Structured Abstract:

Background Context:

Demineralized Bone Matrix (DBM) is widely used for spinal fusion, but its reliance on human donors raises concerns related to availability, variability in quality, and cost. Synthetic bioactive glass, such as NanoFuse™ Biologics (NF) (NanoFuse Biologics LLC®, Burlington, MA, USA), a combination of synthetic Bioactive Glass (BAG) with Demineralized Bone Matrix (DBM), offers a potential solution by enhancing osteogenesis and reducing the need for human donor tissue. However, there is limited evidence directly comparing DBM alone to DBM combined with synthetic BAG in anterior cervical discectomy and fusion (ACDF).

Purpose:

To assess the fusion rates and clinical outcomes of using DBM combined with synthetic bioactive glass versus DBM alone in single-level standalone ACDF.

Study Design/Setting:

This was a prospective pilot study conducted in a single outpatient surgical center, involving 81 patients who underwent single-level standalone ACDF between 2018 and 2022.

Patient Sample:

Eighty-one patients were enrolled (mean age, 45 ± 10 years; 51.9% female): Group 1 (44 patients) received a combination of DBM and BAG (NanoFuse™), and Group 2 (37 patients) received DBM alone.

Outcome Measures:

Self-reported outcome measures included the Visual Analog Scale (VAS) for assessing neck pain

and the Neck Disability Index (NDI) for evaluating functional disability. Radiographs were used to assess bone fusion, with follow-up imaging conducted at specified intervals to confirm fusion success.

Methods:

Patients were enrolled over a four-year period and followed up for a minimum of two years postoperatively. Preoperative assessments and postoperative radiographs and clinical evaluations were performed at set intervals. Group 1 received DBM plus bioactive glass, and Group 2 received DBM alone. Surgical complications, deviations, and revisions were recorded, with follow-up data collected for at least twelve months.

Results:

Both groups achieved 100% fusion at the one-year mark. Group 1 (DBM plus bioactive glass) showed a greater improvement in VAS pain scores (72.3%) compared to Group 2 (DBM alone), which showed a 64.1% improvement ($P<0.001$). NDI scores improved similarly in both groups. No surgical complications were reported, and all procedures were successfully completed in an outpatient setting.

Conclusions:

The combination of synthetic bioactive glass with DBM in single-level ACDF provides fusion rates equivalent to DBM alone, with superior pain reduction outcomes. This approach may help reduce reliance on human donor tissue, potentially lowering costs and addressing ethical concerns, while improving clinical outcomes. Further studies with larger patient populations are warranted to confirm these findings.

Keywords: Cervical; NanoFuse™ Bioactive Glass; BAG; Demineralized Bone Matrix; DBM; Fusion; Anterior Cervical Discectomy and Fusion; ACDF; Synthetic Biologics; Donor.

Introduction

Interbody fusion provides anterior column spinal stabilization for the treatment of various spinal pathologies, such as degenerative disc disease (DDD), herniated disc, spondylolisthesis, and deformity [1]. In the United States, interbody fusion is the most commonly performed spinal surgery, with over 400,000 cases annually [2]. Degenerative disc disease can lead to chronic pain in the cervical spine, often necessitating surgery [3]. Previous studies have demonstrated that anterior cervical discectomy and fusion (ACDF) is effective for treating cervical degenerative disc disease [4-13]. Demineralized bone matrix (DBM) has been shown to be effective and safe for ACDF [14, 15]. In addition, propensity score-matched case-control studies have reported comparable effectiveness and outcomes in performing 1-2 level ACDF with and without cervical plating [16].

The gold standard biological material used in spinal fusion is autologous iliac crest bone graft. Its osteogenic, osteoconductive, and osteoinductive properties promote fusion. However, the morbidity and complications associated with harvesting make it an undesirable solution [17]. The use of synthetic biologics is an attractive alternative to harvesting bones from human donors. An ideal synthetic graft should perform similarly to or better than human tissue, with low immunogenicity and no risk of disease transmission. The orthobiological field has seen rapid development of various allografts and synthetic grafts, including DBM, collagen, calcium phosphate (hydroxyapatite [HA] and β-tricalcium phosphate [β-TCP]), ceramics, calcium sulfates, biodegradable polymers, and bioactive glass [18-20]. DBM combined with local bone has proven to be an equivalent substitute for autogenous bone harvesting [21]. Bioactive glass (BAG) 45S5, invented by Professor Larry Hench at the University of Florida in 1969, has been shown to stimulate osteogenesis through the release of biologically active ions, promoting bone

