RADIOGRAPHICAL ANALYSIS OF ALLOGENOUS FIBULAR STRUT GRAFT USAGE IN ANTERIOR CERVICAL CORPECTOMY AND RECONSTRUCTION

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ABSTRACT

Introduction: The published body of knowledge within spinal surgery specifies that the performance of cervical corpectomy and reconstruction surgery is well established within the surgical discipline. Clinical observations suggested the hypothesis that an increased usage of this procedure by spinal surgeons, as evidenced by a marked upsurge in anterior cervical corpectomy and reconstructions has important long-term significance.

Aim: To investigate the radiographical outcomes of allogenous fibular strut grafts post anterior cervical corpectomy and reconstruction procedures

Methods: A descriptive retrospective study using a purposive sampling technique was applied to select the population for this research study. All 29 adult patients who underwent an anterior cervical corpectomy and reconstruction using an allogenous fibular strut graft, at Charlotte Maxeke Johannesburg Academic Hospital between 01 January 2012 and 31 December 2019 were sampled for this study. The spinal surgery registry at CMJAH was the primary source used for data collection for patients who underwent this spinal surgery (anterior cervical corpectomy and reconstruction) using the allogenous fibular strut grafts during the study period stipulated. These radiographs were independently reviewed by the researcher using a prepopulated checklist.

Results: The allogenous fibular strut graft displayed encouraging biomechanical characteristics with low rates of lucency and subsidence. This study suggested that allogenous fibular strut grafts used in anterior cervical corpectomy and reconstruction procedures whether single level corpectomy or 2 level corpectomy is both a safe, feasible and possibly sustainable alternative grafting material in the spinal surgical sphere.

Conclusion: This research study has endeavoured to describe the novel initial investigation into using allogenous fibular strut grafts as a viable and safe grafting material in anterior cervical corpectomy and reconstruction procedures.

NOMENCLATURE

AP	Anterior Posterior
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
ICBG	Iliac Crest Bone Grafting
N-HA/PA66	Nano-hydroxyapatite/polyamide66
PACS	Picture Archiving and Communication System

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CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

The published body of knowledge within spinal surgery specifies that the performance of cervical corpectomy and reconstruction surgery is well established within the surgical discipline. Firstly, within the ethical construct as a safe surgical procedure. Secondly, as being effective, well-recognised and practised within the spinal surgical construct of success (1-3). As a consequence of this recognised safety and reproducibility of outcomes, there has been an increased usage of this procedure by spinal surgeons, as evidenced by a marked upsurge in anterior cervical corpectomy and reconstructions reported in published literature in the United States of America (1, 4) .

This recent increase can best be explained by multifactorial reasons, these include: an upsurge in the disease prevalence; changing expectations and preferences from patients in the digital age; the scientific expansion and application of novel spinal surgical technologies; increased self-declared spinal surgeons; reimbursement patterns and economic forces (5, 6). Scientific accredited output with regards to the procedure from a South African context appears to be presently non-existent. Consequently, there are no published comparable statistics which exist with regards to anterior cervical corpectomy and reconstruction procedural trends referring to the South African health sector.

The corpectomy procedure directly provides for spinal decompression and subtraction of any elements causing compression on the cervical spinal cord (7). Adequate decompression is vital to safeguard against the clinical symptoms caused by spinal cord compression. In addition, in order to attain long-term cervical spinal column stabilisation, the reconstruction process post-corpectomy is similarly critical. Solid bony fusion is the ultimate purpose regardless of the reconstruction technique used after decompression (8) .

In the course of performing the anterior cervical corpectomy surgery, bone graft material is incorporated, and spinal plating is then applied to reduce motion at the spinal surgical site and this further enables fusion and spinal stability (9). A plethora of bone graft materials have been used to fill the corpectomised space during cervical reconstruction and fusion with varied and often controversial surgical outcome measures. The selection of an optimal grafting material is currently controversial and published research has not reached a consensus on which grafting material has superior and safer patient outcomes (3).

Section 1.2 that follows adopts a succinct discussion of the body of accredited research regarding allogenous fibular strut graft usage in anterior cervical corpectomy and reconstruction

1.2 LITERATURE REVIEW

Spinal arthrodesis scientifically is best defined as ***the process of abstracting of motion from across an intervertebral segment, resulting in the culminated consequence of fusion (bony union)(9, 10).*** During the anterior cervical corpectomy surgery, end-to-end bone surfaces undergo decortication, followed by the incorporation of bone graft material, and instrumentation in the form of plating is then applied to decrease motion at the surgical site and facilitate fusion. Devlin *et al.* lists the commonest published indications for performing spinal arthrodesis as being: trauma, tumours, infection, rheumatologic disorders, spinal deformities and degenerative spinal disorders. (9). Table 1.1 categorises the most common indications for performing spinal arthrodesis.

Table 1.1: Most common published indications for performing spinal arthrodesis (9).

Indications for performing a spinal arthrodesis	
Disease Category	**Clinical Example**
Trauma	Burst fractures, fracture-dislocations, flexion-distraction injuries.
Tumour	Pathologic spine fracture secondary to metastatic or primary tumour.
Infection	Spinal instability due to disc space infection or vertebral osteomyelitis.
Rheumatologic disorders	C1–C2 instability due to rheumatoid arthritis.
Spinal deformities	Scoliosis, kyphosis, congenital deformities.
Degenerative spinal disorders	Degenerative spondylolisthesis with spinal stenosis.

The selection of the optimal bone graft material used to fill the post-corpectomy space during cervical reconstruction and fusion is highly varied and numerous. Several options are now available (3). The grafting materials used by spinal surgeons can be categorised into

autogenous strut bone grafts, allogenous strut bone grafts and synthetics which include metal interbody cages (11). Autograft bone is sourced from the patient's fibula, ribs, and ilium; this has led to autogenous strut grafts being subcategorised into autologous Iliac Crest Bone Grafting (ICBG) and non-iliac crest autologous bone graft.

Human cadaveric bone known as allograft bone possesses the ability to be stored as both a fresh-frozen graft and freeze-dried graft preparation. It is available in an assortment of shapes and has a constructional foundation like autograft bone. Allograft bone graft undergoes processing by acid extraction to eliminate pathogenic material and bone mineral. However, it maintains its collagen and non-collagenous proteins. Demineralised bone matrix is the end product produced, with osteoinductive activity. Additionally, allogenous strut grafts can also be subdivided into allogenous fibular shafts and allogenous tricorticate iliac crests grafts. Furthermore, other graft materials are available for usage in spinal fusion procedures, these being fusion cages, ceramics, bone morphogenetic proteins, composite materials and polymers (9) .

1.2.1 AUTOGENOUS BONE GRAFTS

Autogenous cancellous bone has well established osteoconductive, osteoinductive, and conceivably osteogenetic properties (12). These osteogenic properties are primarily due to the remaining osteocytes and mesenchymal stem cells (12, 13). The iliac crests possess relatively easy surgical access intraoperatively and have a large quantity of available cortical and cancellous bone at the disposal of the surgeon. These two unique characteristics make iliac crests the most commonly harvested donor sites recorded in the literature (14). It is widely recognised in literature that when an anterior cervical corpectomy and reconstruction is performed using autologous bone graft as the grafting material, the fusion rate is greatly enhanced (15). ICBG still remains the ideal yardstick (*gold standard*) amongst the choice of graft material employed in many surgical procedures across various specialties (16, 17). This is due in part to its biological and non-immunogenic properties, as well as its ability to induce fusion (17, 18).

However, the question of whether iliac crest harvest is a model source of autograft material remains controversial. Nevertheless, harvesting of autologous ICBG has led to some very well defined donor site complications including the following: infection, hematoma, fracture,

increased operative time and blood loss, poor wound healing and donor site pain (17, 19, 20). Bone grafting complications among patients who received autologous ICBG were found to be wide-ranging across studies as reported in a systematic review published in 2017. In that study, pain at the patient donor site fluctuated from 7.2% to 22.7% at final clinical follow-up. Additionally, the study reported complications at the iliac crest donor site encompassed hematoma/seroma (1.6% to 4.5%); infection (2.4% to 6.8%); wound dehiscence (6.8%); osteomyelitis (2.3%); thigh dysesthesia (4.5%); osteomyelitis (2.3%);and unsightly scarring (25%) (3) .These statistics illustrate the importance of the need for the current investigation as allogenous grafts mitigate all the aforementioned surgical complications.

The development of these complications after autologous ICBG has driven surgeons to question whether the benefit gained in the form of high fusion rates is worth the morbidities posed by autologous ICBG. To mitigate morbidities to patients, surgeons have had to consider other alternatives such as other autologous bone harvesting sites, and allograft or synthetic substitutes for spinal fusion surgery (17).

