.19 kN (average ± standard deviation) which was slightly lower than the bolt-cutting technique force of 29.66 ± 1.29 kN.

4. The shear-cutting technique produced better cut end surfaces compared with the bolt-cutting technique.

5. In order to ensure that any design developed, using either a shear or bolt-cutting technique, would be able to cut all spinal rods, six standard deviations were added to the experimentally determined averages. This factor of safety was chosen to ensure

that all spinal rods could be cut. A shear cutting design needed to provide a minimum of 29.55 kN of cutting force while a bolt-cutting design should provide a minimum of 37.04 kN of cutting force.

6. Of the two design alternatives developed, the higher scoring design was the shear cutting design. The bolt cutting design score was slightly lower than the shear cutting design. A prototype of the shear cutting design was developed and tested, but it fractured upon initial testing. The likely cause of this fracture was material selection, friction and component sizing. Rather than redesign this alternative, the second alternative design was developed.

7. A mechanical advantage of 8.17 was identified for the bolt cutter mechanism and a 3 inch (76.2 mm) diameter pneumatic cylinder was sized to meet the force requirements necessary to cut rods using the bolt cutter design.

8. Due to time constraints, the fabrication and testing of the bolt cutting design alternative was not performed. A 3D printed model was used to demonstrate the main mechanism kinematics. The bolt cutting design shows optimistic potential for further development.

The development of the selected bolt cutting design did not reach a final product-readiness stage, but future work should be performed to test and iterate upon the design developed. It was considered likely that in this future work some of the design criteria would be modified and a design evolution would occur. The following recommendations are made for furthering this work.

1. Optimization of the bolt cutter linkage lengths and leverage points should be performed with the intent to maximize the mechanical advantage these links provide.

2. Finite element analysis should be performed to optimize the sizing of the design components. This could help to reduce the overall weight and size of the design, which would improve its performance.

3. Safety of operating the designed cutter should be addressed because the current state of the design had pinching points that would be a hazard in the operation of the cutter.

4. Ergonomics and marketing are aspects that should eventually be considered.

Since the engineering design process is an iterative process which results in the evolution of the design, only immediate and milestone based recommendations can be made at the present stage. Furthering the development of this *in-situ* rod cutter will reveal more aspects of design which will need to be considered. The work presented in this thesis provides a researched foundation for the development of an *in-situ* spinal rod cutter.

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