PROMETHEE ANALYSIS OF CERVICAL DISC DEVICES

A THESIS SUBMITTED TO THE GRADUATE SCHOOL OF APPLIED SCIENCES OF NEAR EAST UNIVERSITY

By

RUKAYAT OYIZA SALAWU

In Partial Fulfillment of the Requirements for the Degree of Master of Science in Biomedical Engineering

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I hereby declare that all information in this document has been obtained and presented in accordance with academic rules and ethical conduct. I also declare that, as required by these rules and conduct, I have fully cited and referenced all material and results that are not original to this work.

Name, Last name:

Signature:

Date

To my Family

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ABSTRACT

Aging naturally causes the spine to undergo gradual degradation. The vertebra is degraded diseases like neck pain and cervical spondylosis. People within ages above 60 years often experience this conditions. Spinal treatment procedures include both surgical and non-surgical procedures. One of the most common surgical procedures that exists a standard for the treatment is anterior cervical discectomy fusion (ACDF). Although studies have explored its use extensively, drawbacks detected such as, reoccurrence of symptoms, reoperation and infection of the cervical spine, necessitated the need for new alternatives. One of such alternatives is cervical disc arthroplasty (CDA) for better and in some cases restored motion in the cervical spine. The existing CDA devices available have nonetheless achieved high success rate, however few flaws that require re-implantation of the devices have been recorded in long term studies. Therefore a need to adequately evaluate the existing device types based on the different parameters that can affect the patient. The objective of this study is to evaluate the parametersand features affecting the choice of CDA devices and customization for each patient. The study modelled a new CDA device using the best ranking feature from each evaluated devices. The new model weighed 7.35 g and 1867.18cm^3. fuzzy PROMETHEE a multi-criteria decision-making tool was used for the analysis. The result showed PCM to be the least favorable. The rankings were based on the weights, criteria and parameters used for the analysis.

Keywords: Anterior cervical discectomy fusion (ACDF); cervical disc arthroplasty (CDA); fuzzy PROMETHEE; decision-making

ÖZET

Doğal olarak yaşlanma, omurganın kademeli olarak bozulmasına neden olur. Omurga, boyun ağrısı ve servikal spondiloz gibi bozulmuş hastalıklardır. 60 yaşın üzerindeki insanlar genellikle bu koşulları yaşarlar. Spinal tedavi prosedürleri hem cerrahi hem de cerrahi olmayan prosedürleri içerir. Tedavi için bir standart olan en yaygın cerrahi işlemlerden biri, ön servikal diskektomi füzyonudur (ACDF). Her ne kadar çalışmalar yaygın olarak kullanımını araştırmış olsa da, semptomların tekrar ortaya çıkması, servikal omurganın yeniden işlenmesi ve enfeksiyonu gibi tespit edilen dezavantajlar yeni alternatiflere ihtiyaç duyulmasını gerektirmiştir. Bu tür alternatiflerden biri, daha iyi ve bazı durumlarda servikal omurgada restore edilmiş hareket için servikal disk artroplastisidir (CDA). Mevcut mevcut CDA cihazları yine de yüksek başarı oranına ulaşmış, ancak cihazların yeniden yerleştirilmesini gerektiren az sayıda kusur uzun vadeli çalışmalarda kaydedilmiştir. Bu nedenle, hastayı etkileyebilecek farklı parametrelere dayanarak mevcut cihaz tiplerini uygun bir şekilde değerlendirme ihtiyacı. Bu çalışmanın amacı, CDA cihazlarının seçimini ve her hasta için kişiselleştirmeyi etkileyen parametreleri ve özellikleri değerlendirmektir. Çalışma, değerlendirilen her cihazdan en iyi sıralama özelliğini kullanarak yeni bir CDA cihazı modellemiştir. Yeni model 7,35g ve 1867,18 cm^3 ağırlığındaydı. bulanık PROMETHEE analiz için çok kriterli bir karar verme aracı kullanılmıştır. Sonuç PCM'nin en az elverişli olduğunu gösterdi. Sıralamalar, analiz için kullanılan ağırlıklara, kriterlere ve parametrelere dayandırıldı.

Anahtar Kelimeler:Anterior servikal diskektomi füzyonu (ACDF); servikal disk artroplastisi (CDA); bulanık PROMETHEE; karar verme

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ABBREVIATIONS

ELECTRE:	Elimination and Choice Expressing Reality
MCDM:	Multi-Criteria Decision-Making
PROMETHEE:	Preference Ranking Organization Method for Enrichment of Evaluations
CDA:	Cervical Arthroplasty Disc Device
CAD:	Computer Aided Designs
ACDF:	Anterior Cervical Discectomy Fusion
ASD:	Adjacent Segment Degeneration

CHAPTER 1

INTRODUCTION

The cervical spine is commonly associated with several pathological conditions such as cervical radiculopathy, neck pain and myelopathy which are common diseases related with the severe non-inflammatory disc degenerative disease known as cervical spondylosis and cervical stenosis due to aging. Spondylysis is a multifactorial disease following the degeneration of the cervical intervertebral disc (Rose Bist et al. 2018). This degeneration takes place at the invertebral disc stem due to the development of osteophytes in the amphiarthrodial joint, contrasting with arthritis, which is associated with diarthrodial joints and synovial space. Cervical spondylosis affects about 95% of people over the ages of 65 years (Mullin et. al. 2019). This condition could result in lower back pain, symptomatic radiculopathy, and myelopathy.

Surgical treatment in most of the cases include the use of fusion techniques such as anterior cervical discectomy fusion (ACDF), anterior cervical corpectomy, posterior microdisectomy and posterior cervical laminectomy. ACDF has be used as a reference point in the long term treatment spine related problems, results have shown that above 90% of patients who have undergone this treatment suffer another degenerative change in the neighbouring spinal segments. Symptoms show for 1 in four of these changes which would necessitate surgery in about 10 years. Meanwhile reoperation rates reach 2.9% level/year (Latka D et.al 2019). These clinical evidences paved the way for the invention of a concept called adjacent segment degeneration (ASD) (Latka D. et al 2019). These shortcomings from the use of disc fusion prompted the need for an alternative approach. Disc arthroplasty offers the opportunity to preserve and re-establish motion in an intervertebral segment which may have required surgical fusion. The shortening or removal of the adjacent level disc degeneration has been controversial in the clinical setting nonetheless it is expected to preserve segmental motion (Fong S, et al 2006). Latka et al 2019 described cervical disc arthroplasty as a concept for motion preservation in adjacent and index disc segments to further reduce the risk of ASD. Cervical arthroplasty prosthesis (CDA) aimed

at maintaining normal range of motion in the vertebra include; the Bryan disc, Prestige, ProDisc-C, Discovery, PCM, Mobi Disc, Cervicoree.t.c each of these prosthetic devices are produced under certain principles of design. The design principles take into consideration the fixation, integration and type of material for construction, articulation of the vertebral bodies (SekhonLHS, 2005).

The existing prostheses are discussed in the next chapters with an insight on the design criteria advantages and shortcomings of each type. Comparisons would also be made to obtain the rankings of each in terms of bearing type and material, wear rate, particle generation, shock absorption, reoperation, and device failure, follow up, adjacent level disease. The thesis seeks to evaluate the existing prosthesis and design a new prosthesis based on the design principles, cost and reoperation rates based using a fuzzy based ranking method (fuzzy PROMETHEE) and CAD methods using solid works.

1.1.Thesis Problem

- Disc degeneration is an inevitable condition when aging which differs in degree and progression (Qi-Bin Bao, et al 1996), hence a treatment type available is necessary to ensure correctness in treatment. Anterior cervical discectomy ASDF is one of the commonly performed surgical procedures for the spine (Sundseth, J., Fredriksli, O.A., Kolstad, F. et al. 2017). Surgical treatment of spinal condition often involving ACDF often requires a patient to undergo surgeries again within a time space of 10 years Latka et al 2019 due to the degeneration of adjacent segments.

- The risk of infection and repeated surgeries and preserved motion in the vertebra required the need for alternative approaches. Cervical disc arthroplasty provides mobility and has shown a slightly higher result in the treatment of spinal condition. Existing prosthetic devices for CDA have to be scrutinized in order to create better long lasting designs.

1.2.Aims of the Study

- To evaluate and rank the most common CDA devices using fuzzy-PROMETHEE.

- To simulate and determine the most desirable treatment device tailor made for specific patients based on some contributing factors.
- To determine with a degree of confidence the most efficient treatment that results in the least negative effects on the patient.
- To design a new prosthetic device for CDA

1.3.Significance of the Study

- The findings of this study will reduce incidence of re-operative procedures due to infections and degeneration and provide guided and informed device type to be implanted.
- It would also enable patients get a direct information on how device types would affect them in vivo.
- The findings of this study will also make it easier to make a decision on the best treatment option to undertake that will result in desirable results with the least negative effects on the patient.
- An outflow ranking of the most suitable devices based on several factors would be provided in this study.
- The study would incorporate design features which rank best in the each existing device for the design of a new cervical disc device.

1.4.Limitations of the Study

- In order to verify the consistency of the data used in this study, original data from patients would be required, nonetheless, secondary data was obtained and used.
- The weight of each parameter differs depending on the clinician.
- VISUAL PROMETHEE software is one of the readily available decision making tools and it was used in this study, however additional software would greatly improve validity of results.

- Each type of device is designed differently hence there is no real reference point for comparison.
- in vivo testing for the new disc could not be conducted due to lack of available laboratories and time

1.5.Overview of the Thesis

Chapter 1 covers the introductory chapter of the entire thesis work. It gives a description of the thesis problem, aim of the study, significance of the research and the limitations present in the study. Chapter 2 gives a comprehensive clinical background of the spine and diseases associated with the spine, surgical and non-surgical procedures available for treatment. Chapter 3 presents a literature review of earlier studies performed in this area of research and Chapter 4 explains the method employed in the analysis of prior methods used and design of a new CDA device. Chapter 5 and 6 presents the results of the study, the discussion and the conclusion respectively.

CHAPTER 2

LITERATURE

2.1 OVERVIEW

This section presents the pathology cervical diseases and the existing devices for the treatment of the diseases. Brief illustration of studies on the advantages and limitations of the devices would be provided.

2.2 RADICULOPATHY AND MYEOLOPATHY

Cervical disc degeneration and cervical spondylosis are common problems associated with aging which can affect the cervical spine examples of such are; radiculopathy and myeolopathy (Yang B, et al. 2012). One common consequence this is, spinal cord dysfunction in the cervical spine (Bakhsheshian, Joshua et al. 2017). About sixty percent of the population have shown significant evidence of degeneration of the cervical spine (Yang, Baohui et al. 2012). A huge amount of incidences related to radiculopathy and myelopathy can occur when a patient has spondylosis and degenerative disc diseases. A vast majority of people with spondylosis show no symptoms and those that are symptomatic have a tendency to be older or with 40 years old. Symptomatic patients show three major symptoms; neck pain cervical myelopathy and radiculopathy.

2.2.1 RADICULOPATHY

Radiculopathy shows a spinal nerve root issue. Symptoms of cervical radiculopathy generally start with either herniated nucleus pulposus, neural foramine or spinal canal osteophytic stenosis. Symptoms of cervical radiculopathy normally presents itself in patients' <55 years old owing to a herniated nucleus pulposus, while those older often have stenosis due to osteophytes. Common symptoms include; motor and sensory symptoms related to soft herniated disc and hard herniated disc respectively,

paresthesias, hyperesthesia, hyperalgesia, weakness and atrophy (Mullin, Jeffrey &Shedid, Daniel &Benzel, Edward. 2019).

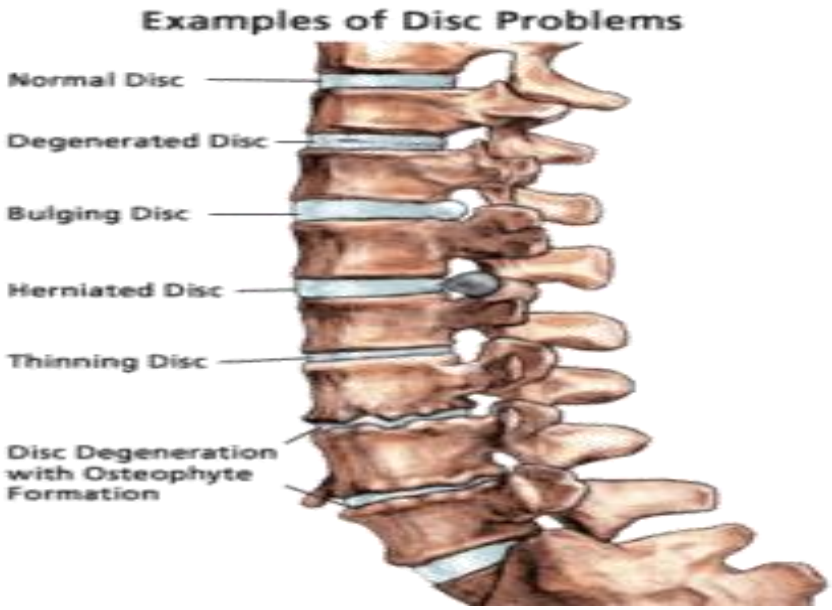


Figure 2.1 Cervical disc and associated disc problems(retrieved from https://www.cawleypt.net/2017/04/20/causes-neck-pain-affecting-arm-hand/ 20-Aug-2019)

2.2.2 MYELOPATHY

Myelopathy is a spinal cord related issue. Due to inhibition of the spinal afferent or efferent (pyramidal) nerve tract, it infers the existence of long-tract indications. Sarah et al. 2018 reported that 4 in 100000 people in North America experience cervical myelopathy (Sarah McCartney, Richard Baskerville, Stuart Blagg and David 2018) which is also more prevalent in a ration 2.7: 1 for men and women respectively but however varies by region (Vijay Kumar GomatamRaghavan, Ray Dibyendu Kumar, Das Rupant Kumar, 2019). Some treatments for cervical myelopathy are surgical, non-surgical and management techniques. Surgical treatment takes place either in two forms posteriorly or anteriorly. With the posterior method laminectomy is done while in the anterior case, ACDF is carried out. Symptoms of cervical myelopathy include; sensor and motor changes, neck and shoulder pain. Gait changes in patients' with the myelopathy has recorded a decrease in length of stride and increase time of support.