Other autologous bones as an alternative to ICBG have been held as suitable graft material substitutes. Autologous local bone from the corpectomy and autologous fibular bone have been suggested (14, 21, 22). The usage of *in situ* local autograft bone circumvents the complications of harvesting autologous iliac crest bone. The primary concern when performing *in situ* local autografts is whether the quantity of fragmented laminae and spinal processes bone gained after corpectomy is adequate for fusion. Additionally, there are also concerns on whether the *in situ* local graft bone comprises ample cancellous bone mass for adequate fusion (14).

Autologous fibular graft usage in the reconstruction process following anterior cervical corpectomy was principally used for its ability to provide anterior stabilisation of the multi-level spondylotic cervical spine. This autologous, rigid, tubular, and cortical fibular strut graft prevented immediate collapse of the corpectomised vertebral segments into kyphosis and allowed acute axial stability (2, 10). Early data published using autologous fibular strut grafts showed much promise in the form of high fusion rates, but with time it became plainly evident that, like its autologous ICBG counterpart, it was susceptible to the same donor site morbidities. Reported donor site morbidities were found to be as high as 19%. Additionally, it was discovered that because of the cortical and tubular nature of fibular strut grafts, they took longer to show characteristics of radiological fusion. Additionally, autologous fibular grafts are

associated with tibial stress fractures, superficial peroneal neuromas, prolonged incisional pain and ankle instability (23). These factors combined eventually led to a steady decline in the use of autologous fibular strut grafts by spinal surgeons (2, 24, 25).

1.2.2 ALLOGENOUS BONE GRAFTS

The employment of allogenous fibular shafts and allogenous tricorticate iliac crests are able to mitigate and prevent against the complications inherent in mesh cages and act as structural supports and have additionally a better biocompatibility profile than metal interbody cages (11). Furthermore, with regards to allogenous grafts, in their efforts to mitigate complications at the donor site, surgeons have opted to employ numerous allograft materials as substitutes for autograft bone grafts. Nevertheless, questions remain around the comparative effectiveness of allogenous grafts and their ability to aid in the fusion process post-cervical corpectomy and reconstruction. Several allograft materials have successfully been substituted for autologous ICBG, allogenous fibular strut grafts being one such substitute. Predictably, reports show that current trends demonstrate declining usage of autograft (86% to 10%; $p = 0.0001$) with a reciprocal upsurge in allograft usage (14% to 59% : $p = 0.0001$) (5). These statistics support the development of the current research question.

The utilisation of allograft eliminates the development of donor site risks associated with autologous ICBG to the patient while preservation osteoconductive properties. However, the body of knowledge shows that allogenous grafts are liable to incorporate slower than autologous grafts. This prolonged allogenous graft integration ultimately leads to slower fusion using allogenous grafting material compared to autologous grafting material and mesh cages. Allogenous cortical strut grafts have had widely reported complication rates, which include: resorption, displacement, graft bone fracture, and fusion collapse or pseudarthrosis (26). The factors that contributed to the high incidence of complications reported after usage of allogenous graft in cervical corpectomy and fusions were multifactorial. These factors include: freeze drying or radiation of the harvested allograft which decreases the strength of the graft (27); unstable surfaces between host vertebral bone and bone graft and poor bone quality of host vertebrae (25).

Surgeons have developed subsequent approaches to mitigate against the development of the allogenous complications such as the usage of fresh frozen cortical strut grafts. Utilising fresh frozen allografts as a preservation method has allowed a higher concentration of the original bone quality to be maintained and therefore improves the fusion stability and union rate (11).

Weakening of the allograft preceding intraoperatively implantation due to the preparation process has been reported (13, 28). Pelker *et al.* reported that freeze dried tricortical iliac crest graft material displayed a 70% reduction in torsion strength and a 10% reduction in compression strength when it was measured against autologous tricortical iliac crest bone (28). Fresh frozen allogenous bone grafts are not without their inherent complications. Extremely rare infection risks associated with allograft usage have been reported. Published infectious reports detail two cases of human immunodeficiency virus, three cases of viral hepatitis, and twenty-six bacterial infections (29-31). Freeze dried allogenous grafts undergo further processing to mitigate against and prevent disease transmission from the allogenous graft.

In the South African health sector, there is a limitation to only using freeze dried allogenous fibular strut grafts owing to the high viral burden of hepatitis and human immunodeficiency virus. Although there were confirmed strength differences between allogenous fresh frozen and freeze dried grafts, there were no apparent differences in fusion percentages using different graft preparation or preservation methods (3, 11, 28).

1.2.3 FUSION MESH CAGES AND OTHER INORGANIC GRAFT SUBSTITUTES

Fusion cages are biological devices that deliver structural support to the anterior spinal column following corpectomy. Largely they are used in conjunction with bone graft and supplemental fixation. The cage provides immediate restoration of mechanical stability of the anterior spinal column post corpectomy and reconstruction. The biological cages are available in an assortment of shapes and materials (titanium, carbon fibre, cortical bone, and polyetheretherketone) (9). Titanium mesh cages filled with autograft from the resected cervical vertebrae is a recognised and well utilised alternative to autologous and allogenous bone graft in the reconstruction of the cervical spine after corpectomy (32, 33). Titanium mesh cages hold the following advantage over other grafting materials: they mitigate the need for bone grafting procedures and its associated complications, additionally they provide immediate post-operative robust anterior column support (34).

Studies on the usage of titanium mesh cages during anterior cervical corpectomies and reconstruction were encouraging, by way of high fusion rates ranging from 95% to 100% with implant complication rates of 6% to 28% (35). Majd *et al.* exhibited a 97% rate of successful fusion and an accompanying quantitative excellent or good score in their clinical outcome measurements in 80% of their patients, with only one cage extrusion (2.9%) being reported in their study (36). Following this study of complications using mesh cages, Hee *et al.* showed

vastly different results, revealing an overall complication rate of 33% in the study sample they investigated (37). The leading complications associated with the usage of titanium mesh cages are the catastrophic failure of the cage and plate construct. These then demand the additional posterior stabilisation in select cases where spasticity is a key feature or in cases where patients have undergone more than 2-level corpectomies with severe osteoporosis (37). Moreover, high rates of radio-opacity, stress shielding and subsidence have been extensively recounted in previous studies when titanium mesh cages were used (37, 38).

Daubs *et al.* concluded in their study that titanium mesh cage, in combination with anterior plating, showed higher failure rates compared to strut grafting in combination with anterior plating in multilevel cervical corpectomy reconstructions. The titanium mesh cage, which design characteristics include sharp edges and small surface area of contact, both make it more vulnerable to pistoning subsidence, and ultimate fatigue failure. This has been particularly evident in patients with osteopenia. When using titanium mesh cages during multilevel cervical corpectomy and reconstruction, additional posterior stabilisation and instrumentation ought to be strongly considered as part of the surgical procedure (34). Recently, numerous amalgamated materials comprising of inorganic Hydroxyapatite and organic polymers are increasingly being used as bone substitutes. The nano-hydroxyapatite/polyamide66 (n-HA/PA66) which is characteristically a biomimetic composite synthesised from nano-scale Hydroxyapatite and the polar polymer PA66 has recently gained approval for clinical application. Preliminary reports have shown acceptable clinical results when using n-HA/PA66 struts in anterior cervical corpectomies and reconstruction. Nevertheless, the body of knowledge appraising the long-term results of using the n-HA/PA66 strut as a substitute in anterior cervical corpectomy and reconstruction is comparatively rare (39-41).

1.2.4 CRITICAL EVALUATION AND LIMITATIONS OF PREVIOUS STUDIES

In their systematic review of autograft versus allograft usage for cervical corpectomy and reconstruction, Tuchman *et al*. stated that only a lone study displayed similar fusion percentages. The systematic review generally presented that 74% to 100% of patients using allograft material were considered fused compared with 62% to 100% of patients utilising autologous grafting material (3). Regardless of this, a study by Bishop *et al*. in their prospective comparative analysis reported a considerably lower percentage of patients who achieved fusion in the allograft group compared with the ICBG group at three months (50.0% *versus* 83.0%), 12 months (64.0% *versus* 92.0%), and at final follow-up (88.0% *versus* 97.6%, $p < 0.05$),

respectively (42). In the body of knowledge, just one study explored the comparative association concerning fibular allograft *versus* non–iliac crest bone grafting autograft. This specific study showed that the freeze-dried fibular allograft group (70/118, 59%; $p < 0.01$) demonstrated a lower fusion rate than the fibular strut autograft group (98/134, 73%). Furthermore, the non-union rate was high in both groups: 41% of the allograft group and 27% of the autograft group (10).