growth and bonding to existing bone [22]. NanoFuse™ Biologics (NanoFuse Biologics LLC®, Burlington, MA) is the only U.S. Food and Drug Administration (FDA)-approved osteobiologics that consists of a combination of DBM with synthetic ceramic-based calcium phosphor-silicate particulate 45S5 bioactive glass, coated with gelatin. When combined with aqueous body fluids, NanoFuse™ Biologics formulations form a 3D ultra-porous calcium hydroxyapatite matrix scaffold for bone formation. It releases calcium, sodium, silica, and phosphate ions, increasing local pH to improve angiogenesis, osteogenesis, and antimicrobial activity [19, 20, 23, 24]. While there is extensive literature on the use of DBM in standalone ACDF, there is a lack of studies directly comparing DBM to combinations of DBM and bioactive glass, such as NanoFuse™ Biologics. To our knowledge, this study represents the first direct comparison between DBM alone and DBM plus bioactive glass in single-level standalone ACDF procedures. This novel comparison aims to provide critical insights into the efficacy of these materials, potentially influencing clinical decisions regarding graft material selection in cervical spinal fusion surgeries.

We hypothesized that FDA-approved NanoFuse™ Biologics would produce fusion rates and clinical outcomes equivalent to those of DBM alone in single-level ACDF surgeries, given that it possesses the osteoinductive properties of DBM with the added osteoconductive and osteostimulatory properties of bioactive glass. Fusion was determined using radiographs, following the criteria outlined by Nathan et al., who identified bone bridging the interspace anterior to the cage on a lateral view as a clear indicator of fusion, termed the sentinel sign [25].

Materials and Methods

Prospectively collected data were retrospectively reviewed from a single center involving 81 patients who underwent single-level standalone anterior cervical discectomy and fusion (ACDF) using the A-CIFT Solofuse® polyetheretherketone (PEEK) interbody cage device (LESSpine, Burlington, MA, USA) in an outpatient setting. Patient enrollment spanned from January 2018 to 2022, with all participants followed up for a minimum of two years.

We reviewed the charts of 44 patients in Group 1, who underwent single-level standalone ACDF using a combination of NanoFuse™ Biologics (DBM plus synthetic bioactive glass). Group 2 consisted of 37 patients who underwent single-level standalone ACDF using DBM alone (DBM Pure, LESSpine Inc., Burlington, MA, USA). All surgeries were performed by a single surgeon in an outpatient setting to minimize variability in surgical technique, and informed consent was obtained from all participants.

Patients were considered for surgery after six months of persistent cervical radiculopathy and failure of conservative management, including physical therapy and pain management. Indications for ACDF surgery included symptomatic cervical spondylosis, herniated discs causing stenosis (Figure 1), degenerative disc disease with instability, myelopathy, radiculopathy, and facet arthritis. Exclusion criteria included acute severe trauma, fractures, malignancy, infection, unstable chronic medical conditions, a body mass index (BMI) >42 [11, 26], and prior anterior cervical fusions, anterior corpectomy, or total disc replacement. Patients requiring laminectomy were also excluded based on outpatient surgery criteria at this institution [11].

Preoperative assessment included the recommendation to discontinue narcotics at least two weeks prior to surgery for patients who had been on narcotics for more than six months [27].

Patients with stable medical conditions, such as hypertension, diabetes mellitus, hypercholesterolemia, heart disease, and asthma, were cleared for surgery by their primary care physician or cardiologist, where applicable. Institutional Review Board (IRB) approval was granted for this study through the Western Institutional Review Board (WIRB®), now known as the WIRB-Copernicus Group (WCG® IRB) (WIRB#20181251). Informed consent was obtained from all individual participants.

ACDF Surgical Technique

Anterior cervical fusion was performed by modified approach to the standard Smith-Robinson operative technique [10, 28]. A midline anterior cervical incision was made to achieve the surgical exposure of the desired vertebral level. Subcutaneous dissection was performed to allow adequate tissue mobilization. The posterior longitudinal ligament was retained *in situ* after total discectomy of the affected disc with pituitary ronguers, curette, and burr drills [29, 30]. An appropriately sized standalone PEEK cage was measured, packed with bone graft, inserted, and fixated to the vertebrae by two screws, one cephalad and one caudal (Figure 2). In Group 1 patients, NF was reconstituted into an injectable putty form by adding sterile normal saline to the granules. We used 2.5 cc of NF putty per level, which was placed within and anterior to the PEEK cage to aid with fusion (Figure 3A). For Group 2 patients, 2.5 cc of DBM was placed within and anterior to the PEEK cage using a similar approach (Figure 3B). Once hemostasis was achieved, a Penrose drain was placed anterior to the spine for wound drainage for at least twenty-four hours.