2.3 TREATMENT TECHNIQUES

2.3.1 ANTERIOR FUSION

Anterior cervical discectomy fusion is the most widely used technique to remove damaged discs in the cervical vertebra and filling the space between the discs with a bone. This method reduces the pressure in adjacent vertebra and nerves, hence easing weakness, pain and numbness. In their meta-analysis of random controlled tests/trials (RCTs) for cervical radiculopathy surgical therapy, Gutman G, Rosenzweig DH, Golan JD (2018) showed that ACDF is efficient as one of the therapy methods in the therapy of cervical radicular diseases, however there was insufficient evidence to indicate if the ACDF technique is the most effective to provide a long lasting symptom relief. ACDF is one of the frequently used standards for symptomatic therapy of cervical diseases (Laratta, J. L., Shillingford, J. N., Saifi, C., &Riew, K. D. 2018). ACDF is considered to be the thumb rule for the therapy of cervical disc disease-initiated radiculopathy and myelopathy as it is generally a reliable technique to achieve broad neural decompression, stabilization of the spine and the clinical results it offers are outstanding. Nonetheless with the ACDF technique fusion regrettably causes the inevitable removal of motion which could increase stress levels across the adjacent disc spaces, leading to adjacent segment pathology (Laratta, J, et.al 2018) acceleration of adjacent segment degeneration and potential risks include pseudoarthrosis (Hu Y, et. al 2016). However with time, degeneration or instability sometimes occurs in the segments adjacent to the fused spinal segments. The instability could lead to an imbalance of stress distribution along the vertebra and compensatory increase in activity of the fusion segment. Although there are high chances of adjacent segment degeneration (ASD) occurring after an ACDF surgery, in a study to compare the effect of postoperative between total disc replacement (TDR) and ACDF it was discovered that there was no significant difference in both techniques. Nonetheless ASD has an adverse long term effect on ACDF surgery patient's recovery, hence it is a main concern for anterior cervical complication (Si-Dong Yang et al. 2017).

2.3.2 CDA

The development of CDA was to maintain the biomechanics and natural motion of the cervical spine and segments without fusion. Therefore the CDA techniques was made to reduce some of the draw backs of ACDF by eliminating non-fusion and decreased adjacent segment pathology. This would subsequently decrease iatrogenic adjacent segment degeneration. Due to these, CDA has gradually become an acceptable surgical treatment for symptomatic cervical problems (Laratta, J. L., 2018). Cervical arthroplasty has been seen to preserve mobility and excellent clinical outcomes for almost 40 months after surgery. The differences between anterior cervical fusion and arthroplasty in 2-level degenerative disease were found in a research by Fay et al. (Fay Ly, et al. 2014). The complication and the issue of preserving motion regarding ACDF in cervical biomechanics led to the development of cervical disc arthroplasty (CDA). There have been studies in this field such as in the area of single and multilevel CDA and hybrid surgeries (Laratta et al, 2018, Hu Y. et al. 2016) etc. The theoretical advantage of CDA biomechanically has shown that it can sustain segmental range of motion and preserve the cervical kinematics thus the avoidance of hampering on the adjacent segment degeneration (Hu Y. et al. 2016). Nevertheless, (Hu Y. et al. 2016) mentioned some of the possible drawbacks of CDA, such as subsidence (implant migration), an increased incidence of heterotopic ossification. Also in another comparison of ACDF with a CDA prosthesis (Mobi-C) a huge overall success in the CDA group was recorded in terms patient satisfaction, neck disability index (NDI) scores within a period of 4 years. Laratta, J. L, et al 2018 reported the following in their study;

- Patients of ACDF undergo a higher follow up surgery compared to CDA patients and the reoperation rate was considerably lower for the CDA group.

- In terms of adjacent radiographic disk degeneration, the rate of adjacent radiographic section disease (RASP) was also discovered to be greater in the ACDF group relative to the CDA group.
- Two-level arthroplasty and anterior cervical fusion clinical results are comparable about 40 months after surgery.
- Cervical arthroplasty maintains mobility without increasing adverse effects at index concentrations. In 2-level cervical disease, the CDA is more of a cost-effective operation than the ACDF.

A meta-analysis conducted by (Hu Y et al 2016) to compare the medium to long-term effectiveness and safety of CDA with ACDF in the treatment of cervical symptoms reported the findings about the advantages of CDA in terms of;

- superior adjacent segment
- Neck Disability Index (NDI) success
- adverse events related to implant/surgery
- neurological success
- secondary procedure
- overall success
- efficient outcomes
- beneficial to patient

Recommendations

A 7-year follow up to a prospective randomly conducted studies by the U.S food and drug administration FDA for the ProDisc C device found the ACDF group with more than 400 percent more revision procedure than the CDA groups. The CDA groups were also with higher mean savings and quality adjusted life year (QALY) than the ACDF group (Laratta, J. L., et al 2018).

Indications

Arm pain in single-level, neck related pain and function, and overall health status in patients with symptoms.

Osteoporosis, severe kyphosis, instability, disc height loss of more than 50%, facet arthroplasty, ossification in the posterior longitudinal ligament, multilevel spinal diseases and inflammatory arthroplasty.

Incidence

In addition to ASD degeneration in the anterior segment, dysphagia is another complication arising from anterior cervical processes with an incidence of up to 21 percent in 2 years. Dysphagia happens in 33 percent to 40 percent of patients in multilevel fusions. A reduced incidence of postoperative dysphagia after disk arthroplasty (CDA) was half that in ACDF in a potential randomized trial, which could be due to a reduced anterior implant profile and a reduced retraction needed during instrumentation compared to ACDF. Due to the conservation of cervical biomechanics, CDA would not necessarily prevent adjacent segment pathology, there is a reduction relative to ACDF. CDA offers comparable clinical results in one-level illness and with notable decrease in secondary techniques and complete cost of health care. In mid-term studies of 2-level CDA, significant improvements in clinical outcomes have conducted to reduce the occurrence rate of index level and reoperation of adjacent level compared to two level ACDF in properly diagnosed patients (Laratta, J. L., et al 2018).

CHAPTER 3

LITERATURE REVIEW

3.1 The CDA Device Design

CDA devices are implanted to preserve motion in segments of the cervical spine in the design of a CDA device, the kinematics of the cervical covers the extent and quality of cervical range of motion. A flexion-extension motion of a typical cervical spine ranges from, 68° to 76° (Range 24°-114°) for lateral bending, 139° to 145° (Range80°-200°)for axial rotation and 45° (Range 22°-81°). With age motion in the cervical decreases linearly across the lateral, axial and extension axis although the largest loss occurs in the extension axis (Laratta, J. L., 2018). Several prostheses can cover bending ranges from 15 ° to 20 °, 7 ° to 10 ° and 20 ° to 360 °, lateral bending and rotation respectively. Each sub axial cervical spine disc space has a multi-parameter rotation center (COR). Cervical movement is coupled and flexion is strongly linked to anterior translation and axial rotation happens at the same time as lateral bending. However, the COR is situated in the frontal body of the working vertebra and in the sagittal axis due to lateral bending and rotation (Laratta, J. L., et al 2018). During the rotation of the upper cervical vertebra towards the left, the lower articular process on the left moves cranially and anteriorly towards the upper vertebral process below it, while the contralateral lower articular process shifts subsequently and caudally leading to a lateral bending movement towards the rotation side and the same procedure happens when the cervical rotation is contralateral. The instant center of rotation (ICR) is responsible for the shift in position of the COR for each cervical segment. The position of the ICR translates superiorly throughout the caudal region during flexion-extension, and the anterior posterior shift in the segment of the ICR position declines with every movement. Various CDA implants endeavor to mimic the coupling and re-estimate the cervical spine's innate movement (Laratta, J. L., et al 2018).

3.2 DESIGN CHARACTERISTICS

Design characteristics of implant are important for proper functioning and longevity of TDR (Pierce D et.al 2018) so also a CDA device. The articulating surfaces of the device should be able to minimize friction, tolerate the expected load without failure or fatigue,

minimal debris generation, wear characteristics that are better than others, and permanent fixation of the implant to the adjacent vertebral bodies (Pierce D et.al 2018).

3.2.1 Degrees of Variation

Cervical disc prosthesis have moderate degrees of variation, such as implantation techniques, bearing design, materials, and articulation type. Bearing designs can be; semi-constrained, constrained or unconstrained.

***Constrained*:** a device with this type of bearing has a physical stop that permits movement within the natural cervical ROM. The stability of the operated joint is greatly enhanced hence reducing shear forces along the facet joints. A drawback of this means a more difficult operation would be carried out because the bone implant connection is of concern as well as its exact placement and positioning to properly imitate the natural axis of rotation.

***Semi-constrained*:** Semi-constrained bearings combine physical stops to allowing a ROM outside the natural one.

Unconstrained: unconstrained bearings do not have a physical stop permitting for increased mobility operating as the reverse of the constrained device at the cost of reduced stability. This bearing type does not place emphasis on the implant forces but on the adjacent facet joints.

3.2.2 Material types

Due to continuous research and development of materials for arthroplasty, there are broad range of materials used for cervical disc devices: Ti alloy-ceramic composites, polyethylene, polyurethanes, titanium (Ti) alloys, cobalt-chrome (CoCr) alloys and stainless steel. The choice for materials used places emphasis on the outer surface of the prosthesis that is in contact with the vertebral body. The materials for bearing surfaces of the prosthesis have to be made to minimize loading without fatigue (fracture), generation of wear debris and friction, and have better wear characteristics. The ultra-high molecular weight polyethylene (UHMWPE) is an example of a construct for articular surfaces from certain polymers. A cervical artificial disc's initial stability rests on the device design and

its geometry, surrounding soft tissue tensioning. Long-term fixation relies on the surface of the prosthesis for bony ingrowth. Coatings on the surface of the device enhance bony ingrowth like wire meshes, porous CoCr, plasma spraying all made from titanium and bioactive materials e.g. calcium phosphate and hydroxyapatite.

***Stainless steel*:** this metal inhibits the use of MRI hence the rare use for arthroplasty. It is an iron alloy mostly composed of carbon and other elements. Stainless steel has at least a mass percent of 10.5 chromium. This prevents stains, corrosion or rust, an example of stainless steel such; Marine grade stainless 316 steel is mostly applied in medical implantations due to the high rate of immunity from sensitization. The Bristol/Cummins disc uses stainless steel in its design and has recorded 22 implanted device in about 20 patients with a long term follow up of 12 years. However its use is waning due to the development of newer metals with better yields strengths. Both titanium and Cobalt are the most commonly used materials and the success in use of titanium for arthroplasty devices can be attributed to this due to the high rates of long-term success.

***Cobalt-Chrome (CoCr)*:** the alloy is composed of cobalt and chromium that has an extremely high specific strength with 2 times the stiffness of titanium. CoCr alloy is composed of 5–7% molybdenum which is mostly used for surgical implantation typically referred to as cobalt chromium molybdenum (CoCrMo). Their good qualities such as excellent biocompatibility and corrosion resistance, allergic reaction, lower risks of irritation as well as immune response makes it greatly used for implantations typically owing to the development of chromium oxide films spontaneously on the surface of the bony implant during synthesis rendering it to be a biocompatible material with the surrounding physiological environment.

Titanium Alloy:Titanium metals are low density metals with high strength, very high corrosion resistance. Titanium metal is generally alloyed with metals such as molybdenum, vanadium, iron and aluminum for light weight manufacturing and powerful alloys. The biocompatibility of the metal alloy makes it a suitable substance for implantation of medical devices. For biomedical usage as implants the alloying is done with about 4 to 6% aluminum and 4% vanadium. In terms of osseointegration the alloys have an ability to mimic that of a bone with better mechanical compatibility. This can be attributed to their

low young's modulus compared to other metals and their alloys. Bonding of bone to pure titanium does not need intervening materials such as membrane or scaffold. Porous titanium spray-coatings are developed to encourage long term fixation on the outer surfaces of a cervical implants in the spine. More so hydroxyapatite as a surface coating has been greatly significant for titanium alloys. Titanium alloys have shown higher wear rate as a bearing surface in arthroplasty compared to cobalt-chrome and stainless steel due to the reduced abrasion resistance qualities. The strength of the implant-bone fusion determines the success of the titanium material when it is used for other arthroplastic devices. To improve success rates surface features or characteristics were developed such as screw fixations, spikes, wire mesh, increased porosity, keels and specialized coatings i.e. calcium phosphate, hydroxyapatite, titanium, aluminum oxide and plasma-sprayed.

***Polyethylene*:** the extensive use of polyethylene polymers were based on the applications it found in supporting hip and knee arthroplasties. Polyethylene is a thermos-plastic polymer made up of long chain hydrocarbons with outstanding chemical resistance.

Ultrahigh molecular weight polyethylene-(UHMWPE):

Polyethylene polymer with lengthy chains enabling more efficient load transfer for very high impact resistance.