Regarding the surgical procedure of anterior cervical corpectomy and reconstruction, up to date existing data demonstrates that there is no evidence reliably describing differences in fusion rates when making use of allograft *versus* autologous ICBG. There is a shortage of published literature addressing the comparative safety of graft types, failing also to draw distinctions between grafting materials (3). With regards to anterior cervical corpectomy and reconstruction, the current clinical body of knowledge has not displayed a general difference with regards to long-term fusion rates when comparing autologous ICBG to allograft. Tuchman *et al.* noted that most studies related to the comparative nature of the grafting types had study design limitations, which influenced the conclusions reached by the authors. Tuchman *et al.* further reported that not a single study to date has had any primary level of evidence rating exceeding class III (3). In a systematic review of the current published body of knowledge with regards to the usage of these grafting types, all have further limitations that includes but is not limited to: the lack of control for confounders, disproportionately high loss to follow-up ratios, insufficient (small) sample size, and absence of blinding (3).

Tuchman *et al.* in their systematic review highlighted substantial limitations in the current literature and suggested numerous possibilities for further study with respect to graft choice for cervical corpectomy and reconstruction. Insufficient evidence exists to compare the fusion when using allograft *versus* non-ICBG autograft. The study found that just 11 cohort's studies directly paralleled cervical fusion with allograft *versus* ICBG autograft *versus* allograft. Furthermore, only two of the studies were prospectively sampled and none of the studies were randomised. Moreover, current published literature displays very little consistency amid studies with respect to the definition of fusion, follow-up time and reporting of complications and outcomes. Tuchman *et al.* concluded that the discrepancies considerably restricted their ability to adequately gather data and execute a formal meta-analysis. Consequently the general quality of the current body of knowledge in the literature with regards to optimal grafting choices in cervical corpectomy and reconstruction remains limited (3).

In the available published literature, the evidence unconvincingly argues that allograft and ICBG demonstrated comparable effectiveness with regards to of fusion rates following anterior cervical corpectomy and reconstruction. Consequently, unsubstantiated scientific conclusions or submissions with regards to the use of allograft and ICBG ought to be made both cautiously and judiciously. Presently, the usage of substitutes to autologous IGCB remains an area of clinical equipoise and consequently is not merely a thought-provoking area for further investigation but a necessary avenue that warrants clinical research (3). The knowledge gaps identified within the available literature give rise to the problem which this research study aims to partially address.

1.3 STUDY RELEVANCE

This study will contribute to the body of knowledge in the global spinal surgical sphere as very limited published literature exists on the use of allogenous fibular strut grafts as a safe and reproducible alternative to other grafting material. The present exploratory study may be regarded as pertinent in the South African context as there currently is no available published literature in the body of knowledge regarding the use of these cadaver harvested allogenous fibular strut grafts and their application in anterior cervical corpectomy and reconstruction procedures of the human spine. The study thus has been embedded to ensure that both practical as well as academic knowledge is created and transferred.

CHAPTER 2: METHODOLOGY

2.1 INTRODUCTION

This section discusses the methodology employed to conduct this study. Firstly, the research question is discussed in section 2.2. This is followed by the study aim and objective in section 2.3. In section 2.4, the philosophical worldviews are discussed as a prelude to the method that was followed, and the reason for selecting this method is discussed. In Section 2.5 the research design was discussed in terms of the variables of the research as well as the rating system that was applied to conduct the research. Section 2.6 was dedicated to a discussion of the data analysis with specific reference to the statistical models that were applied to analyse the results. This is followed by a discussion of the population and sampling technique that was selected in section 2.7. Section 2.8 discussed the data collection method. Section 2.9 and 2.10 discussed validity and reliability of the study.

2.2 RESEARCH QUESTION

What are the radiographical subsidence and lucency rates when using allogenous fibular strut graft in anterior cervical corpectomy and reconstruction?

2.3 STUDY AIM AND OBJECTIVE

AIM:

To investigate the radiographical outcomes of allogenous fibular strut grafts post anterior cervical corpectomy and reconstruction procedures.

OBJECTIVE:

Based on the stated aim, the following theoretical, methodological and practical objectives were formulated.

THEORETICAL OBJECTIVES:

- To discover what is already known within the established body of knowledge regarding graft materials used in anterior cervical corpectomy and reconstruction procedures.
- To formulate a research question that has theoretical and scientific merit to ensure that new research can enter into a dialogic relationship within the established body of research

METHODOLOGICAL OBJECTIVE:

To approach sub aim one using a quantitative descriptive method

PRACTICAL OBJECTIVES:

- To assess whether using fibular strut grafts post anterior cervical corpectomy and reconstruction display high rates of graft subsidence at the graft vertebral interface on routine post-operatively cervical spine radiographs.
- To assess whether using fibular strut grafts post anterior cervical corpectomy and reconstruction display high rates of graft lucency.

2.4 PHILOSOPHICAL WORLD VIEWS AND STRATEGIES OF INQUIRY

A research paradigm consists of the following components: ontology, epistemology, methodology (43). Philosophers have always been interested in knowing what constitutes the world, i.e., what entities and beings exist, and what the essential nature of their existence is. The branch of philosophy that deals with the nature of existence is called ontology. This research investigated the radiographical outcomes of allogenous fibular strut grafts post anterior cervical corpectomy and reconstruction procedures. Therefore, the ontology for this research is singular with a scientific outcome.

Epistemology is concerned with the nature and forms of knowledge. Epistemological assumptions are concerned with the ways in which knowledge can be created, acquired and communicated, in other words what it means to know (44). Every paradigm is based upon its own ontological and epistemological. Different paradigms inherently contain differing ontological and epistemological views; therefore, they have differing assumptions of reality and knowledge which underpin their particular research approach (45). This view suggests that the current research is embedded on positivism. Accordingly, the role of the independent, neutral and detached researcher has been the collection and interpretation of data in an objective way focussed only on facts (44, 46)

2.5 SELECTING THE RESEARCH METHODOLOGY

The research question had a theoretical and scientific merit to ensure that new research can enter into a dialogic relationship within the established body of research. In order to answer the research question, a descriptive quantitative research methodology was selected to conduct the

research (44). A descriptive research design is appropriate for this study because it involves identifying the characteristics of an observed phenomenon or exploring possible associations among two or more phenomena (45). This is a quantitative study within the positivist paradigm. radiographical images were analysed objectively on a predetermined score sheet that was objectively applied across all the radiographical images that were analysed (2) . The aim of this type of research is to classify features in terms of specific variables, count them, and to explain what is observed (46)

2.6 RESEARCH DESIGN

A research design is an arrangement of conditions for collecting and analysing data in a manner that aims to foster relevance with the research purpose (44).

The study was a descriptive retrospective study of adult male and female patients,18 years and older, who underwent anterior cervical corpectomy and reconstruction using allogenous freeze dried fibular strut as a grafting material in the surgical procedure. A descriptive quantitative approach, places greater emphasis on objectivity in measuring and describing the collected data (44). The advantage of using this approach is to allow for the quantitative measurement of concepts and the explanation of causal relationships so that findings can be generalised (46).

A single centre study, conducted at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in central Johannesburg, South Africa, was used. The was conducted from the 1st of January 2012 to the 31st of December 2019.