Discharge and Follow Up

All patients were discharged within 2-4 hours of completing surgery after being deemed oriented and neurologically intact by the post-anesthesia care unit team, anesthesiologist, and operating surgeon. A protocol developed by the outpatient center based on published literature was used as the discharge criteria [31, 32]. Outpatient postoperative instructions were discussed with all patients and caregivers and written copies were provided [11]. Patients were educated on potential complications, including dysphagia, transient-to-persistent soft tissue edema with possible airway compromise, postoperative hematoma, and infection [11]. The drain was removed in the office. Patient-reported outcomes included the Visual Analog Scale (VAS) for neck pain and Neck Disability Index (NDI). Scheduled follow-up visits were conducted within the first 2 weeks and 3, 6, 12, and 24 months postoperatively. Additional postoperative complications and revisions were also recorded. Fusion was defined as <1 mm of motion on plain radiographs, including flexion and extension views [33]. At least one of the locations (anterior, within, or posterior to the cage) confirmed the presence of continuous trabecular bone bridges on the plain lateral radiographs.

Statistical Analysis

Statistical analyses were executed utilizing Visual Studio (VS) Code (Version 1.87.1), the anaconda3 (Python 3.12.0) kernel within VS Code, and a comprehensive suite of Python coding and statistical packages including: ‘pandas, ‘scipy.stats’, ‘matplotlib,’ and ‘seaborn.’

An independent samples t-test was applied to determine any statistically significant difference in mean scores between the two independent groups that were normally distributed. A paired sample t-test was used to assess the mean difference between the paired variables. Shapiro-Wilk Test for Normality was applied to address the mixture of normal (parametric) and non-normal

(non-parametric). Kruskal-Wallis Test was applied to the data for an overall comparison of mean VAS scores across multiple time intervals and multiple groups without the assumption of normality for all sets of scores. Finally, the Mann-Whitney U Test for Pairwise Comparisons was applied to compare differences in sets of scores during different time intervals, following any significant results from the Kruskal-Wallis test. Similar to the two previous tests listed above, the Mann-Whitney test accounted for non-normal distribution of data between time intervals and, therefore, was an appropriate method of analysis.

Results

Group 1 (NF) consisted of 44 patients, with a majority of women (59.1%). The average age within this group was 44.9 ± 10.8 years, and the mean Body Mass Index (BMI) was noted as 32.3 ± 25.3 kg/m^2. Control Group 2 (DBM) included 37 patients, of whom 43.2% were female and 56.8% were male. This group's average age was higher at 46.6 ± 9.7 years, with a mean BMI 30.8 ± 7.2 kg/m^2. Comparative analysis between the two groups revealed no significant statistical difference in sex distribution based on age, BMI, length of surgery (LOS), or estimated blood loss (EBL) (P = 0.348, P = 0.456, P = 0.678, and P = 0.345, respectively). At 12-month postoperatively, both NF and DBM groups achieved 100% fusion rates (Figure 4 and 5).

The study details in Table 1 included demographics, length of surgery, fusion rates, expected blood loss, and spinal levels of pathology treated, among other variables. Independent samples t-test showed no significant difference in preoperative and postoperative VAS scores between the two groups after 24 months (P = 0.776 and P = 0.156, respectively). However, successive follow-ups highlighted statistically significant intragroup improvements in the VAS scores at different time intervals.

NF's mean VAS score decreased (51.7%) from 7.72 to 2.14 after 12 months (P<0.001). The VAS score continued to decrease (an additional 20.6%) to 2.1 after 24 months (P<0.001). The mean preoperative NDI score compared to the cumulative postoperative NDI score up to 24-months for NF patients decreased by 66.83% from 49.7% to 16.5% (P<0.001). Patients with DBM also exhibited significant improvements in mean VAS scores. Their postoperative score decreased (38.8%) from 7.65 to 4.68 after 12 months (P<0.001) and continued to decrease (25.3%) to 2.14 (P<0.001) after 24 months. The mean preoperative NDI score compared with the cumulative postoperative NDI score up to 24-months for DBM patients with DBM decreased by 71.2% from 52.7% to 15.2% (P<0.001). Illustrations of the statistical improvements are shown graphically in Figures 6 and 7.