3.2.3 Articulation type

The type of articulation is the defined as the number of rotational centers. Articulation used in existing prosthesis are ball and socket, saddle, press-fit or flanged. The ball and socket type permits rotation only around one specific point. Articulation enables rotation around a single point unlike the form of saddle type articulation that has a multicenter of rotation (Leven, D., et. al, 2017). The most commonly used design for cervical disc prosthesis consists of metal endplates attached to vertebral body above and below with one or more joints present on the metal on metal or metal on polymer bearing surface (Martin H. et al, 2015).

3.2.4 Bearing types

Cervical arthroplasty devices should articulate with bearings to produce motion, reduce friction during motion when load is applied. When these qualities are not fulfilled the implant fixation could fail and cause wear debris formation which makes the choice of a good bearing design of high importance.

***Metal on polymer*:** this is a bearing design that allows for multiple joint articulation. The bearings design have been used extensively due to their excellent clinical outcomes. Most cervical implants approved by the FDA for use in the U.S combine duplicates of metal alloy prosthetic endplates that articulate alongside an essential polymer core generally combined with CoCr alloy and polymers such as UHMWPE (Leven, D., et. al, 2017).

***Metal-on-Metal*:** this is a bearing design earlier used was a feasible alternative compared to metal on polymer devices due to the decreased friction hence reduced long term wear rate, osteolysis and inflammation however it was discovered that it produced ion toxicity, and hypersensitivity. Other studies have been unable to show how these metal on metal designs would affect the cervical compartment with long term use (Leven, D., et. al, 2017).

3.3 Cervical Disc devices Available

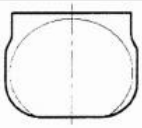
3.3.1 Bryan (The Medtronic Bryan)

The Bryan disc prosthesis is product of Medtronic sofamorDanek and it is a single unit composed of a polyurethane center (PCUcore) that articulates with a two convex titanium alloy shells (Fong, S.Y et al. 2006) with pores on its surfaces for end plate bony in-growth. The polyurethane core is covered by another flexible polyurethane membrane to protect the articulating surfaces from neighboring tissue. A shock absorber for lubrication in the form of a fluid is added inside the membrane to lubricate the articulating core thus imitating the pillowing system of the natural vertebral disc. The polyurethane core has a low immunologic potential compared to polyethylene. The Bryan device is a biarticulating unconstrained device and features 11 different angular motion with 2 millimeters translation in the coronal and sagittal plane joined to the adjoining soft tissues. The device exists in five different diameters. When the device is implanted, the vertebral end plates are rasped into a concave surface to insert the implant and a device is used to find the axial center of the cervical vertebra accurately with the aid of the midline flanked by the

uncovertebral joints for guidance. The vertebral body is then milled for correct implant placement using the main location point. These features have undergone several past and future studies in vivo and vitro tests, analyzed using clinical and radiographic. Some findings showed that the Bryan cervical disk arthroplasty device offers long-term kinesis through movement in the surgical section to offer both surgeons and patients trust in joint replacement as a proven operational strategy or option for spinal disorders therapy. More studies indicate that the (ROM) may be too fundamental in the environment of disc arthroplasty which could cause misaligned components, an increased rate of failure of device and abnormal segmental motion. Secondary problems like the persistent postoperative focal plate kyphosis develop after 6 months with distinct rates of activity. Some papers conclude that the Bryan disc arthroplasty device exhibits a tendency of kyphotic orientation that may cause intraoperative lordotic distraction.

3.3.2 Prodisc-C (Johnson and Johnson)

Prodisc-C device has been approved in several places with a variety of design and names such as Prodisc-C Nova, Prodisc-C and Prodisc-C Vivo. The ProDisc-C device functions as a 2-piece semi-constrained disc in a ball-and-socket bearing. The end plates are made of a porous exterior of cobalt chrome alloy. The inner side of the inferior plate is joined to an out-curved ultra high molecular weight polymer to articulate with a concave inner surface of the upper endplate. The devices rotates around three axes but restricts translation. The endplates of the implant has its exterior with titanium plasma spray with slotted keels for bony ingrowth and long term stability. The keels and porous coatings reduce end plate preparation (Leven, D., et al 2017).

					
	Bryan	**Prestige, Prestige LP**	**Prodisc-C**	**PCM**	**CerviCore**
Footprint					
Footprints available	Diameter mm 14 15 16 17 18	Width depth mm 12* x 12 12* x 14 12* x 16 12* x 18	Width depth mm 15 x 12 15 x 14 17 x 14 17 x 16 19 x 16 19 x 18	Width depth mm 15 x 12 17 x 12 20 x 17	Width depth mm 12x12 12x14 14x16 16x18
Heights	11 mm 10.3 mm compressed	6 mm 7 mm 8 mm	5 mm 6 mm 7 mm	6.5 mm 8.0 mm	5-10 mm
Articulation	Stainless steel-polycarbonate-urethane	Chrome cobalt; metal-on-metal	Chrome cobalt; metal-on-polyethylene	Chrome cobalt; metal-on-polyethylene	Chrome cobalt; metal-on-metal

* Estimated width.

Figure 3.1: Cervical devices and their sizes (Philips F. et al, 2005)

3.3.3 PCM

PCM for (porous-coated motion) cervical artificial disc arthroplasty has upper and lowerend plates generally composed of CoCr alloy enclosing at its center a core made of UHMWPE. The core is sealed off by a lower endplate to work with the upper endplate. The design enables large radial motion and translational increase at the rotational arc when the contacting surface is extended across the entire bearing. For bony ingrowth by the cervical the device uses a titanium calcium phosphate coating on the exterior superior and inferior Cobalt chrome alloy.

3.3.4 DISCOVER (Johnson and Johnson)

The discover device also articulates using a ball and socket process, composed of 2 trapezoidal titanium alloy endplates to imitate the natural working principle of a cervical vertebra. The alloy end plates encloses an ultra-high molecular weight polyethylene operating as an unconstrained device. The endplates are bordered by a 1millimeter teeth

around them and a porous plasma sprayed titanium and hydroxyapatite coating. The devices is multi directional (Leven, D., et al 2017).

3.3.5 Mobi-C

The Mobi-C disc device is a three-component device with two end plates made of cobalt, chromium, 29 molybdenum ISO 5832–12 alloy and an ultra-high-molecular-weight polyethylene center. The edges of the end plates have a ridge of teeth on the lateral exterior titanium plasma coated with a hydroxyapatite spray. The internal contact sides of the lower end-plate is designed to be spherical while the upper end-plate is plane. The middle piece is designed at the center of the lower plate hoisted laterally by two stops, and repeatedly takes the central position each time the top plate moves. The device provides 5 different degrees of motion independent of each other with two translational and three rotational motions. After decompression of a joint, drilling or chamfering of the vertebral bodies may no longer be necessary so as to spare the posterior longitudinal ligament. Once proper implantation is confirmed, space between the joint is compressed using the distraction pins between vertebral bodies.

3.3.6 M6

This is a single-piece device with end plates made with titanium alloy. It is composed of a complex center piece made of a polycarbonate urethane polymer material as a core and it is further surrounded by a polyethylene construct also covered by a polymer to prevent ingrowth of tissue and debris entry. The M6 device permits motion in 6 degrees of motion.

3.3.7 PRESTIGE Medtronic Prestige ST/Prestige LP

The prestige disc is an unconstrained device composed of two individual metal parts. There are two existing variations to the device: a stainless steel, ST model and a titanium LP model. These devices are different in the implantation methods. The original Medtronic Prestige ST artificial disc uses a convex ball made of superior stainless steel articulating with a lower stainless steel that narrows into a concaved trough. The Prestige devices allows more translation with a composite material of titanium and ceramic and a ball and trough socket design. It also has the exterior surface of the plasma end plate lined with titanium coating to encourage bony development in the device.

3.3.8 Cervicore

Cervicore device is composed of a 2-piece semi constrained devices completely made of cobalt-chromium-molybdenum. Each exterior surface contains three spikes and each base is titanium plasma spray coated with two paddles. The device uses a saddle bearing design, to promote motion in two different centers of rotation. One of the centers of rotation is in the vertebral body and completely inferior to the device which represents flexion and extension motion. The second center of rotation is located in the vertebral body directly superior to the implant device for lateral bending. There is an anterior stop to avoid posterior dislocation of the device. A model with vertical processes is introduced into the disc by utilizing the vertical processes to accurately align with the midline. Channels are drilled after a fluoroscopic imaging for proper placement have been done. The drilled channels are further chilled down to properly accommodate the fins of the device end plates (Leven, D., et al 2017).

3.3.9 SECURE-C Device

This is a semi constrained device with a three piece component placed into a disc space as a single entity with two CoCr alloy end-plates and a sliding fiddle made of ultra-high-molecular-weight polyethylene. A porous coating of plasma sprayed end plates with teeth keels permits a press fit and also encourages instant stabilization. The lower and upper exteriors of the middle portion are shaped differently to allow for anteroposterior sliding hence additional physiologic loading coupled with a moving prompt axis of rotation along the sagittal plane. In contrast to other disc type, the lateral annulus and the vertebral end plates are undisturbed during a discectomy (Leven, D., et al 2017).

3.4 Adverse Biologic Effects of CDA Devices

Biocompatibility of implants are highly considered during the construction of a cervical prosthetics the long term effects of the materials used are now more clinically relevant in the course of follow up studies. Effects such as wear debris formation which can result in implant loosening, osteolysis and immune response, pseudotumor formation, and hypersensitivity.

3.4.1 Wear Debris

Debris of the articulating surfaces can be generated due to the gliding of the joints which could adversely cause tissue reactions that might affect the long term use of the device. The host body for the device reacts to wear debris can be linked to particle volume or quantity, the shape and concentration of the debris produced. Materials such as polyethylene-on-metal promotes low friction on the contacting surfaces but with time the wearing produces debris generates that could cause of hip and knee arthroplasty failure according to literature. Several ways to improve polyethylene have been developed like the cross linkage of ultrahigh molecular weight polyethylene with gamma irradiation at the cost of some mechanical properties(Leven, D., et al 2017). For metal on metal articulation the wear rates are lower but produce higher debris volume (quantity) with smaller particles. The metal on metal technique reduces shock absorption and produces needle like particles which have been linked to increased inflammation. The debris formed for metal on metal designs could form molecular complexes due to corrosion products. Wear debris is unavoidable in all bearing but it is encouraged by poor device placement or otherwise.

3.4.2. Immune Response and Osteolysis: when wear occurs immune responses such as hypersensitivity, pseudotumors, metallosis can be arise. In metal on polymer designs in the cervical, minor and major polymeric debris can be produced that can trigger an inherent immune response by the macrophages surrounding tissue activation and enormous cells. Unlike hip arthroplasties, the spine rarely experiences vertebral osteolysis. Due to long term complication osteolysis can be caused by wear debris(Leven, D., et al 2017). One of the most widely recognized osteolysis mechanism implicates implant particulate debris from wearing of any type of material to further participate in inflammation that results in bone erosion, long term tissue damage and implant loosening.

3.4.3. Clinical evaluation: a large degree of clinical notion to avoid the adverse biological effect of wear debris is important for proper diagnosis and treatment. Several inflammatory diseases can cause a type of neuro-inflammatory induced pain at prosthesis sites which may require the removal of the implant depending on the severity. The formation of large pseudotumor due to inflammation can lead to the appearance of cervical radiculopathy or cervical myelopathy, loosening of device and segmental causing axial mechanical pain.

Consistent pain in the neck or arm should constitute a need for proper evaluation using CT, MRI and dynamic radiographs scans for early diagnosis of associated complications.

3.5 Surgical Implantation

The patient lays on the operation table in a supine position with the neck secured in a neutral form with tape across the forehead. The shoulders are also secured in place with a tape permit correct fluoroscopy visualization. During the visualization, the endplates are observed on the lateral fluoroscopy to visualize the parallel positioning. A horizontal incision about 2 inches is made on one side of the patient's neck to expose the damaged disc for removal. The vertebral body is prepared for the device implant by a discectomy and decompression procedure however the foraminotomies are broader than those performed in a typical ACDF(Leven, D., et al 2017). A magnifier (microscope or magnifying glasses for surgical use) ensures that the disc is completely removed and the nerves are properly decompressed. After the completion of the discectomy, the uncovertebral joints are bilaterally decompressed. The decompression is carried out in a careful manner to avoid removing all the osteophytes by curtailing the use of a high speed burr during the process of end-plate preparation. To also minimize HO potential across the disc space hand held devices are recommended. Fluoroscopy is used to ensure accurate alignment of the implant proper implant size in all proportions.