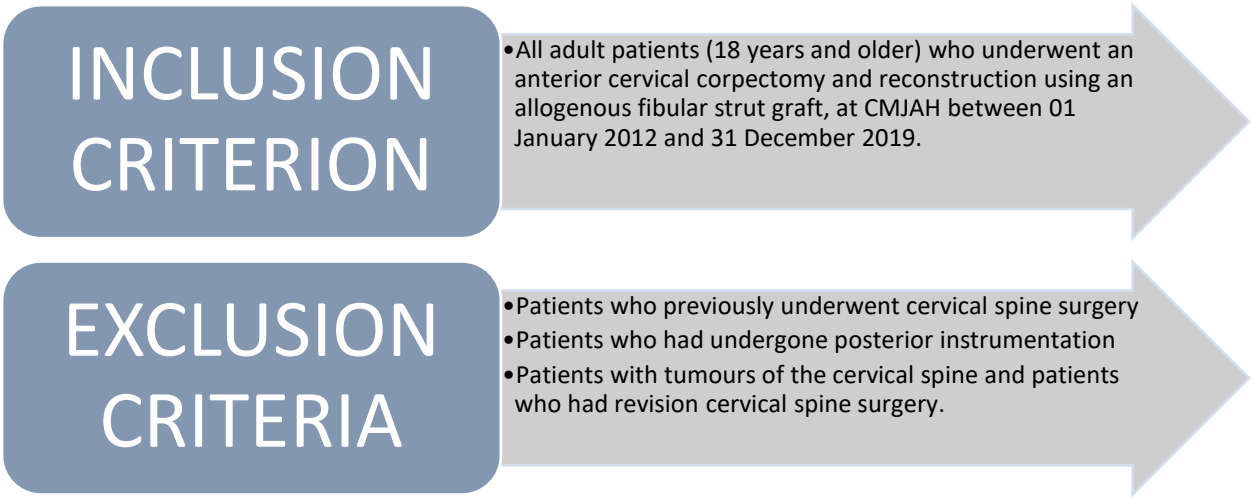
2.7 SELECTION CRITERIA

2.7.1 SAMPLE SIZE

A purposive sampling technique was applied to select the population for this research study. The researcher used judgement and practicality in selecting the sample. The anticipated sample size was 29 patients, given the rarity and novelty of using allogenous fibular strut grafts in the South African spinal surgical setting. The sample size selected was deemed acceptable for two reasons. The first is that all prior studies within this area of research has used similar comparative sample sizes (2, 22, 24, 27, 47). The second reason was that, after consultation with a statistician, meaningful data analysis can be conducted using this sample size. Statistical power on the sample size will be calculated to determine whether the probability that a significant effect will be revealed through statically testing (48).

The final sample size ended up consisting of only 17 patients for several multifaceted reasons. Firstly, all 29 follow-up radiographs of the purposive sample were either available on the hospital Picture Archiving and Communication System (PACS) system or on hard copy radiographs in the radiographic record keeping department. Of the radiographic records that were found, not all met the selection criteria for the study. The 17 radiographs that were traced and found to meet selection criteria were deemed acceptable radiographs in the study. The 12 radiographs were excluded on two grounds. The first was they were not captured on the PACS. The second was that they were neither available on hard copy in the department nor ordered routinely post operatively then lost to outpatient follow up or interprovincial relocation. In addition, the challenges faced in acquiring post-operative radiographs were:

- Poor and inconsistent record keeping of the purposive sample patients' radiographs,
- The 2019 COVID 19 pandemic severely influenced access to records at CMJAH.
- Access and availability to radiographic staff resources were limited due to reallocation of staff and the staff being severely affected by the pandemic.
- The Republic of South Africa went into a level 5 hard lockdown in March 2020 for 6 weeks, followed by subsequent 6 weeks of a level 4 lockdown and an extended level 3 lockdown thereafter.
- During this period ending 2020, the country experienced two severe waves of the SARS COV2 pandemics. CMJAH, being a large tertiary state facility serving the greater Johannesburg area, stopped all non-essential clinical work that did not involve COVID 19 patient diagnosis, care and treatment. Just as the hospital opened up after the second wave of the COVID 19 pandemic, tragedy struck at CMJAH when a deadly fire broke out that led to all 600 patients being evacuated and the hospital closed. Data collection was then impacted by a fire that arose at the hospital which resulted in an indefinite closure. The hospital is still closed as of August 2021 undergoing reconstruction.



2.8 DATA COLLECTION

The spinal surgery registry at CMJAH was the primary source used for data collection, as it contains all the names and hospital identifiers of patients who underwent this particular spinal surgery (anterior cervical corpectomy and reconstruction) using the allogenous fibular strut grafts during the study period stipulated. Using these names and patient identifiers (patient date of birth and unique hospital numbers), a comprehensive patient list was formed within the spine unit. A unique study number was assigned to each patient to maintain patient confidentiality and anonymity using this list, the patients' three, six or twelve month routine follow up radiographs were retrieved through either a manual search from the CMJAH radiology's record department or through the PACS instituted at CMJAH since 2016. PACS is a medical imaging technology which provides CMJAH economical storage, retrieval, management, distribution and presentation of medical images taken. A combination of these two methods was utilised to retrieve the routine post-operative radiographs of the patients identified from the spinal registry. Permission from the head of radiology and the hospital chief executive officer was granted to retrieve these retrospective patient radiographs. Once retrieved, these radiographs were independently reviewed by the researcher.

Thereafter, the radiographs were independently reviewed by the supervisor to ensure that the scoring of the radiographs were consistent. This process further ensured that any differences were discussed and reconciled prior to the commencement of the data analysis. Attached in Appendix A is the data collection sheet that was availed to the researcher to complete after reviewing the measured outcomes on the radiographs collected.

2.9 DATA ANALYSIS

The raw data was entered on Microsoft Excel and analysed using Stata version 15.0. The study primarily focused on using descriptive statistics to describe the set of data. Descriptive statistics was used to describe the data. Basic statistical measures were calculated (mean, median and mode) and the data were plotted on appropriate graphs in order to observe tendencies, relationships and outliers (49).The data were plotted to identify outliers and likely distributions.

Due to the nature of the data being non-numeric, only descriptive analysis could be conducted. Data analysis: The total number of patients that required surgery were 29 patients, however scans and patient profile data were only available for 17 patients. Scans and profile data were qualifiers if patients could be considered as part of the sample. Therefore, the sample size was 17 patients. The only numeric data available were the age of patients and the number of months the patient conducted a follow up checkup. Average and median analysis were conducted on the age and follow up duration.

The Shapiro-Wilk test, a normality test, was considered as it could determine which inferential statistical procedure will be required to assess if allogenous fibular strut graft usage in anterior cervical corpectomy and reconstruction displays low rates of graft subsidence and lucency at the graft vertebral interface on routine post-operatively cervical spine radiographs. However, this was not the case within the current investigation.

If the data were normally distributed, the statistical measure used to determine the variability of the data would have been standard deviation (46). This measure could then have been calculated for both the high subsidence and lucency incidence and the low subsidence and lucency incidence data group. This measure may have then provided information relating to how the data values will be distributed (50). Further statistical analysis in this case was not available and has been delineated under the limitations of the study.

2.10 VALIDITY

Validity and reliability refer respectively to whether a set of indicators really measures a concept and whether that measure is consistent (51). In order to achieve validity and reliability, the data has to be analysed in a systematic and unbiased manner (52).

External validity is the extent to which the results of a study can be generalised from a sample to a population (45, 46) The sample size, even though small, is consistent in the analysis and can be applied to other subsets within the population. The process was objective and unbiased through validation by an objective second review by the supervisor.

Content validity refers to the appropriateness of the content of an instrument (53, 54). In order for a study to also be valid, another researcher should be able to carry out the study in another context (49). This is the case with the procedure applied in the current research.

2.11 RELIABILITY

Reliability can be inferred as the consistency of the research method (54). The researcher was as objective as possible when conducting this research Guidance for research was obtained from a qualified supervisor who was both experienced and published in this area which also adds to the validity of the research. The radiographs were analysed by trained and experienced medical doctors (the researcher and supervisor) who have performed these procedures and reviews many times previously.

2.12 ETHICS

No data will be collected prior to ethics clearance from the Human Research Ethics Committee (HREC) (Medical), University of the Witwatersrand, as well as permission from the CEO at CMJAH. To maintain confidentiality and anonymity, study numbers will be used to protect the identities of the patients.

CHAPTER 3: RESULTS

Chapter 3 is dedicated to the graphic representation of the results for illustrative purposes. Chapter 4 which proceeds provides an in-depth analysis and discussion of the results.