LOS and EBL were also analyzed and revealed no significant differences between NF group patients at 74.7 ± 33.6 minutes and 50.0 ± 0.0 cc, and DBM group patients at 81.6 ± 32.3 minutes and 48.8 ± 6.9 cc (where P=0.833 and P=0.300, respectively). There were no unplanned postoperative admissions for complications such as pain or nausea. There were no surgery-related complications; however, one patient experienced an anesthesia-related incident (negative pressure pulmonary edema). There were no revisions at the surgical level; however, one patient from group 1 required additional surgery for adjacent segment disease at 14 months. The overall spinal levels treated by group are summarized in Table 1. The total number of ACDF procedures performed at each spinal level is shown in Figure 8.

Discussion

This study aimed to evaluate the effectiveness of combining NanoFuse™ Bioactive Glass with Demineralized Bone Matrix (DBM) in standalone single-level anterior cervical discectomy and

fusion (ACDF) procedures. The use of DBM alone has been well-documented for promoting fusion in spinal surgeries, but synthetic biologics like bioactive glass present a novel opportunity to reduce reliance on human donor tissue while maintaining fusion efficacy. This study addresses the gap in research regarding the combined use of DBM and synthetic bioactive glass in ACDF and compares it to DBM alone.

Key Findings

Our results demonstrated equivalent fusion rates between the two groups: patients treated with a combination of NanoFuse™ bioactive glass and DBM (Group 1) and those treated with DBM alone (Group 2). In addition to equivalent fusion rates, patients in Group 1 exhibited superior improvements in postoperative pain (VAS) and function (NDI scores) compared to Group 2. The use of synthetic bioactive glass combined with DBM showed greater osteoinductive and osteoconductive potential, contributing to better clinical outcomes without increasing surgical risks. This combination offers a viable, safe alternative for single-level ACDF while reducing the need for larger quantities of human-derived DBM, optimizing the use of biological grafts.

Comparison with Similar Research

Previous studies have supported the use of osteobiologics in promoting bone fusion, with autografts being the traditional gold standard [34, 35]. However, autografts carry risks of morbidity, and DBM alone lacks the osteoconductive properties of autografts. Research on bioactive glass, particularly the 45S5 formulation used in NanoFuse™, shows its ability to release ions that stimulate bone growth and integration, offering a more consistent alternative to DBM alone [22]. Kirk et al. [19, 23] demonstrated the biocompatibility and efficacy of NanoFuse™ in preclinical models, and our findings align with these results, showing that NanoFuse™ plus DBM provides a similar mechanical load-bearing capacity and bone healing

potential as autografts. Unlike DBM, which varies depending on manufacturing methods, bioactive glass can be tailored for optimal performance, as seen in its consistent osteoconductive and osteostimulatory effects.

Limitations

The primary limitation of this study is its sample size and single-center design, which may limit the generalizability of the results to other surgical centers or patient populations. All procedures were performed by a single surgeon, which reduces variability but may not reflect the outcomes across different surgeons or institutions. Another limitation is the exclusive use of PEEK cages, which may have influenced the results, as different cage materials could yield varied outcomes.

Clinical Implication

The findings of this study suggest that the combination of synthetic BAG and DBM is a promising alternative to DBM alone in single-level ACDF procedures. The superior pain reduction observed in the bioactive glass group, along with comparable fusion rates, highlights its potential to improve clinical outcomes while also reducing the reliance on human donor-derived DBM. By requiring smaller quantities of cadaveric DBM, this approach may optimize resource use, potentially lowering costs and addressing ethical concerns related to the availability and use of donor tissue.

Implications for Further Research

Future research should focus on multi-center studies to validate these findings in a broader clinical setting and with a larger sample size to ensure reproducibility. Additionally, studies comparing the combination of bioactive glass and DBM with other synthetic biologics or autografts would further clarify the relative benefits of this approach. There is also a need for

longer-term follow-up beyond two years to assess the durability of fusion and clinical outcomes over time.