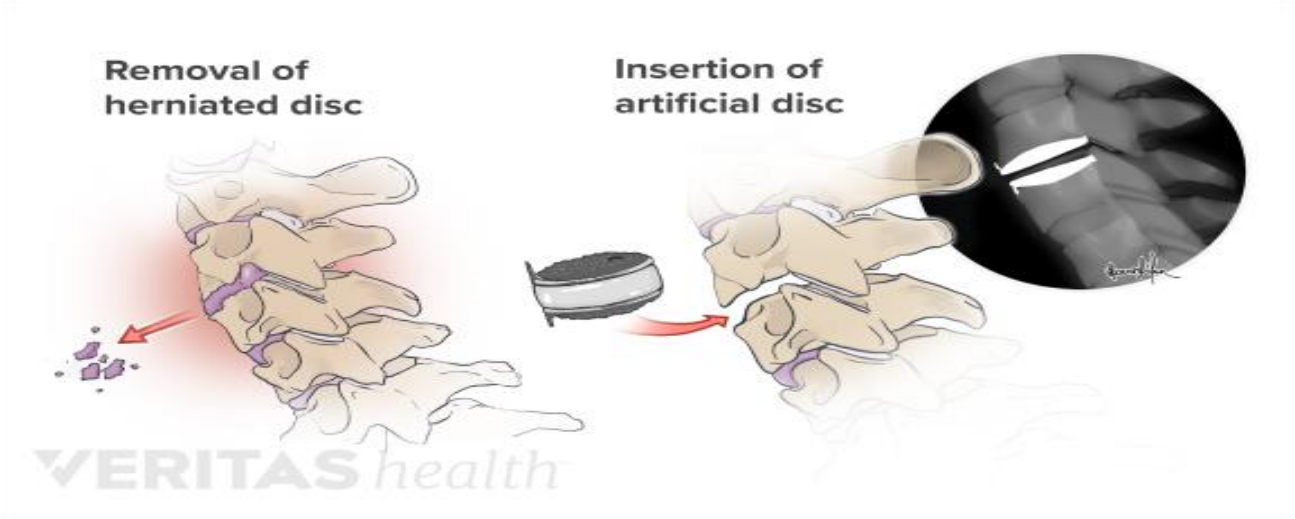


Figure 3.2: Insertion of the cervical disc device between vertebrae**(**retrieved from *https://www.spine-health.com/conditions/herniated-disc/spine-surgery-a-cervical-herniated-disc 20-Aug-2018)*

The proper implant size is selected and placement is done in the prepared disc space on lateral fluoroscopy and confirmed on the AP-view after device placement the incision is closed although extra care is taken to avoid electrocautery on the anterior surface of the vertebral. This is to avoid the formation of HO and most times the incision may be drained after the procedure.

CHAPTER 4

METHODOLOGY

This chapter describes the method applied in the study. Secondary data was sourced for qualities and parameters for cervical disc prosthesis to be used in the study. Fuzzy PROMETHEE as a multi criteria decision making tool was used to articulate these data and the one with the most advantages and feature was used to design a new prosthesis.

4.1 Multi-criteria Decision-Making Method and PROMETHEE (Preference Ranking Organization Method for Enrichment Evaluations)

Data sourced for several studies can be vague, crisp and sometimes uncertain. Fuzzy set theory for modelling complex environments are included in MCDMs to handle the randomness and vagueness in decision making processes (Galindo Hose, 2008). Multi-criteria decision-making (MCDM) has shown good results for analyzing various alternatives in several aspects of research studies (Zionts, 1979 and Mardani et al., 2015). MCDMs are developed for determining the best alternative by qualitative and quantitative means (Seyed et al, 2015). MCDMs can be divided into two categories with respect to the methods of weighing method of each alternative (Majumder, 2015).

i. Compensatory decision making to evaluate the criteria of the parameters, assigns a weight or importance to each parameter and compute the overall score of each alternative according to the weight. The alternative with the best score is selected. This method makes a compromise between the results of poor and good criterion (Seyed et al, 2015) an example of a software that uses this method is TOPSIS (technique for order of preference by similarity to ideal solution).

ii. Outranking type to evaluate the criteria of the parameters as couples to determine the ranking of each parameter (Yang and Wang 2012) e.g. ELECTRE (elimination and choice expressing reality)

Outranking methods have been described as a set of MCDM approach for weak as well as incomparable preferences for real decision representation (Geldermanet, al 2000). Outranking methods such as ELECTRA and PROMETHEE have been implemented as MCDMs by comparing alternatives using generalized preference values Figure 4.1.

PROMETHEE is a tool that allows a user to analyze and rank available alternatives based on the criteria of each alternative. PROMETHEE compares the available alternatives based on the selected criteria. The choice for PROMETHEE usage stems from (Galindo Hose, 2008);

- Simple suitability
- Model preferences are simple and flexible in its own environment
- Intuitive multi criteria decision nature
- Adaptability to finite number of action with respect to criteria

To combine fuzzy sets and PROMETHEE several versions of PROMETHEE were developed such as; FPROMTHEE, FPROMETHEE2T, PROMETHEE III and PROMETHEE V (Galindo Hose, 2008).

4.2 Fuzzy PROMETHEE

This is a multi-criteria tool used for the selection of alternatives out of crisp data available. The method has been implemented by a number of researches in different fields such as for material selection (Muhammet et al. 2018), supplier selection (Senvar O et al, 2014), for ranking equipment failure modes (Maracela P, et al 2009) and fuzzy PROMETHEE (José Ramón San Cristóbal Mateo, 2012) etc. it was developed by Bans and Vincle in 1985 and consequently improved by Brans et al in 1986 (Muhammet et al, 2018). Fuzzy PROMTHEE uses fuzzy preferences and weights in the selection of an alternative in qualitative and quantitative terms.

The steps expressed by Brans et al 1986 for the PROMETHEE method are as follows;

Step I determining a function f_k as the general preference of $p_k(d)$of each criterion

Step II the weight of each criterion

$$w^T = (w_1, \ldots, w_k) \tag{4.1}$$

can be normalized by making the weights equal or by using

$$\sum_{k=1}^{K} w_k = 1 \tag{4.2}$$

Step III determine the outranking relation π for every alternative a_t, $a_{t'} \in$ A equation;

$$\begin{cases} AXA \rightarrow [0,1] \\ \pi(a_t, a_{t'}) \end{cases} = \sum_{k=1}^{K} w_k . \left[p_k \left(f_k(a_t) - f_k(a_{t'}) \right) \right] \tag{4.3}$$

Step IV determine the strength of the positive and negative outflows equation 4.4 and 4.5 where T is the number of alternatives. The positive outflow shows the superiority of the alternatives a_t and each and the reverse for a negative outflow character.

Positive outflow a_t:

$$\Phi^+(a_t) = \frac{1}{T-1} \sum_{\substack{t'=1 \\ t' \neq t}}^{n} \pi(a_t, a_{t'}) \tag{4.4}$$

Negative outflow $a_{t:}$

$$\Phi^-(a_t) = \frac{1}{T-1} \sum_{\substack{t'=1 \\ t' \neq t}}^{n} \pi(a_{t'}, a_t) \tag{4.5}$$

Step V the higher positive outflow and lower negative outflow depicts the best alternative a_t. In PROMETHEE I if a_t is superior compared to $a_{t'}$ $(a_t P a_{t'})$

$$\begin{cases} \Phi^+(a_t) > \Phi^+(a_{t'}) \; and \; \Phi^-(a_t) < \Phi^-(a_{t'}) \; or \\ \Phi^+(a_t) > \Phi^+(a_{t'}) \; and \; \Phi^-(a_t) = \Phi^-(a_{t'}) or \\ \Phi^+(a_t) = \Phi^+(a_{t'}) \; and \Phi^-(a_t) < \Phi^-(a_{t,} a_{t'}) \end{cases} \tag{4.6}$$

PROMETHEE I weighs the probable incomparabilibilty in the analysis and hence partial rankings found may be used. When incomparability or indifferences ($a_t I a_{t'}$) are found the positive and negative outflows are identical.

($a_t I a_{t'}$) if: $\Phi^+(a_t) = \Phi^+(a_{t'}) \; and \; \Phi^-(a_t) = \Phi^-(a_{t'})$ (4.7)

When a_t is superior to$a_{t'}$ with respect to the positive outflow then both alternatives are incomparable ($a_t R a_{t'}$) and the reverse applies to the negative outflow.

$$(a_t R a_{t'}), \text{if} \begin{cases} \Phi^+(a_t) > \Phi^+(a_{t'}) \text{ and } \Phi^-(a_t) > \Phi^-(a_{t'}) \\ \Phi^+(a_t) < \Phi^+(a_{t'}) \quad \text{and } \Phi^-(a_t) < \Phi^-(a_{t'}) \end{cases} \tag{4.8}$$

Step VI: PROMETHEE II gives a complete ranking through the netflow. A high netflow for $a_t$indicates that $a_t$is superior to $a_{t'}$

$$\Phi^{net}(a_t) = \Phi^+(a_t) - \Phi^-(a_t) \tag{4.9}$$

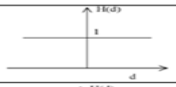
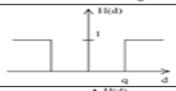
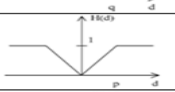
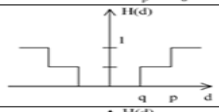
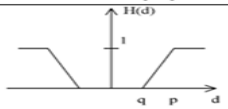
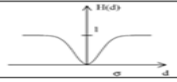
Type of genera- lazed criteria	Analytical definition	Shape	Parameters to define
Type I. Usual criterion	$H(d) = \begin{cases} 0, & d = 0; \\ 1, & \lvert d \rvert > 0. \end{cases}$		--
Type II. Quasi-criterion	$H(d) = \begin{cases} 0, & \lvert d \rvert \le q; \\ 1, & otherwise. \end{cases}$		q
Type III. Criterion with linear preference	$H(d) = \begin{cases} \frac{\lvert d \rvert}{p}, & \lvert d \rvert \le p; \\ 1, & \lvert d \rvert > 0. \end{cases}$		p
Type IV. Level-criterion	$H(d) = \begin{cases} 1, & \lvert d \rvert \le q; \\ 1/2, & q < \lvert d \rvert \le p; \\ 1, & otherwise. \end{cases}$		q, p
Type V. Criterion with linear preference and indifference area	$H(d) = \begin{cases} 1, & \lvert d \rvert \le q; \\ \frac{\lvert d \rvert - q}{p - q}, & q < \lvert d \rvert \le p; \\ 1, & otherwise. \end{cases}$		q, p
Type VI. Guassian criterion	$H(d) = 1 - \exp\{-\frac{d^2}{2\sigma^2}\}$		σ

Figure 4.1: Types of Generalized Criteria

4.2.1 Implementation to the project

Table 4.1: Linguistic scale of importance

Linguistic scale for evaluation	Triangular fuzzy scale	Importance ratings of criteria
Very high (VH)	(0.75, 1, 1)	Bearing type
Important (H)	(0.50, 0.75, 1)	Reoperation rate
Medium (M)	(0.25, 0.50, 0.75)	Wear rate

Low (L)	(0, 0.25, 0.50)	Shock absorption
Very low (VL)	(0, 0, 0.25)	

All parameters for the CDA devices are collected from secondary sources and the Gaussian preference was used in the evaluation. The fuzzy PROMETHEE software used was Visual PROMETHEE which would create a method for the weights and parameters to be evaluated properly even with crisp data. In table 4.2, the type of cervical discs and the criteria selected, these data were gotten from secondary sources and are represented as Bearing type (BT), Bearing material (BM), Wear rate (WR), Particle generation (PG), Shock absorption (SA), reoperation (Re-op), Device failure (DF), Follow up (FU), Adjacent level disease (ALD). A Gaussian preference function was selected for the analysis as used in (Ozsahin, 2016).

Criteria	**BT**	**BM**	**WR**	**PG**	**SA**	**Re-op**	**DF**	**FU**	**ALD**
Unit								years	
Preference									
Min\Max	Max	Max	Min	Min	Max	Min	Min	Min	Min
Weight	0.92	0.92	0.92	0.92	0.75	0.50	0.92	0.75	0.92
Preference function	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian
Evaluations									
Bryan disc	Average	Very good	Moderate	Low	Very good	1	0	2	1
Prestige	Bad	Average	Low	Moderate	Average	15	0	7	11
Prodisc	Average	Good	Moderate	Low	Good	0	0	5	2
PCM	Average	Good	Moderate	Low	Good	3	8	7	0
Discover	Average	Good	Moderate	Low	Good	2	0	2	2

Table 4.2: Cervical disc alternatives along-side criteria using VISUAL PROMETHEE

Criteria	BT	BM	WR	PG	SA	Re-op	DF	FU	ALD
Unit								years	
Preference									
Min\Max	Max	Max	Min	Min	Max	Min	Min	Min	Min
Weight	0.92	0.92	0.92	0.92	0.75	0.50	0.92	0.75	0.92
Preference function	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian	Gaussian
Evaluations									
Bryan disc	Average	Very good	Moderate	Low	Very good	1	0	2	1
Prestige	Bad	Average	Low	Moderate	Average	15	0	7	11
Prodisc	Average	Good	Moderate	Low	Good	0	0	5	2
PCM	Average	Good	Moderate	Low	Good	3	8	7	0
Discover	Average	Good	Moderate	Low	Good	2	0	2	2
New device	Very good	Very good	Very high	Very low	Very good	0	0	2	0

Table 4.3: Cervical disc alternatives for the new disc using PROMETHEE analysis

4.3 COMPUTER AIDED DESIGN (CAD):

This is an environment for engineers to create and modify manufactured design, using specialized computer packages for simulation, solving and optimizing design problems, to produce solutions to such problems (chee, et al. 2017). Due to advances in computer designs there has been an increase in the manufacture of complex models and materials. These advances provide flexibility for a range of predicted and unpredicted uncertainties for a digital model. The desired design goals and constraints can be tackled with the use of

computer aided designs (Jun Wu, et al 2019). This design technique has been implemented in a number or researches such as in; understanding the biological information using optimized stresses (Tetsuo Oya et al, 2018), in the design of alignment for dental depth images in an intraoral scanner (Min S, et al. 2018), in virtual reality (Seth M, et al, 2018) etc.

4.3.1 Implementation of CAD to Design of CDA device

Solid works software was used to bring to life the desired features of a cervical disc device following the PROMETHEE analysis conducted. The Bryan disc gave the best alternative for cervical devices in terms of the nine criteria selected.