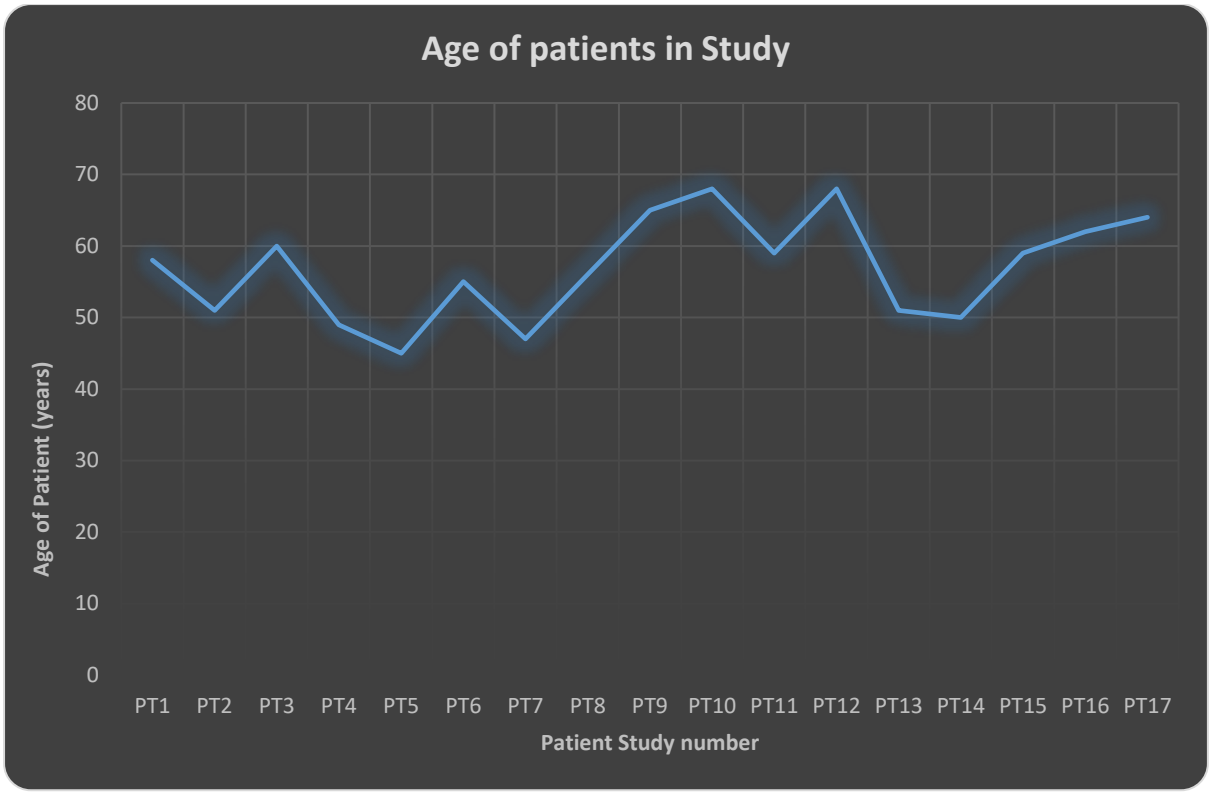


Figure 3.1: Age distribution of study participants.

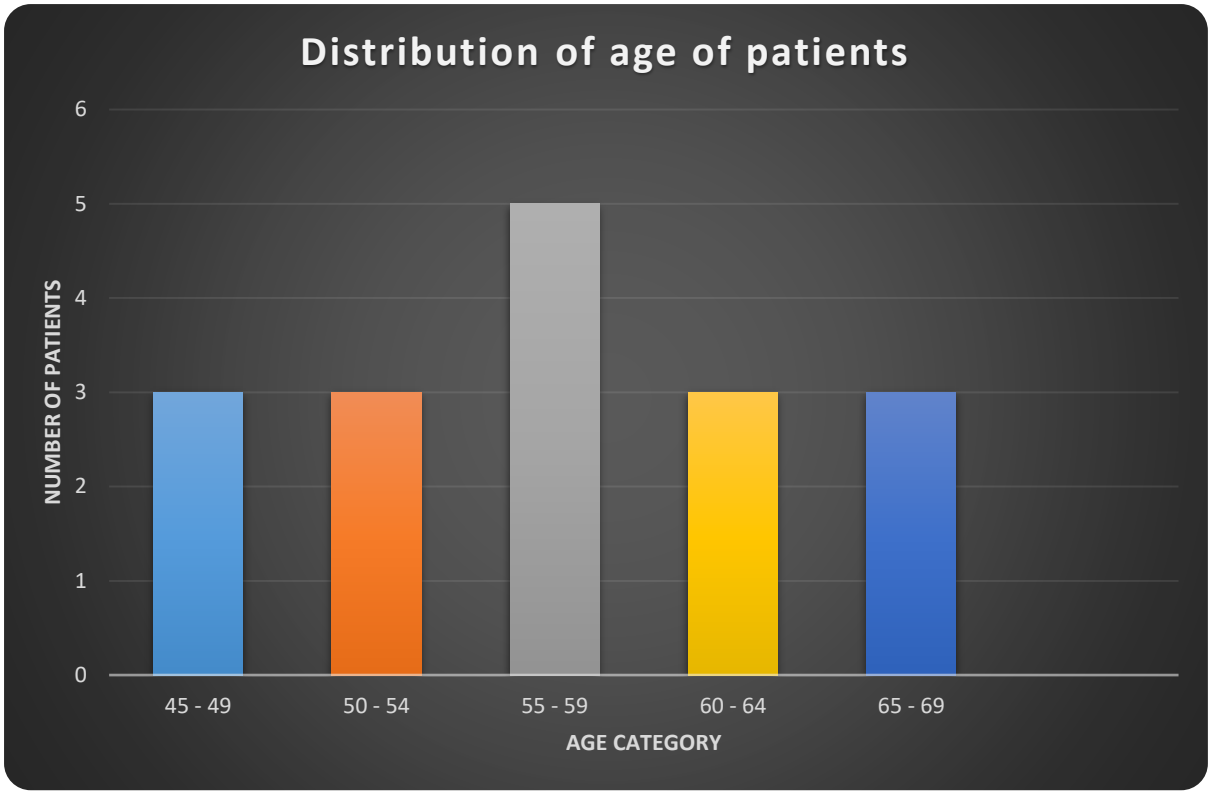


Figure 3.2: Age distribution of study participants.

Average Age of Patient	57
Median Age	58

Table 3.1: Mean age distribution

	Male	**Female**	**Total**
Number of Patients	10	7	17

Table 3.2: Gender distribution of study participants

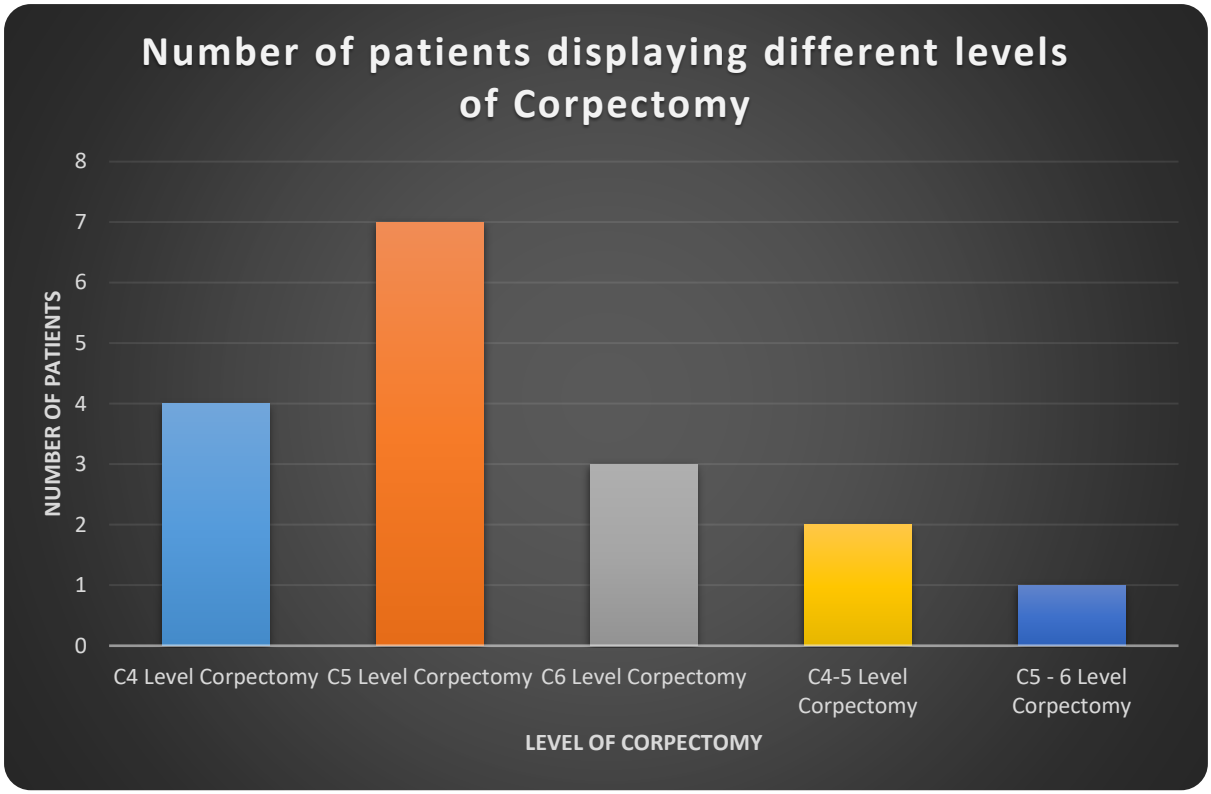


Figure 3.3: Different level of corpectomies performed in the study.