Conclusion

Based on our study and the existing literature, we conclude that NanoFuse™ Biologics, which combines bioactive glass and DBM, is an effective alternative to DBM alone in single-level ACDF procedures. This combination provides equivalent fusion rates and comparable improvements in clinical outcomes while offering the added benefit of extending the utility of cadaveric bone-derived DBM. The ability of bioactive glass to stimulate bone growth and enhance fusion outcomes suggests that this combination may become a preferred choice in cervical spine fusion surgeries, optimizing both clinical and economic factors.

References:

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Figure Legend

Figure 1: Preoperative MRI scan showing a herniated disc at C5-6 causing cord compression.

Figure 2: Intraoperative photographs showing a single-level ACIFT standalone anterior cervical discectomy and fusion.

Figure 3: Intraoperative photographs showing (A) NanoFuse™ Biologics and (B) Demineralized Bone Matrix placed anterior to a standalone anterior cervical discectomy and fusion.

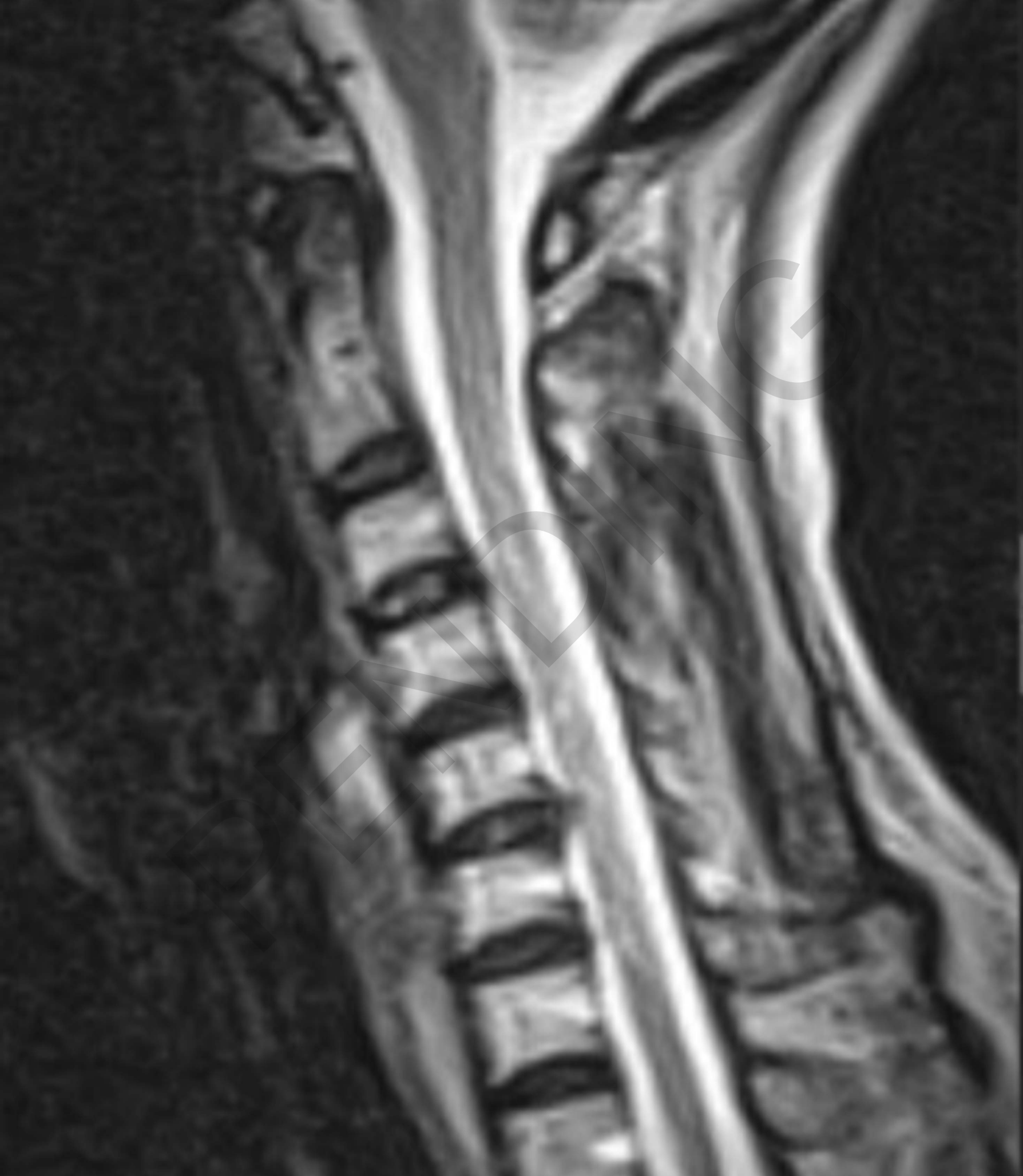
Figure 4: Postoperative lateral radiograph at 12 months showing solid fusion with (A) NanoFuse™ Biologics and (B) Demineralized Bone Matrix.