4.3.2 Structure of the Device

The design is a three part device composed of an inner core padded on the top and bottom side by a porous metal alloy endplate. The metal on polymer articulation was also selected based on the results from the PROMETHEE analysis.Titanium alloy and polyurethane materials were selected for the design due to the advantages mentioned below. For the work the attempted weight is 2.14-5.54g (Fayazzi et al, 2015) as that of the DISCOVER device as seen in Figure 2.1. The device has a height of 6mm and a diameter of 5mm.

- Porous titanium alloy end plate
- The porous titanium alloy end plates is sprayed and coated with hydroxyapatite
- A three piece structure
- A central polyurethane sheath
- metal on polymer design

4.3.3 Choice for porous titanium alloy material

Titanium alloy was selected based on its low modulus of elastic and also due to its low density. The porous titanium alloy Ti-Al-4Vsolution treated and aged (SS)would be used as the endplate material for the following reasons;

- Superior mechanical characteristics
- Biocompatibility and innate ability for osseointegration (Mehta et al, 2015)

- Can be used for fiber metal coatings and sintering
- Safety for use in the human body
- Average in growth of 15% to 30% (Matassi et al, 2013).

Material properties can be seen in the appendix.

4.3.4 Choice for polyurethane (PUR) and polyetherethylketone (PEEK)

Poly urethane was also selected for the inner core of the cervical disc devices due to its high shock absorption properties (Dahl et al. 2011). The PUR material would be used for the design of the inner core while PEEK would be used as a flexible covering for the inner core. Material properties can be seen in the appendix.

CHAPTER 5

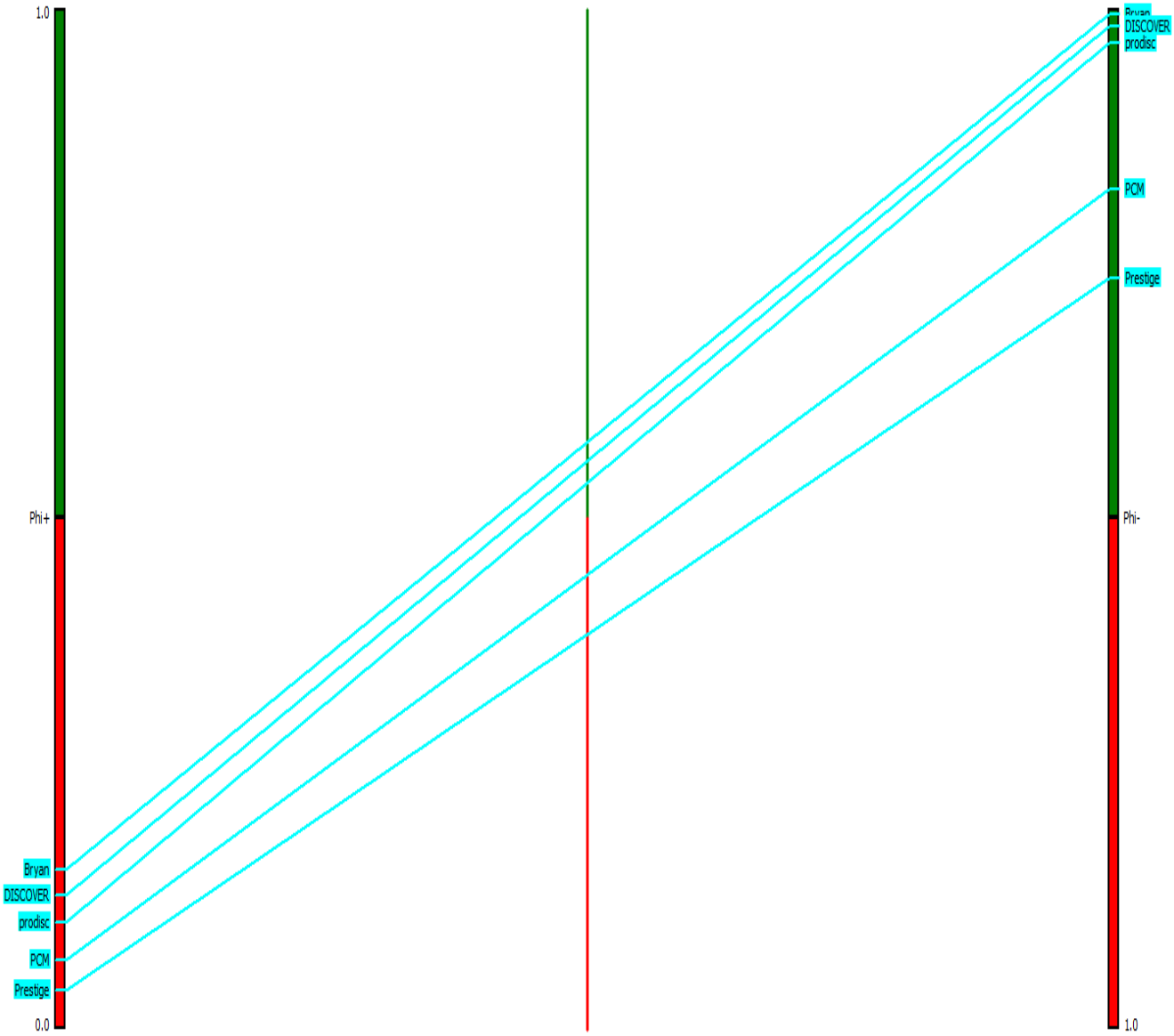
RESULTS

The Fuzzy PROMETHEE method is used to analyze treatment techniques for each scale using the triangular fuzzy number as shown in table one, observing the order of importance of each criterion. It was then applied to measure the weight of each criterion.

Table 5.1: Shows a complete ranking of the treatment techniques, showing the positive, negative and net outranking flow values.

Rank	Net flow	Positive	Negative
Bryan	0,1507	0,1549	0,0042
DISCOVER	0,1144	0,1310	0,0166
Pro disc	0,0716	0,1036	0,0320
PCM	-0,1093	0,0673	0,1767
Prestige	-0,2274	0,0363	0,2637

Figure 5.1: Shows the ranking of each cervical disc device on a net flow-ranking pole of -1 to +1.



Action profile of the high and low points for each of the evaluated CDA devices are shown below