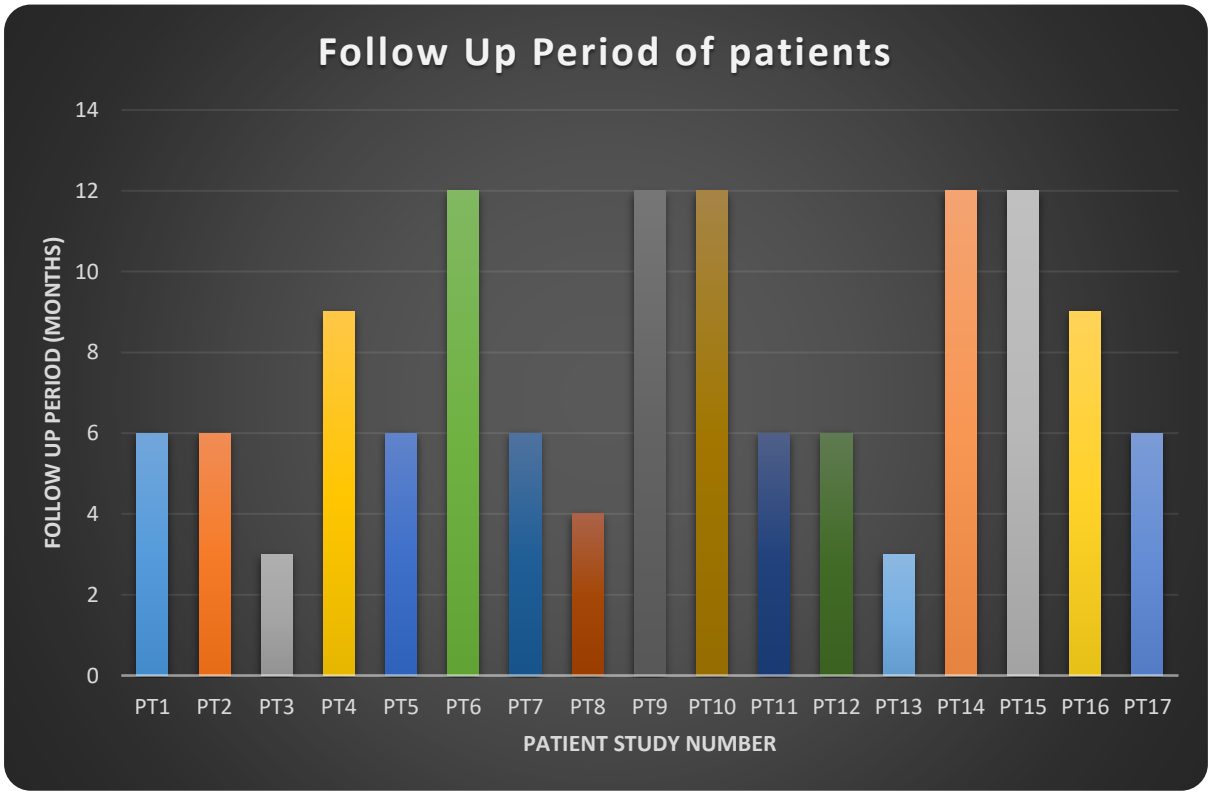
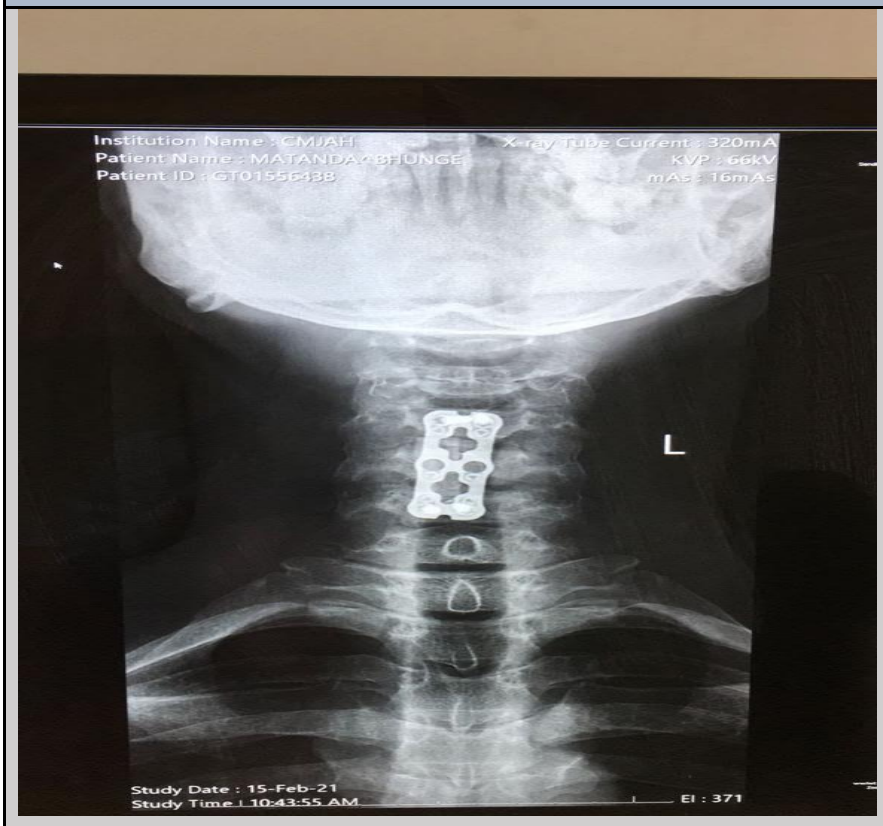


Figure 3.4: Radiographical follow up period assessed

	**Radiograph 3.5: Anterior posterior post-operative radiography showing neither graph lucency nor subsidence.**
	**Radiograph 3.6: Anterior posterior post-operative radiography showing neither graft lucency nor subsidence.**

	**Radiograph 3.7: Lateral view post-operative radiography showing neither graft lucency nor subsidence.**
	**Radiograph 3.8: Lateral view post-operative radiography showing neither graft lucency nor subsidence.**

CHAPTER 4: DISCUSSION

The goal of anterior cervical corpectomy and reconstruction using allogenous fibular strut graft material is to gain early fusion. This is evidenced by minimal post-operative radiographic subsidence and lucency and summative minimal postoperative cervical height loss. Measurement of these two variables (subsidence and lucency) as instruments to evaluate surgical outcomes was the aim and objective of this research report.

Anterior cervical corpectomy is a safe and widely accepted surgical procedure in an appropriate subset of patients. Interbody fusion of the corpectomised space using a graft material is an adjunct employed frequently during the cervical corpectomy to mitigate potential post-operative instability, maintain cervical spine height; angulation and alignment and thus, any post-operative morbidity; culminating in the elimination of instability and preventing neural foraminal compromise postoperatively following corpectomy (42) .

Autogenous iliac bone graft has been the long-standing gold standard for graft material used to fill the corpectomised cervical interbody space. In this series we explored a viable but novel alternative in the context of the South African spinal surgery fraternity; the utilisation of allogenous fibular strut grafts to fill the corpectomised cervical interbody space. The aim is to reduce donor-site complications and attain fusion, thereby earmarking and establishing allogenous fibular strut grafts as a viable and safe alternative grafting material for use in spinal surgery.

This current retrospective fibular strut allograft study included 17 patients. These 17 patients consisted of 10 male participants and 7 female participants who underwent either single (1-level) or multilevel (2-level) corpectomy and fusion. The study sample displayed an average age of 57 years and a mean age distribution of 58 years, with the age range being from 45 to 69 years. In this study, patient age and sex, as independent variables, seem to be unrelated to post-operative radiological subsidence and lucency rates; nevertheless the age range was not particularly broad.

In the post-operative course, an understanding of normal and abnormal radiographic findings are essential when evaluating the outcome of the implanted graft material and its direct implications on any future surgical or clinical decision making. Thus, it is a given that accurate

analysis of post-operative radiographs are not only paramount in order to provide ideal patient care, but also too guide future management (55).

Plain radiographs continue to be regarded as the standard when assessing bone graft healing and incorporation post-operatively at the graft recipient site. The cervical spine radiographs provide the surgeon with clarity and insight about graft material incorporation and potential features that suggest pending failure of the graft–endplate construct (55).

In this study, post-operative radiographical images were assessed retrospectively with the aim of measuring the incidence and occurrence of subsidence and lucency on the post operative radiographs after using allogenous fibula strut grafts in anterior cervical corpectomy and reconstruction procedures.