Figure 5: Postoperative Computed topography (CT) showing solid fusion.

Figure 6: Paired Samples T-Test of Preoperative vs. Postoperative (24 Months) visual analog scale (VAS) Scores for NanoFuse™ Biologics and Demineralized Bone Matrix

Figure 7: Paired Samples T-Test of Preoperative vs. Postoperative (24 Months) neck disability index (NDI). Percentages for NanoFuse™ Biologics and Demineralized Bone Matrix.

Figure 8: Total Number of anterior cervical discectomy and fusion procedures by spinal level.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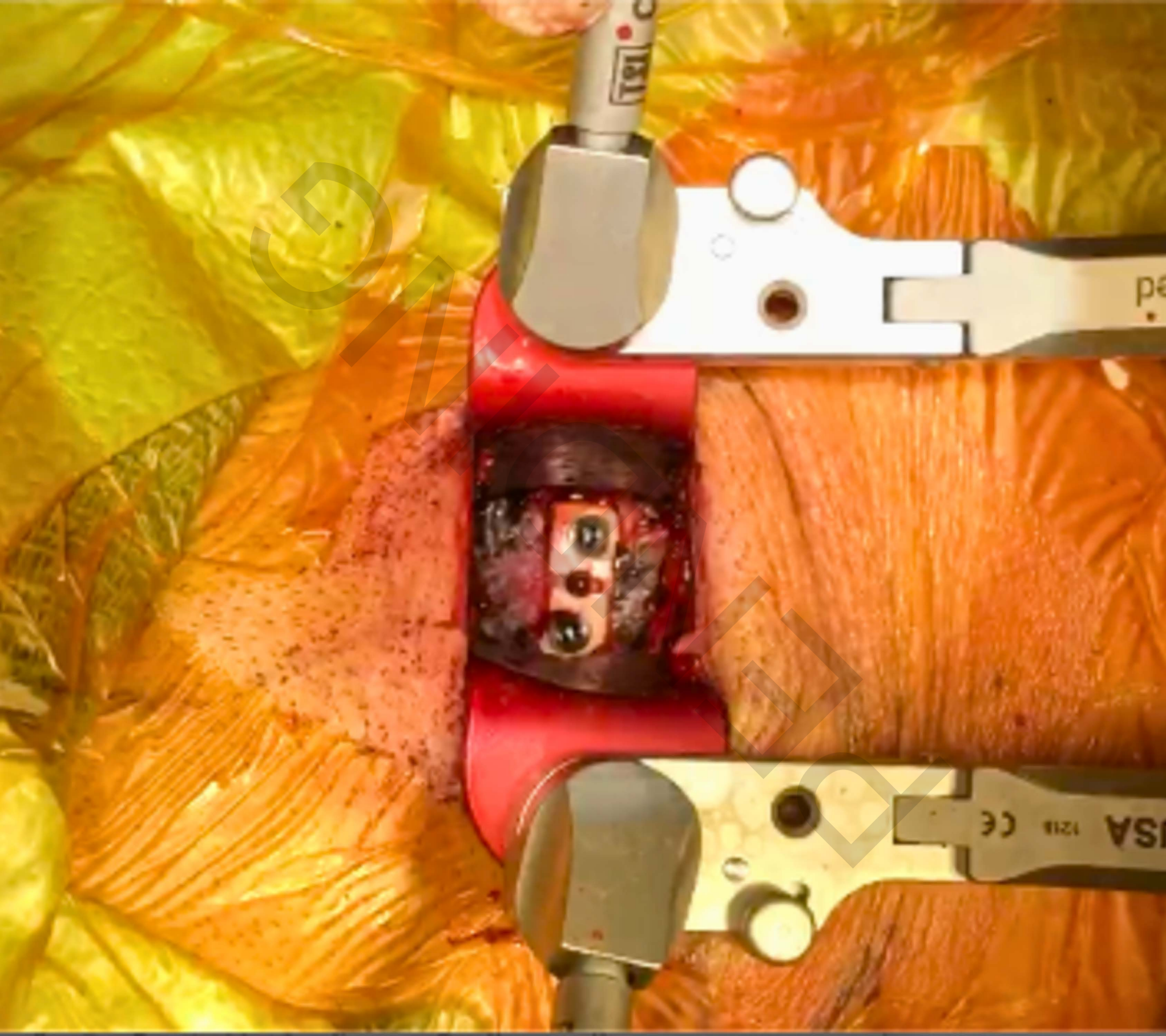