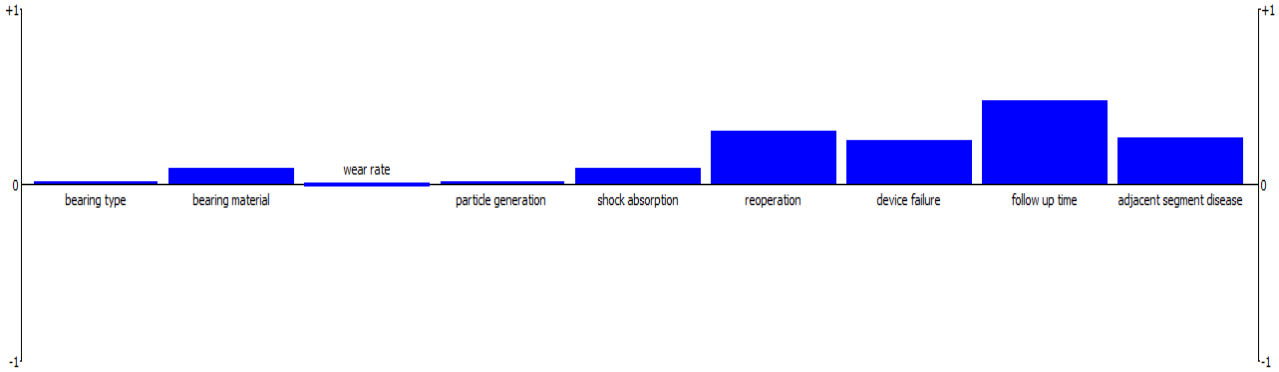


Figure 5.2: Action Profile for Bryan device with a net flow of 0.3817

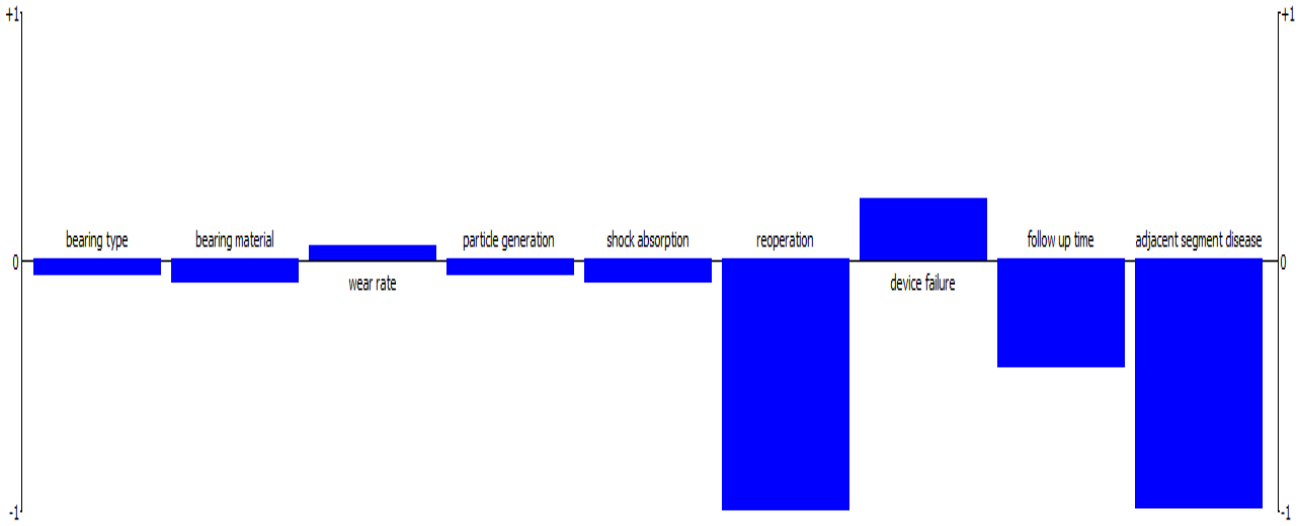


Figure 5.3: Action Profile for prestige with a net flow of -0,5451

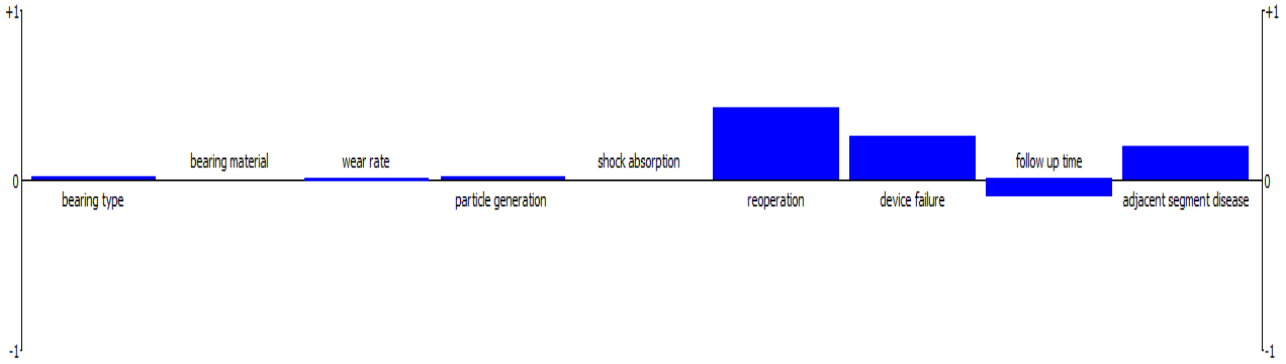


Figure 5.4: Action Profile for Prodisc and net-flow of 0.1005

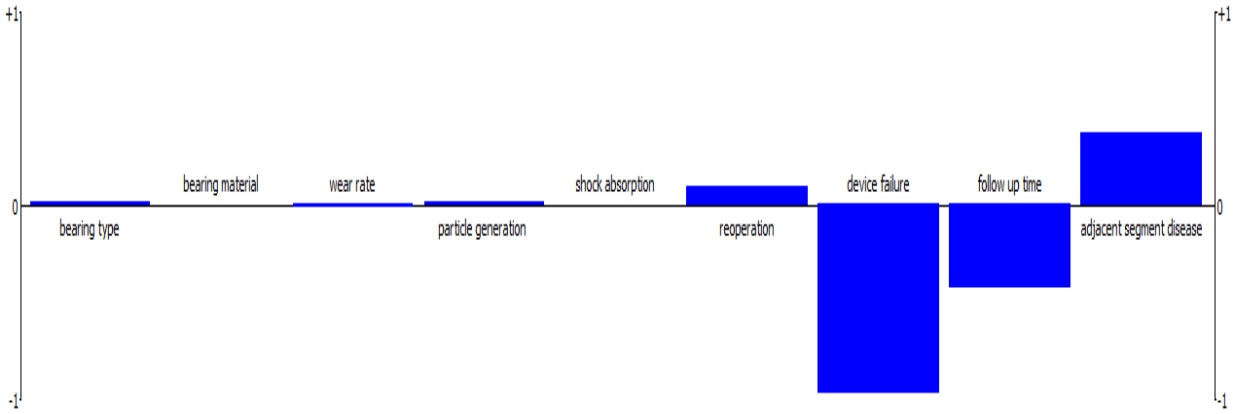


Figure 5.5: Action Profile for PCM with a net-flow discover is -0,0804

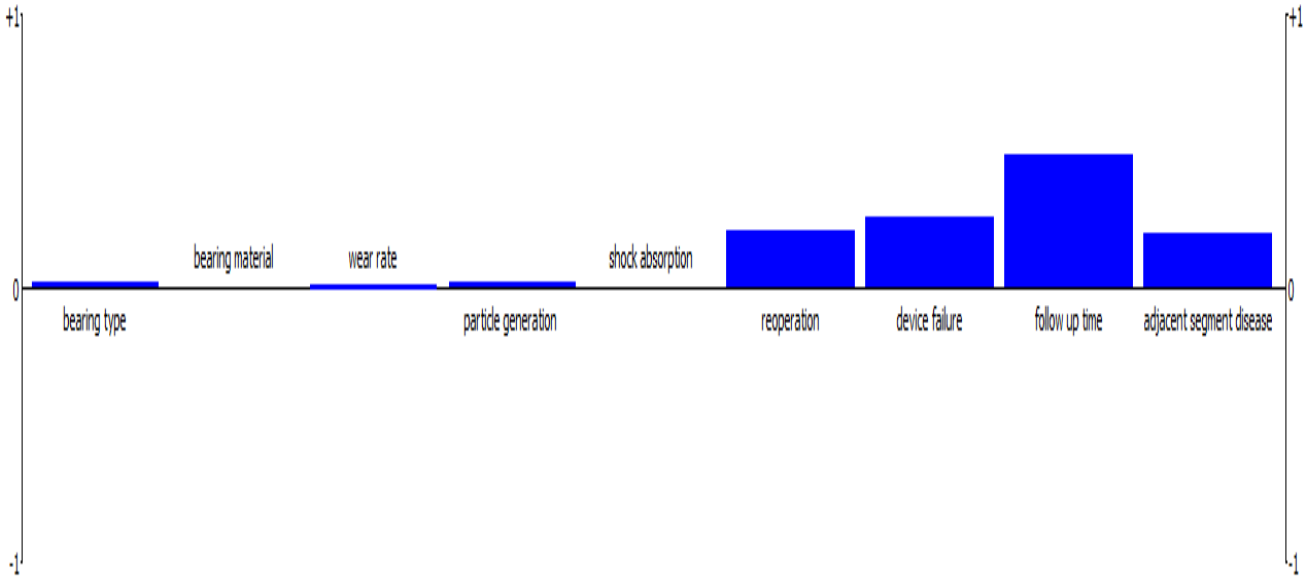


Figure 5.6: Action Profile for DISCOVER with a net flow of 0.1433

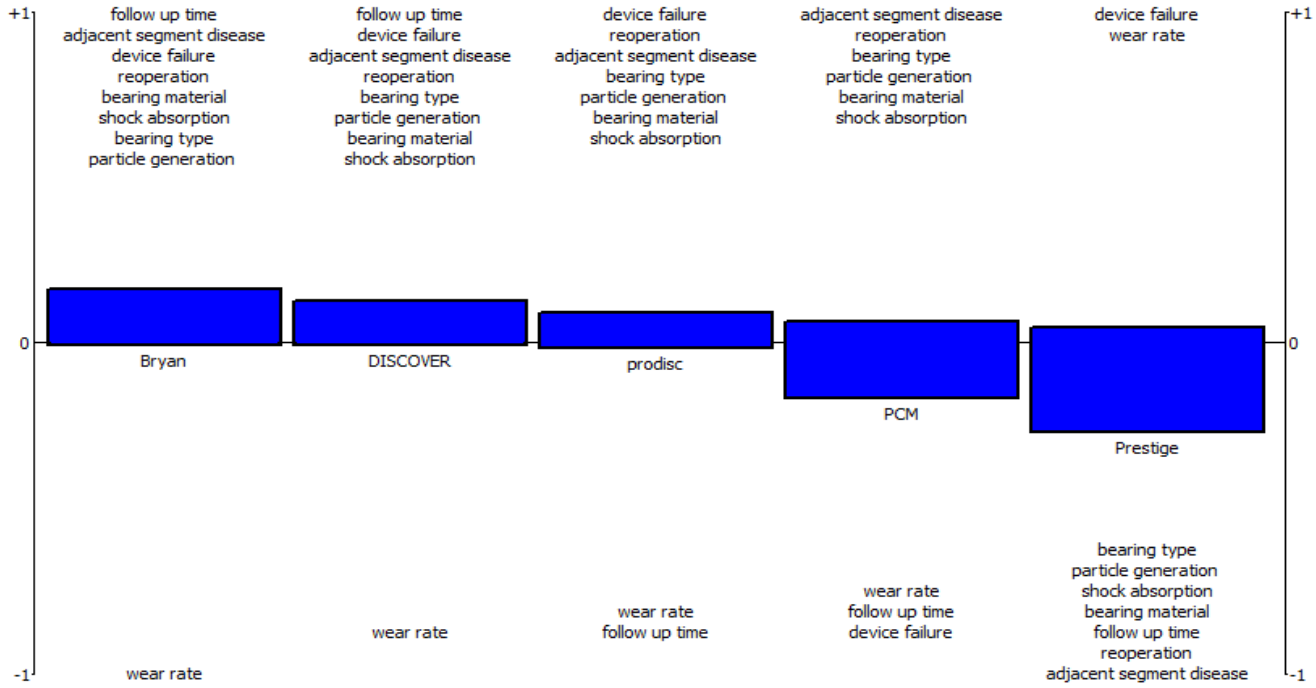


Figure 5.7: Rainbow ranking of all CDA devices

Figure 5.8 is a network ranking view of the treatment alternatives with the negative and positive outranking values. This network view can be used to clearly outline how the device alternatives are ranked and the order in which they can be undertaken, from the most favorable, to the least favorable.

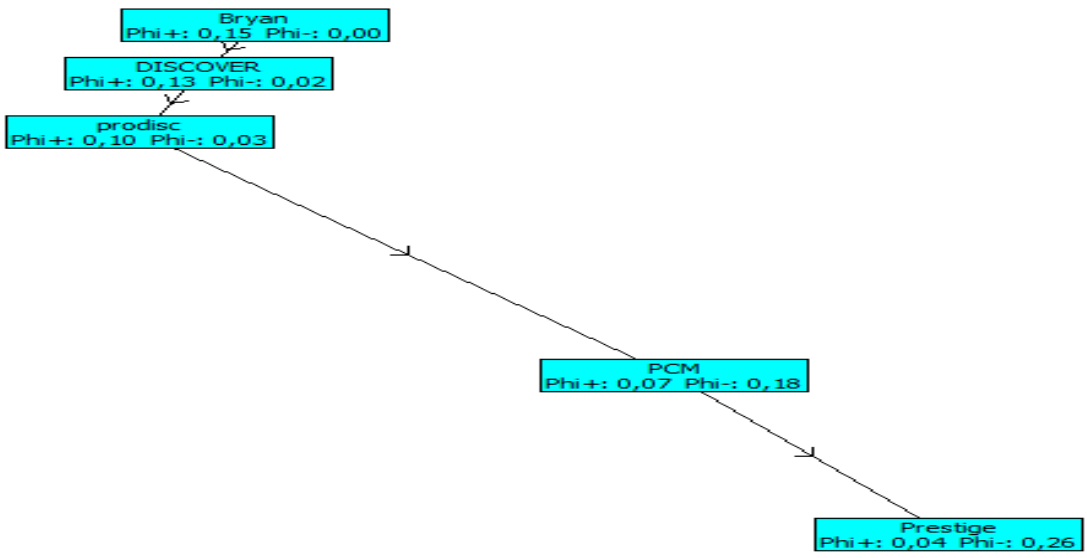


Figure 5.8: Network Ranking View of CDA devices

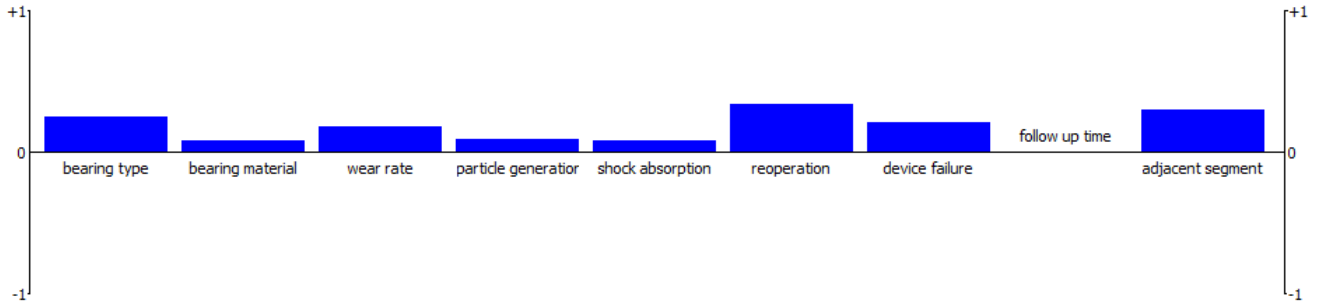


Figure 5.9: Action profile for the new disc

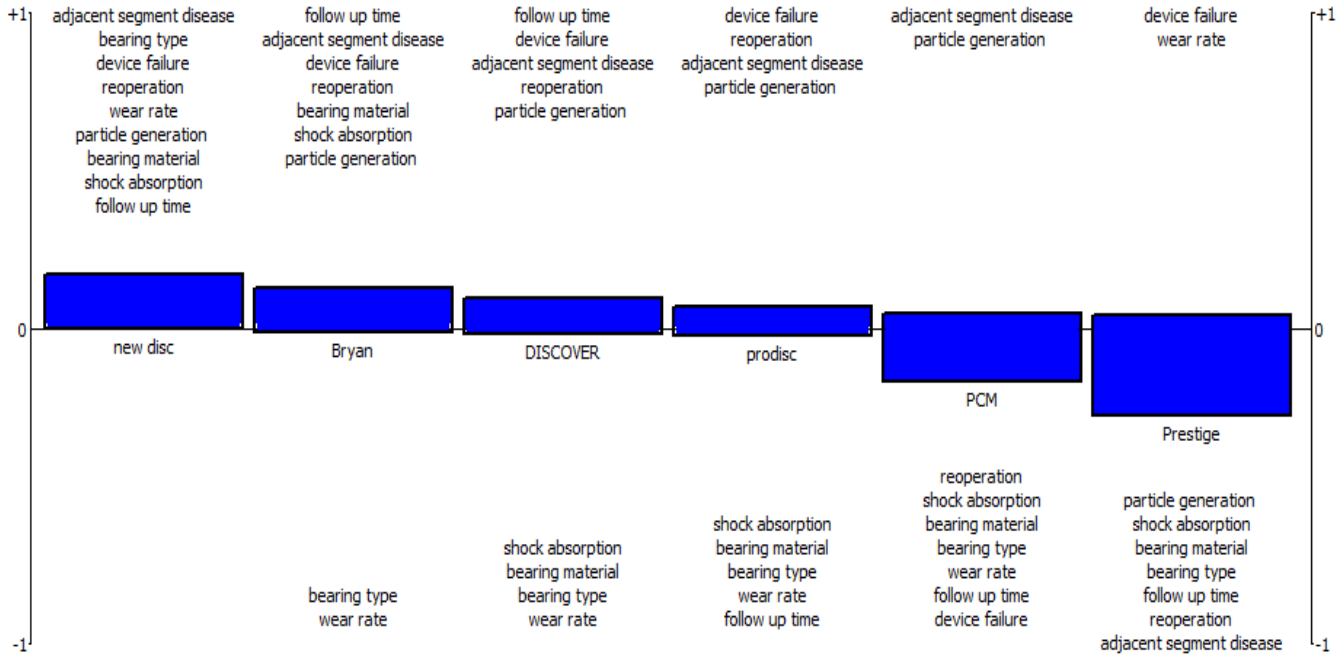


Figure 5.10: Ranking proposed new cervical disc design

CHAPTER 6

DISCUSSION AND CONCLUSION

6.1 Discussion

Gaussian functions are best suited for delineating many processes in different fields of study (HongweiGuo, 2011) and (Ozsahin, et al., 2017). In Figure 1 the Gaussian function was applied to get an even or natural distribution across all the selected devices. The net flow of the Bryan device was 0.3817, followed by, DISCOVER, Prodisc, PCM and prestige, 0.1433, 0.1005, -0.0804, -0.5451 respectively. The positives of the Bryan device can be attributed to the effectiveness of the disc due to the high score in bearing material used, shock absorption properties, follow up time, adjacent segment disease, bearing type, wear particles generated, low rate of device failure and reoperation, compared to the other devices. Even though the rate of wear and device failure in the prestige device standout as a positive for the device the other important parameters are not favored by the device. Anew disc design was proposed such that would fulfil all the positive attributes of a cervical disc for cervical disc arthroplasty derived from the analysis of the evaluated devices for a more efficient device. The designed device should be;

- Is a solid non-destructive three piece device
- Can mimic the cervical range of motion
- Can resist wear and tear
- Have good shock absorbing qualities.

6.2 Conclusions

In this paper the best possible alternative for the choice of CDA device is achieved by using the fuzzy PROMETHEE technique. The parameters used were converted to fuzzy input data by applying the PROMETHEE method and the results were obtained. This study shows that the proposed method would be effective in providing alternative options to decision making problems in health care especially in the aspect of selection of medical devices, such that would best benefit the patient. The Bryan disc was the best device alternative according to the parameters stipulated in the work. It shows a marked distinction with the most advantages when compared to other evaluated devices under

favourable conditions for an average patient. DISCOVER and Prodisc are suitable alternatives when Bryan disc is not used followed by the PCM and Prestige devices. The ranking value can be adjusted according to the criteria that is chosen. With this method clinical practitioners, patients and other medical stake holders would find it easier to adopt certain treatment techniques based on their likes and dislikes. The ideal device for CDA had a low follow up time, less risk of device failure and reoperation, low wear rate, low particle generation, good shock absorption performance, bearing material and type. However in vivo testing for the new disc could not be conducted due to lack of available laboratories and time. The future advances in fuzzy PROMETHEE would include; comparing all the results of this study with a combination of simulations for the cervical discs devices in a number of disc levelsfor improved quality of life after treatment.