The utilisation of adjunctive imaging is a well-established modality if post-operative radiographs are found to be inconclusive. The above adjunct imaging modalities include; computerised tomography, magnetic resonance imaging (MRI), scintigraphy and stress radiographs (55). Plain radiographs are the commonest and most cost effective imaging modality employed in the spine unit that the study was based in and thus were the only modality used to assess the post-operative graft-endplate features after allogenous fibular strut graft usage.

It is well established in current literature that both osteoconduction and osteoinduction is essential for graft incorporation into native bone in order to be considered successful. This being said, no osteoinductive stimulus or osteoconductive material can be macroscopically or microscopically deemed successfully incorporated in the absence of osteogenic cells. Osteogenic cells are successfully transported and subsequently transplanted into the cervical graft via several mechanisms, namely: bone marrow implantation, autologous bone graft, migration from surrounding sites into the cervical graft site - or it can be delivered via the spines vascular system to the graft incorporation site (3, 56). In this study using the allogenous fibular strut graft material, the graft material inherently possessed both osteoinduction and osteoconduction characteristics, we relied on osteogenic cell infiltration at our recipient site via these two mechanisms; delivery from the spine’s vascular system and migration from surrounding sites into the cervical graft site.

Freeze dried allogenous fibular strut graft material, whose composition is similar to that of native bone, is known to be safe and less allergenic when compared to fresh frozen allogenous graft material, with excellent bone fusion capability. Allogenous fibular strut graft material has

been studied and utilised for its properties not only in spine surgery but also in general orthopaedics, maxillofacial, and dental fields (11, 41, 56).

Allogenous bone is generally considered to be only marginally resorbable. The slow resorption rate of this graft material provides a strong scaffold for bone formation and thus results in orderly remodelling over time (56). This minimal resorbability directly provides a scaffold for bone ingrowth, thus supplying the end plate-graft site with a stable structure for the process of bone calcification to occur. This ultimately allows new bone formation while providing constant mechanical strength (40, 56).

A bony fusion was observed in 17 of the 17 eligible participants (100%) between the three month to one-year follow-up radiographs that were followed up. Subsidence was defined as a loss of segmental height of more than 3mm at follow-up compared with the immediate post-operative height. The subsidence rate was 0% (0/17) at the three to six month follow-up and remained 0 % (0/17) at the final follow-up.

Post operative radiographic changes seen when a allogenic bone graft material substitute was used, are starkly different from when an autogenous bone graft material substitute is used. At the outset, bone resorption is commonly visualised at the allograft - endplate margins and peaks in prominence between the post operative period of 7 and 10 weeks post-operatively (55) .

Due to the reabsorbtion and necrosis of the fibula allograft and the presence of additional osteopenia in the surrounding cervical bone, radiographic appearance of radiodensity will then appear. This radiodensity of the implanted graft material begins the process of minimising in size approximately three to six months after transplantation and this process may last up to eighteen months (55).

Burchardt descibed a classification for healing after allograft use. In his paper, he classifies healing into three different classes. Type I is descibed as normal and its radiographic appearance is one of bony union within 16 weeks. Type I accounts for the majority of all allografts on post-operative radiographs studied by Burchardt, and it appears radiographically identical to the autograft in the study. He describes Type II as delayed unions and non-unions. Type II is described as undergoing peripheral resorption of tranplanted bone graft with gradual loss of graft height and size. Type III consists of grafts that have udergone a process of rapidly resorbing. Type III displays no signs of radiographic repair and occur close to 20% of the time (57). All 17 cases assesed and reviewed in this study were categorised into the Burchardt type

I, as all 17 cases underwent bony union with no features of subsidence and lucency that would strongly suggest the presence of non-union or graft failure .

It was observed that graft incorporation could be appreciated radiologically by the third post-operative month in most of the cases in our study. The allogenous graft material had started incorporating and merged and started the formation of a dense-like mass at the bone graft site. The bone mass became more homogenous, with no lucency seen on post-operative radiographs, with a Bridging bone mass seen with no lucent lines present.

A period of 3 to 12-month post-operative assessment of radiographs was chosen in our present study, it was deemed a sufficient time to evaluate incorporation of the bone graft substitutes, due to the low number of post-operative radiographs that were found (extensively discussed in the limitations section). Six months to a year was deemed ideal for radiographic follow up, but was extended to three months to a year to get more participants.

To assess the osteoconductivity and osteointegration of the allogenous fibular strut graft, we recorded the rate of occurrence of a "radiolucent gap" at the interface between the allogenous fibular strut graft and the endplate at the three to one-year and follow-up, which were 0% (0/17) respectively. The fused area or mass is deemed laudable when there is a continuous growth and incorporation of bone that displays no radiolucent areas.

It was reported by Daubs *et al*. that in their study that they observed an extraordinary high early failure rate (75%) following multilevel corpectomies and cervical fusion procedures (34). Jeffrey *et al*. demonstrated that the fusion rate when utilising an autologous or allogenous fibula strut graft increased markedly with progressively increasing numbers of motion segments included (58). This was found to be possibly related to inadequate external immobilisation with regard to time in the orthotic cervical spine brace or the related rigidity of the cervical spine orthosis utilised. The aforementioned factors are hugely influential in outcomes especially when a fibular cortical strut graft is primarily used in a mobile cervical spine region, which is known to be globally exposed to forces such as flexion, extension, and rotation. Correspondingly, the lever arm is particularly long when 2 level or 3-level corpectomy and reconstruction is undertaken using the allogenous fibula strut graft of appropriate length, all of which influences graft incorporation and outcomes (10, 34, 58).

Furthermore, Chen *et al.* demonstrated that 2-level corpectomy, as compared to 1-level corpectomy, displayed a greater inclination towards stark subsidence. The number of corpectomy levels was deemed an independent risk factor for severe subsidence by Chen *et al.* They concluded that multi-level corpectomies have a potency towards poorer post-operative clinical outcomes and major subsidence-related complications (59). In this study using allogenous fibular struts after cervical corpectomy and fusion, a 2-level corpectomy was not found to have a higher susceptibility and propensity to the development of either lucency or subsidence. The study found that there was no further loss of the fused segmental height in 2-level corpectomy group when compared to 1-level corpectomy group.

Single level corpectomy and fusion was performed in 14 of the 17 patients, and a multilevel (2 level) corpectomy was performed in 3 patients in the study population. Cervical spinal vertebrae five (C5) was found to be the commonest spinal vertebrae level at which single level compectomies were performed in this series, followed closely by cervical vertebral level 4 (C4), followed by cervical vertebrae six (C6) being the least performed single level compectomy in this study. With regard to 2 –level corpectomies, cervical spinal level C4 and C5 were corpectomised and fused more commonly when compared to cervical spinal vertebrae level C5 and C6 in this study population.

Additionally, a higher subsidence rate or a lower fusion rate in 2-level corpectomy when compared to a 1-level corpectomy was not found in our series. Thus, it was deduced that allogenous fibular struts after cervical corpectomy and fusion can confirm more than adequate biomechanical stabilisation regardless of 1-level or 2-level corpectomy and reconstruction.

Post-operative radiological graft subsidence is a known common phenomenon after corpectomy and reconstruction. Currently in the book of knowledge the impact and implication of radiographical subsidence post cervical fusion remains controversial (60). Chen *et al.* defined severe subsidence (>3mm) and they found that subsidence occurred in 19.0% of their postoperative patients, they deduced that post-operative radiographic subsidence was associated with bad clinical results and subsidence-related complications (59).

Subsequently Karikari *et al*. systematically reviewed, deduced and concluded that post-operative radiographic subsidence did not have a direct bearing on effective clinical fusion or clinical outcomes (61). In-study vertebrae-graft interface subsidence rate was recorded at 0%

at the follow-up, based on available post-operative radiographs. The study did not correlate the radiographical finds to clinical outcomes, as this study was a retrospective radiographical series, focused on the radiographical measurements of subsidence and lucency. Therefore the current study could not scientifically comment on the relationship between subsidence and clinical outcome, whether positive or negative outcomes.

Subsidence primarily occurs at the vertebral endplates especially in the osteoporotic or decorticated end plate. Whitecloud and LaRocca are best known for describing the surgical technique in which there is formation of a notch at the ends of the superior and inferior ends of the cortical graft strut, followed by locking it into the superior and inferior vertebral bodies' end plates, specifically the anterior cortices of end vertebral bodies as they resist compressive forces best. This technique is aimed at ultimately resisting compressive forces on the endplates which avoid subsidence at this graft endplate interval (2). This notching of the allogenous fibular graft strut was a technique employed during surgery in all of the patients observed in this study. We deduced that this further contributed to the good outcomes seen in our series, as we had a low subsidence and lucency rate post-operatively.