6.3 Future Work

Due to the limitations of the study, the future work would include producing a prototype for mechanical testing and controlled testing in patients with cervical spine diseases.

REFERENCES

Brans, J., Vincke, P., &Mareschal, B. (1986). How to select and how to rank projects: The Promethee method. *European Journal of Operational Research*, 24(2), 228-238.

Bakhsheshian, J., Mehta, V. A., & Liu, J. C. (2017). Current Diagnosis and Management of Cervical Spondylotic Myelopathy. *Global spine journal*, 7(6), 572–586. doi:10.1177/2192568217699208

Chee Kai Chua, Chee How Wong, Wai Yee Yeong (2017). Introduction to 3D Printing or Additive Manufacturing. *Standards, Quality Control, and Measurement Sciences in 3D Printing and Additive Manufacturing*.pg1-29.

Chen, C., Zhang, X., & Ma, X. (2017). Durability of cervical disc arthroplasties and its influence factors: A systematic review and a network meta-analysis. *Medicine*, 96(6), e5947. doi:10.1097/MD.0000000000005947

Dahl, M. C., Jacobsen, S., Metcalf, N., Jr, Sasso, R., &Ching, R. P. (2011). A comparison of the shock-absorbing properties of cervical disc prosthesis bearing materials. *SAS journal*, 5(2), 48–54. doi:10.1016/j.esas.2011.01.002

Fay LY, Huang WC, Tsai TY, et al (2014). Differences between arthroplasty and anterior cervical fusion in two-level cervical degenerative disc disease. *Eur Spine J*. pg23:627–634. doi:10.1007/s00586-013-3123-8.

Fayyazi, A. H., Taormina, J., Svach, D., Stein, J., & Ordway, N. R. (2015). Assessment of Magnetic Resonance Imaging Artifact Following Cervical Total Disc Arthroplasty. *International journal of spine surgery*, 9, 30. doi:10.14444/2030

Fong, S.Y., Duplessis, S.J., Casha, S., &Hurlbert, R.J. (2006). Design limitations of Bryan disc arthroplasty. *The spine journal: official journal of the North American Spine Society*, 6 3, 233-41

Galindo Hose, (2008) fuzzy outranking methods including fuzzy PROMETHEE. Handbook of research on fuzzy information processing in data bases pg786-790.

Gutman G, Rosenzweig DH, Golan JD. (2018). *Spine*(6):E365-E372. doi: 10.1097/BRS.0000000000002324.

Hu, Y., Lv, G., Ren, S., & Johansen, D. (2016). Mid- to Long-Term Outcomes of Cervical Disc Arthroplasty versus Anterior Cervical Discectomy and Fusion for Treatment of Symptomatic Cervical Disc Disease: A Systematic Review and Meta-Analysis of Eight Prospective Randomized Controlled Trials. *PloS one*, 11(2), e0149312. doi:10.1371/journal.pone.0149312

James J. Yue (2008)Motion Preservation Surgery of the Spine: Advanced Techniques and Controversies

Jun Wu, Xiaoping Qian, Michael YuWang. Advances in generative design,Computer-Aided DesignAvailable online 23 July 2019, 102733. https://doi.org/10.1016/j.cad.2019.102733 retrieved 30-07-19

Latka, D., Kozlowska, K., Miekisiak, G., Latka, K., Chowaniec, J., Olbrycht, T., &Latka, M. (2019). Safety and efficacy of cervical disc arthroplasty in preventing the adjacent segment disease: a meta-analysis of mid- to long-term outcomes in prospective, randomized, controlled multicenter studies. *Therapeutics and clinical risk management*, 15, 531–539. doi:10.2147/TCRM.S196349.

Macharis C., Springael J, De Brucker K. &Verbeke A. (2004). PROMETHEE and AHP: The design of operational synergies in multicriteria analysis. *European Journal of operational Research*, 153(2), 307-317.

Majumder M, (2015). Multicriteria Decision Making. Impact of urbanization on water shortage in face of climatic aberration, 35-47.

Marcela P. Moreira ; Carlos J. Dupont ; Marley M. B. R. Vellasco PROMETHEE and Fuzzy PROMETHEE Multicriteria Methods for Ranking Equipment Failure Modes 2009. *15th International Conference on Intelligent System Applications to Power Systems*

Mardani A., Jusoh A., MD Nor K, Khalifah Z., Zakwan N., &Valipour A., (2015). MultipleCriteria Decision Making techniques and their applications-A Review of the Literature from 2000 -2014. *Economic Research-Ekonomskalstrazivania*, 28(1), 516-571.

Matassi, F., Botti, A., Sirleo, L., Carulli, C., &Innocenti, M. (2013). Porous metal for orthopedics implants. Clinical cases in mineral and bone metabolism: *the official*

journal of the Italian Society of Osteoporosis, Mineral Metabolism, and Skeletal Diseases, 10(2), 111–115.

Min S. Ko& Sang C. Park (2018) Alignment of dental depth images from an intraoral scanner, *Computer-Aided Design and Applications*, 15:6, 863-871, DOI: 10.1080/16864360.2018.1486962

MuhammetGul, ErkanCelik, AlevTaskinGumus, Ali FuatGuneri (2018). A fuzzy logic based PROMETHEE method for material selection problems. *Beni-Suef University Journal of Basic and Applied Sciences* Vol. 7, Issue 1, Pg 68-79 retrieved from https://doi.org/10.1016/j.bjbas.2017.07.002

Mullin, Jeffrey &Shedid, Daniel &Benzel, Edward. (2019). Overview of Cervical Spondylosis Pathophysiology and Biomechanics.

Mustapha, M., Ozsahin, I., &UzunOzsahin, D. (2019). Evaluation of Sterilization Methods for Medical Devices. Retrieved June 1, 2019 from https://ieeexplore.ieee.org/abstract/document/8714223

Ozsahin, D., &Ozsahin, I. (2018). A Fuzzy PROMETHEE Approach for Breast Cancer Treatment Techniques. *International Journal of Medical Research and Health Sciences*, 7(5), 29-32.

Ozsahin, D., Isa, N., Uzun, B., &Ozsahin, I. (2018). Effective analysis of image reconstruction algorithms in nuclear medicine using fuzzy PROMETHEE. *Procedia Computer Science*, 120, 699-705.

Ozsahin, D., Uzun, B., Musa, M., Şentürk, N., Nurçin, F., &Ozsahin, I. (2017). Evaluating nuclear medicine imaging devices using fuzzy PROMETHEE method. *Procedia Computer Science*, 120, 699-705.

Ozsahin, I., Sharif, T., Ozsahin, D., &Uzun, B. (2019). Evaluation of solid-state detectors in medical imaging with fuzzy PROMETHEE. *Journal of Instrumentation*, 14(01), C01019-C01019.

Ozsahin, I., Ozsahin, D., Maisaini, U., & MOK, G. (2019). FUZZY PROMETHEE ANALYSIS OF LEUKEMIA TREATMENT TECHNIQUES. *World Cancer Research Journal. 46(6):*2621-2628.

Pham, M. H., Mehta, V. A., Tuchman, A., & Hsieh, P. C. (2015). Material Science in Cervical Total Disc Replacement. *BioMed research international*, 719123. doi:10.1155/2015/719123

Phillips, F. M., &Garfin, S. R. (2005). Cervical Disc Replacement. Spine, 30(Supplement), S27–S33. doi:10.1097/01.brs.0000175192.55139.69

Pierce D Nunley, DomagojCoric, Kelly A Frank, Marcus B Stone (2018). Cervical Disc Arthroplasty: Current Evidence and Real-World Application, *Neurosurgery*, Vol83, Issue 6, Pages 1087–1106, retrieved from https://doi.org/10.1093/neuros/nyx579

RoseBist P. K., Anil Kumar Peethambaran, Gowri Anil Peethambar (2018).Cervical spondylosis: analysis of clinical and radiological correlation. *International Surgery Journal* Vol.5 ISSN 2349-2902. doi.org/10.18203/2349-2902.isj20180338.

Sarah McCartney, Richard Baskerville, Stuart Blagg and David McCartney (2018).Cervical radiculopathy and cervical myelopathy: diagnosis and management in primary care McCartney *British Journal of General Practice*.68 (666): 44-46. DOI: https://doi.org/10.3399/bjgp17X694361

Senvar, O., Tuzkaya, G., &Kahraman, C. (2014). Multi Criteria Supplier Selection Using Fuzzy PROMETHEE Method. *Supply Chain Management under Fuzziness*.

Seth M. Feeman, Landon B. Wright & John L. Salmon (2018) Exploration and evaluation of CAD modeling in virtual reality, *Computer-Aided Design and Applications*, 15:6, 892-904, DOI: 10.1080/16864360.2018.1462570

Seyed Behnam Khakbaz, Maryam KarimiDavijani (2015). Ranking Multi Criteria Decision Making Methods for a Problem by Area Under Receiver Operating Characteristic. *Journal of Investment and Management*. Vol. 4, No. 5, pp. 210-215. doi: 10.11648/j.jim.20150405.21

Shangguan, L., Ning, G. Z., Tang, Y., Wang, Z., Luo, Z. J., & Zhou, Y. (2017). Discover cervical disc arthroplasty versus anterior cervical discectomy and fusion in symptomatic cervical disc diseases: A meta-analysis. *PloS one*, 12(3), e0174822. doi:10.1371/journal.pone.0174822

Vijay Kumar GomatamRaghavan, Ray Dibyendu Kumar, Das Rupant Kumar (2019). Natural history, prevalence, and pathophysiology of cervical spondylotic myelopathy. *Indian Spine Journal* Vol.2 Issue 1 pg: 5-12.

Yang, S., Yan-Bo Zhu, Suo-Zhou Yan, Jun Di, Da-Long Yang & Wen-Yuan Ding (2017). Anterior cervical discectomy and fusion surgery versus total disc replacement: A comparative study with minimum of 10-year follow-up. *Scientific Reports* 16443. 2045-2322 https://doi.org/10.1038/s41598-017-16670-1

Sundseth, J., Fredriksli, O.A., Kolstad, F (2017) *Eur Spine J*26: 1225. https://doi.org/10.1007/s00586-016-4922-5.

Tetsuo Oya, Satsuki Tsunenari&Hayahide Nagase (2018) Material and structural design based on biological information using optimized stress distribution, *Computer-Aided Design and Applications*, 15:6, 841-851, DOI: 10.1080/16864360.2018.1462567

Uzun, D., Uzun, B., Sani, M., &Ozsahin, I. (2018). Evaluating X-Ray based Medical Imaging Devices with Fuzzy Preference Ranking Organization Method for Enrichment Evaluations.

Uzun, D., Uzun, B., Sani, M., Helwan, A., Nwekwo, C., &Veysel, F. et al. (2017). Evaluating Cancer Treatment Alternatives using Fuzzy PROMETHEE Method. *International Journal Of Advanced Computer Science And Applications*, 8(10).

Uzun, B., SarigulYildirim, F., Sayan, M., Sanlidag, T., &UzunOzsahin, D. (2019). The Use of Fuzzy PROMETHEE Technique in Antiretroviral Combination Decision in Pediatric HIV Treatments. Retrieved June 19, 2019 from https://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=8714389

Yang, B., Li, H., Zhang, T., He, X., & Xu, S. (2012). The incidence of adjacent segment degeneration after cervical disc arthroplasty (CDA): a metaanalysis of randomized controlled trials. *PloS one*, 7(4), e35032. doi:10.1371/journal.pone.0035032

Yang W, Wang J, & Wang X (2012). An outranking method for multicriteria decision making with duplex linguistic information Fuzzy sets and systems, 198, 20-33.

Zadeh, L. (1996). Fuzzy Logic Computing with words. *IEEE Transactions on Fuzzy Systems,* 4(2), 103-111.

Zionts, S. (1979). MCDM—If Not a Roman Numeral, Then What?. *Interfaces*, 9(4), 94-101.