The aforementioned favourable outcomes observed in this study when using the allogenous fibular strut graft material, are considered to be a consequence of a variety of factors, which include: the good strength and incorporation of the allogenous fibular strut graft, the dynamic anterior plate utilised intraoperatively, and lastly the intentional preservation of upper and lower end plates integrity.

From the aforementioned radiological results, it appears allogenous fibular strut graft material supports the formation of new bone growth at the endplate-graft site and further bone maturation. We deduced that it can be safely used for spinal fusion and is as effective and safe with an added advantage of no donor site morbidity.

CHAPTER 5: CONCLUSION

This research study has endeavoured to describe the novel initial investigation into using allogenous fibular strut grafts as a viable and safe grafting material in anterior cervical corpectomy and reconstruction procedures. The allogenous fibular strut graft displayed encouraging biomechanical characteristics with low rates of lucency and subsidence. In summary, this study suggested that allogenous fibular strut grafts used in anterior cervical corpectomy and reconstruction procedures whether single level corpectomy or 2 level corpectomy is both a safe, feasible and possibly sustainable alternative grafting material in the spinal surgical sphere.

More recently, literature has strongly recommended the usage of computerised tomography as an alternative to plain radiographs when assessing post-operative radiographic features of graft integration. This regrettably is deemed impractical in the current South African state healthcare system as it is both expensive and has high radiation exposure for the patients in question.
Radiographic fusion may not be the only predictor of post-operative quality of life for the patient, nor is it predictive of the clinical outcome and thus subsequently the attainment of surgical success. This therefore necessitates that future research explore both the clinical and radiographical outcomes in unison to accurately assess the attainment of surgical success post intervention using allograft material.
Future research should be geared towards more studies that specifically study allogenous fibular grafts and their post-operative outcomes. Furthermore, it is essential that larger prospective controlled, randomised trials are conducted with long-term follow-up emphasised, which should include both radiographical and clinical outcomes to get a more holistic outcome measure. Future studies should be well-designed prospective long-term studies that compare autologous and allogenous and other graft substitutes to finally shed much needed light on the questions related to discrepancy in fusion rates, clinical effectiveness, cost implications, and surgical safety.

Limitations exist within the current investigation:

- The sample size of the patients in this study was small due to multiple factors. Firstly, 29 patients in total underwent anterior cervical corpectomy using allogenous fibular strut graft material for the period 1 January 2012 to 31 December 2019 at CMJAH. However, only 17 post-operative radiographs were found and deemed acceptable for review in this study. Cervical corpectomy and reconstruction is not a routine orthopaedic surgery performed

daily but rather a speciality surgery employed in the spinal unit as needed. Additionally, the usage of an allogenous fibular strut graft as grafting material after corpectomy is rarely used in the South African setting and is a novel alternative to the well-established methods previously employed.

- Further methodological limitations included the potential bias within the sample size. There is the inherent lack of comparator groups coupled with a retrospective study within a control group that may further impair objectivity.
- This study focused on the retrospective follow-up of routine post-operative radiographs, taken between the three to twelve month follow up period. The study period, which was between 01 January 2012 and 31 December 2019, inferring that follow-up of patients operated on during the latter half of 2019 would have had their routine follow-up outpatients' clinic radiographs scheduled during the severe acute respiratory syndrome coronavirus 2 (SARS COV2) pandemic. As a result of lockdown measures implemented in South Africa due to the Corona Virus Disease 2019 (COVID-19), many patients were lost to follow-up as of February 2020 as lockdown measures and fear of contracting the virus has seen low follow-up rates in spinal outpatient clinics.
- For the period 2012 to 2016, retrieval of all the routine follow-up radiographs was difficult and yielded very few results, it required manual searching through thousands of stored radiograph films to get the required cervical spine radiographs, as CMJAH computerised PACS went live only in April 2016. The collection of radiographs for the period January 2012 to December 2016 yielded very few cases, this was for several reasons, foremost being the poor storage system of printed radiographs at CMJAH, with most post-operative radiographs from this period simply missing. They could not be accounted for, even after meticulously searches over an extended period of time.
- For the period January 2017 to December 2019, the CMJAH computerised PACS was used. This method of collecting the retrospective radiographs also proved to be lacking and we again yielded low numbers of eligible radiographs that could be used in this study. Again the reasons were several. The computerised system simply did not have any of the post-operative radiographs captured under the patient identifiers used in the study. Upon further inquiries, it was found that this was in part due to radiographs that were captured under different hospital numbers erroneously. Alternatively, as was more often the case, the PACS system went offline, meaning radiographs taken in the spine outpatient clinic on a particular day were sometimes not captured and not printed. If they were printed at all, the

patient departed with the radiograph. This being a retrospective radiographic research study , tracking down patients who had their images in their possession would require a prospective recall to the research , which could not be augmented to this study as the SARS COV2 pandemic deemed it unsafe to have any study with a prospective recall other than research directly involving COVID 19 related disease processes .

- There is inherently a significant limitation in the accessible literature (3). Currently any conclusive clinical judgments or surgical recommendations with regard to the utilisation of allograft or ICBG requires cautious consideration within the construct of the current literature. At this time, allogenous fibular strut graft usage in anterior cervical corpectomy and reconstruction remains an area of clinical and radiographical equipoise.

The study of allogenous graft material is not only a thought-provoking area of research for further investigation but an obligatory one if we are to improve patient outcomes in the future.

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APPENDIX A: RESEARCH INTRUMENT

Data collection form to be used by the Radiologists to assess for post-operative subsidence and lucency of the cervical spine.

Patient Study Number	
Gender	
Age	
Month of post-operative follow up	

Full complement of static cervical Spine Radiographs available?

Please tick in one box only using a cross

	Yes	**No**
Anterior Posterior View		
Lateral View		

Disease Corpectomised Level

Please tick in one box only using a cross

	1- Level Corpectomy	2- Level corpectomy
1 or 2 level Corpectomy		

1- Level Corpectomy	
Cervical Level – C4	
Cervical Level – C5	
Cervical Level – C6	

2- Level Corpectomy

Cervical Level – C4-C5	
Cervical Level – C5-C6	

Presence of graft subsidence on post-operative cervical spine radiographs?

Please tick in one box only using a cross

Yes	
No	

If subsidence is present, how much? (In millimetres measured units please)

Presence of graft lucency on post-operative cervical spine radiographs?

Please tick in one box only using a cross

Yes	
No	

Additional Comments

APPENDIX B: GATEKEEPERS LETTERS

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research and Postgraduate Affairs

TO:	Dr M Bhamjee School of Clinical Medicine Department of Surgery Division of Orthopaedic Surgery Medical School University E-mail: mobhamjee79@gmail.com
CC:	Supervisor: Dr S Khan <Shahzad.Khan@wits.ac.za> and <HREC-Medical Research Office@wits.ac.za>
FROM:	Mr Iain Burns Human Research Ethics Committee (Medical) Tel: 011 717 1252 E-mail: Iain.Burns@wits.ac.za
DATE:	2021/03/02
REF:	R14/49
PROTOCOL NO:	**M201023** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)
PROJECT TITLE:	*Allogenous fibular strut graft usage in anterior cervical corpectomy and reconstruction*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R49 Dr M Bhamjee

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M201023

NAME: **(Principal Investigator)**	Dr M Bhamjee
DEPARTMENT:	School of Clinical Medicine Department of Surgery Division of Orthopaedic Surgery Medical School University
PROJECT TITLE:	*Allogenous fibular strut graft usage in anterior cervical corpectomy and reconstruction*
DATE CONSIDERED:	2020/10/30
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr S Khan
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2021/03/02

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **«Missing mail merge field»** and therefore reports and re-certification will be due in the month of **«Missing mail merge field»** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Mohamed bhamjee 15/11/2021

Signature of Principal Investigator Date

GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL (CMJAH)

Office of the Clinical Director

Enquiries: Ms. TT Mahlangu
Tel: (011) 488-3365
Email: Thandi.Mahlangu4@gauteng.gov
Physical Address: Room 262A,17 Jubilee, Parktown 2193 Postal Address: Private Bag x39, Johannesburg 2000

30 July 2020

Dear Dr Mohamed, Bhamjee

STUDY TITTLE: Allogenous fibular strut graft usage in anterior cervical corpectomy and reconstruction

Permission to conduct the above-mentioned study is provisionally approved. Your study can only commence once Ethics approval is obtained. Please forward a copy of your Ethics Clearance Certificate as soon as the study is approved by the Ethics Committee for the CEO's office to grant you the final approval to conduct the study.

Supported/Not Supported

Dr PN Africa
Acting Clinical Director
Date: 3/8/20

Approved/Not Approved

Ms. G Bogoshi
Chief Executive Officer
Date: 3.8.2020