APPENDIX

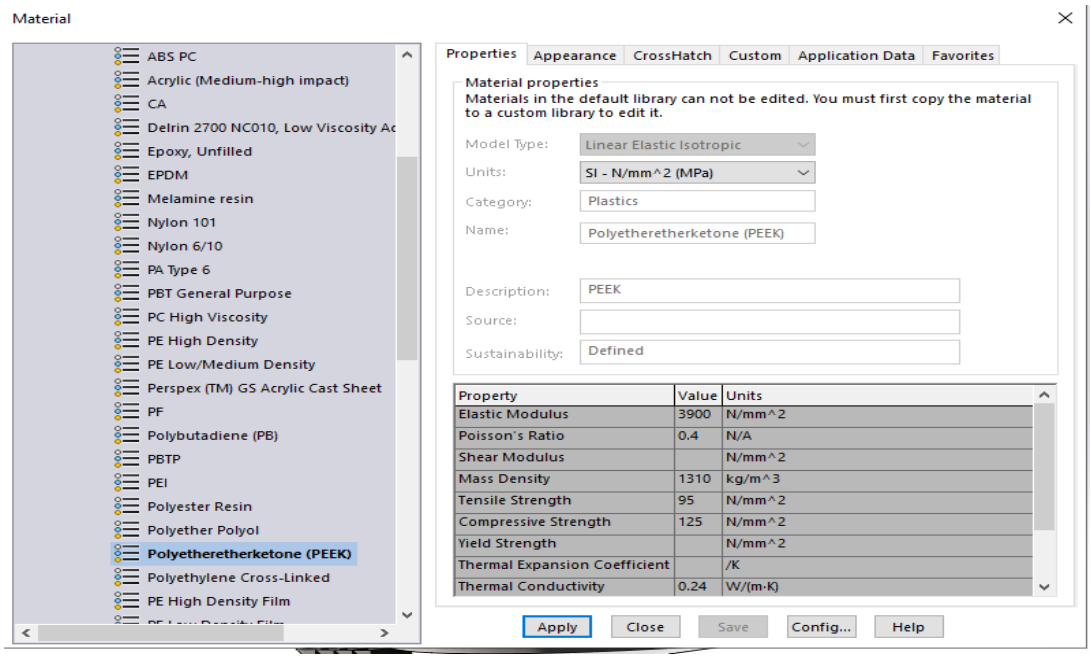


Figure 1: Polyetheretherketone (PEEK) material properties

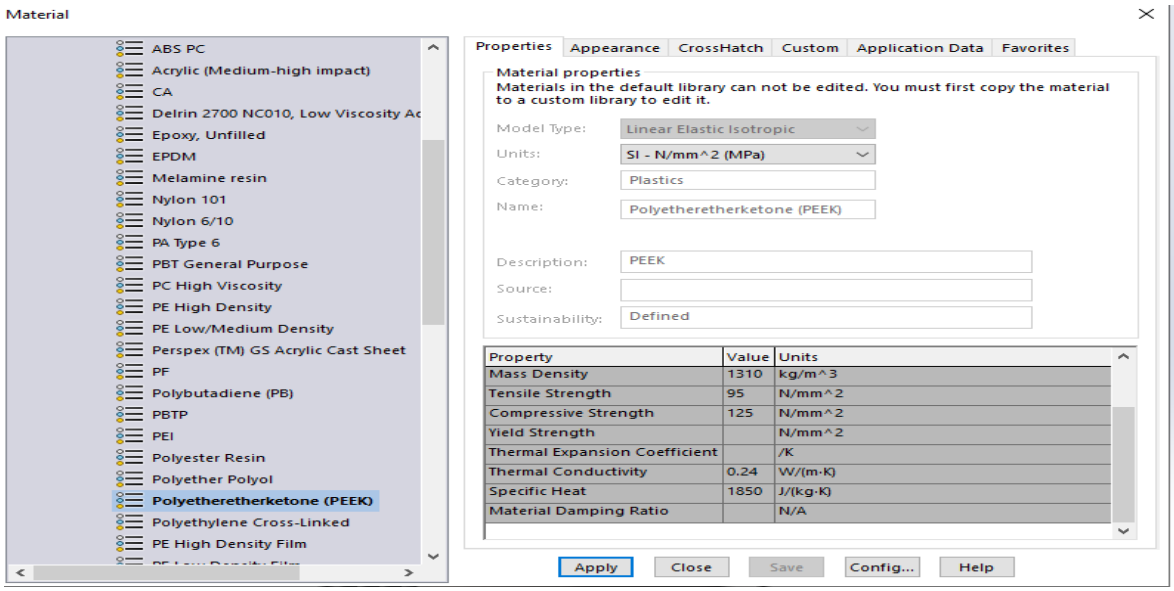


Figure 2: Polyetheretherketone (PEEK) material properties

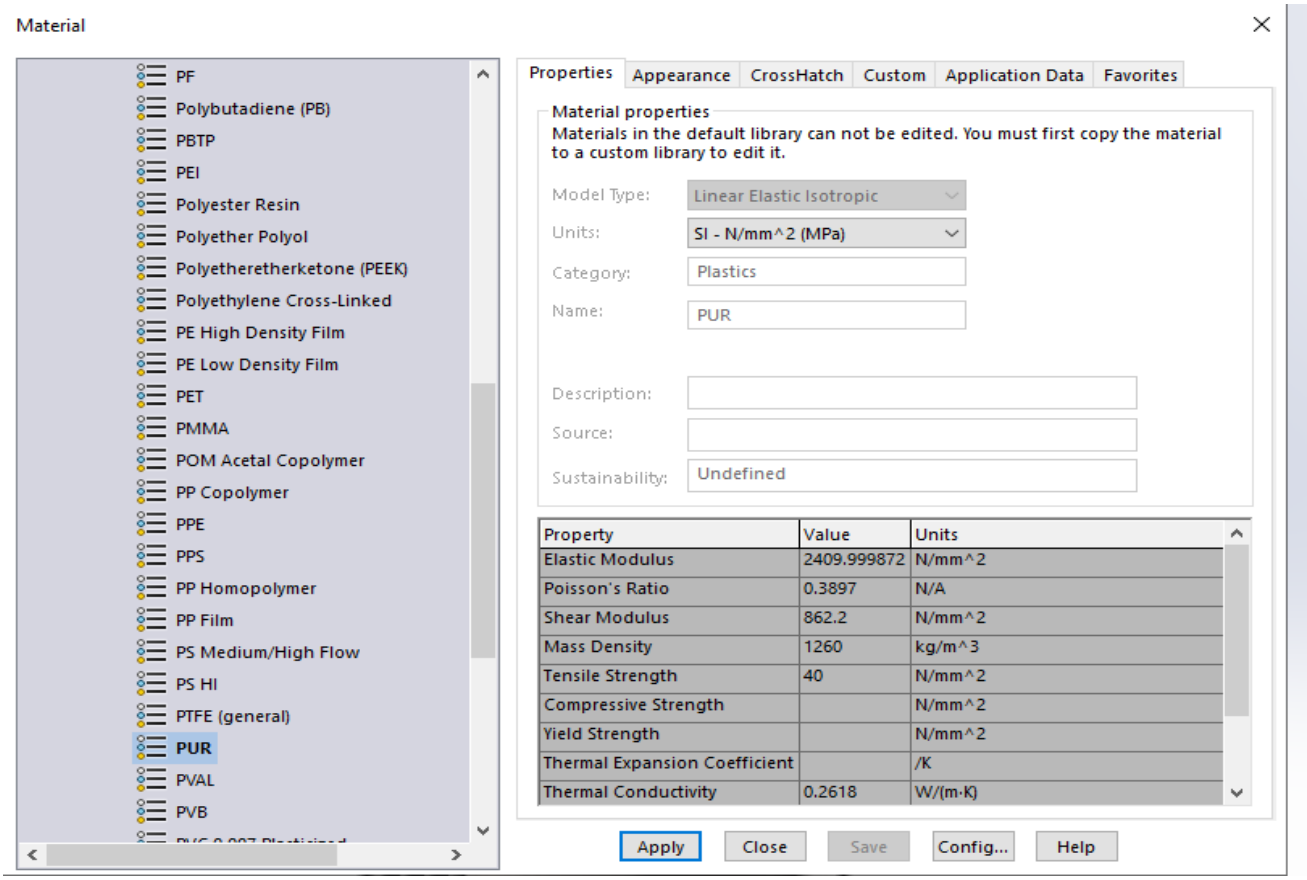


Figure 4: Polyurethane material properties

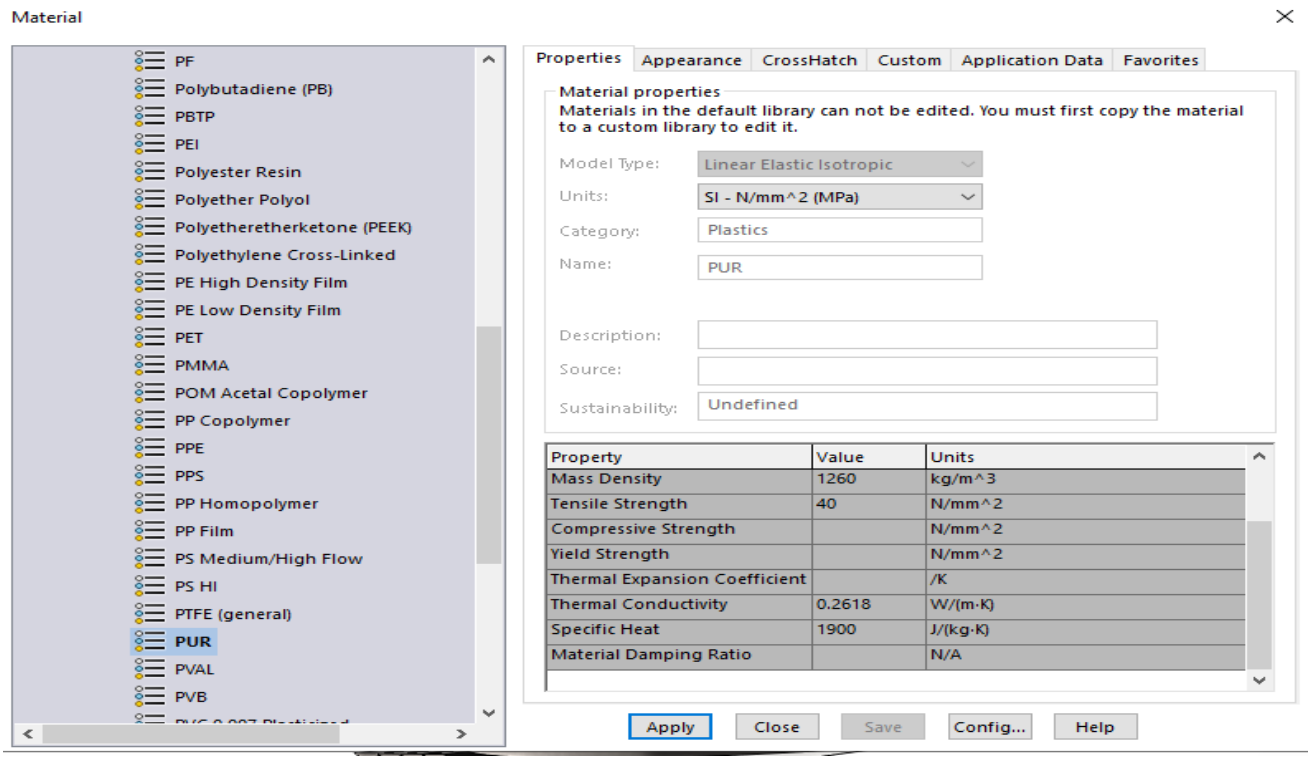


Figure 5: Polyurethane material properties

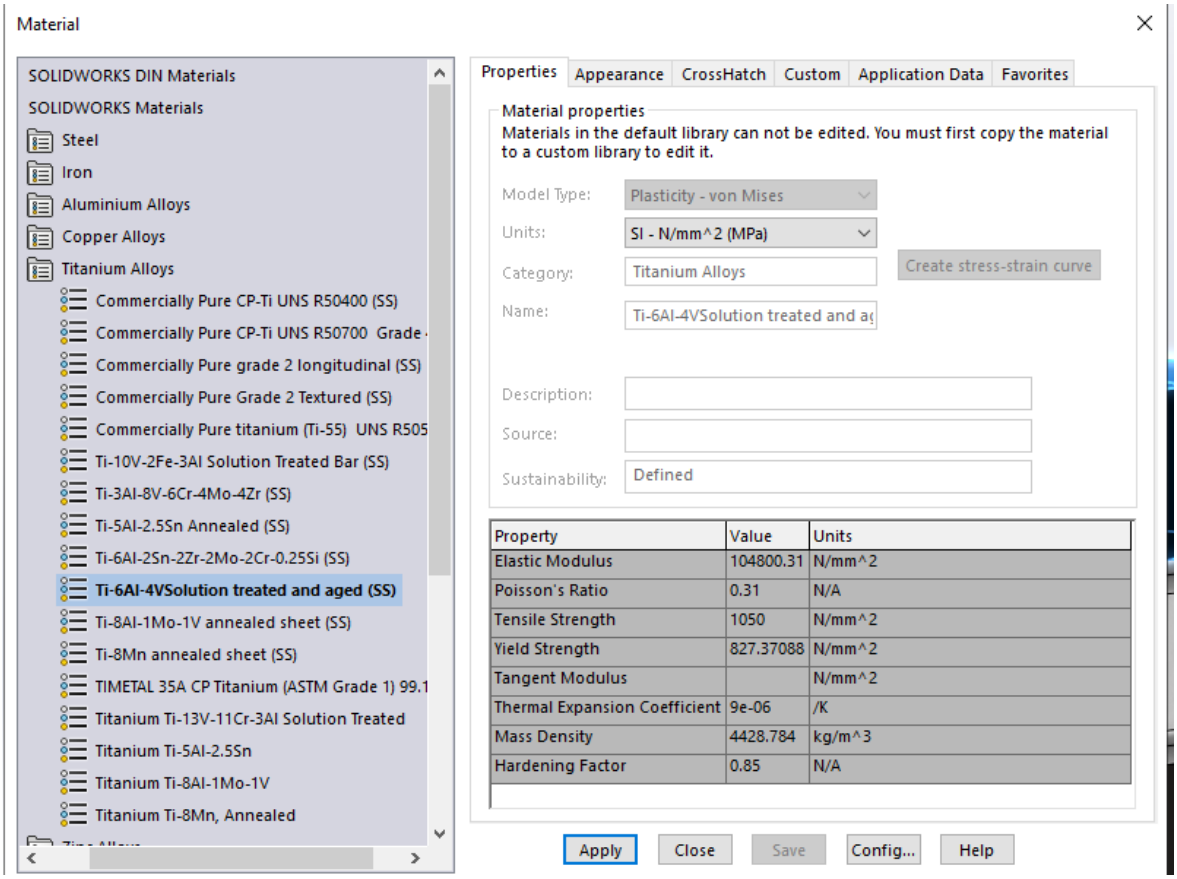


Figure 6: Material properties of titanium alloy Ti-Al-4Vsolution treated and aged (SS)