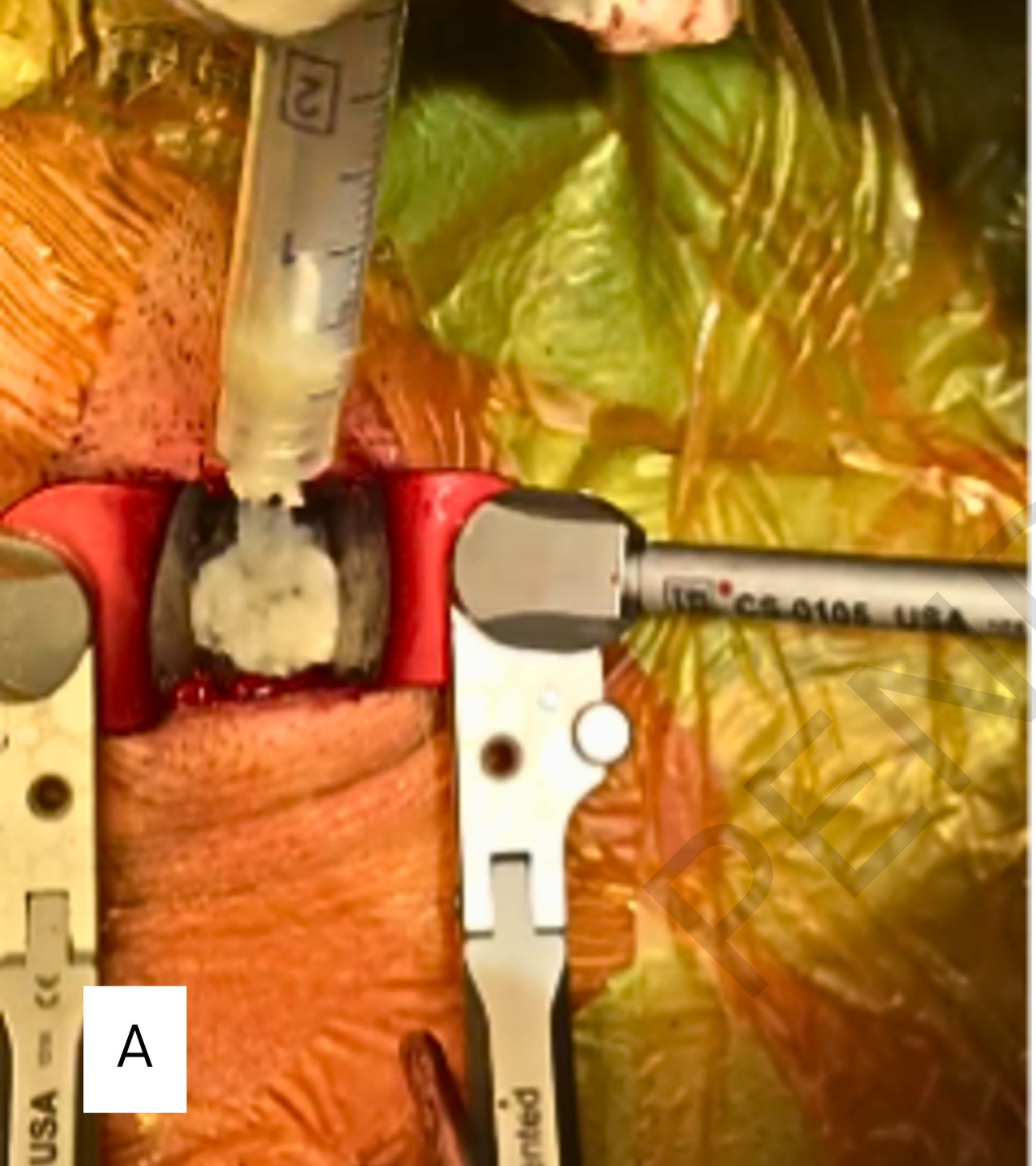

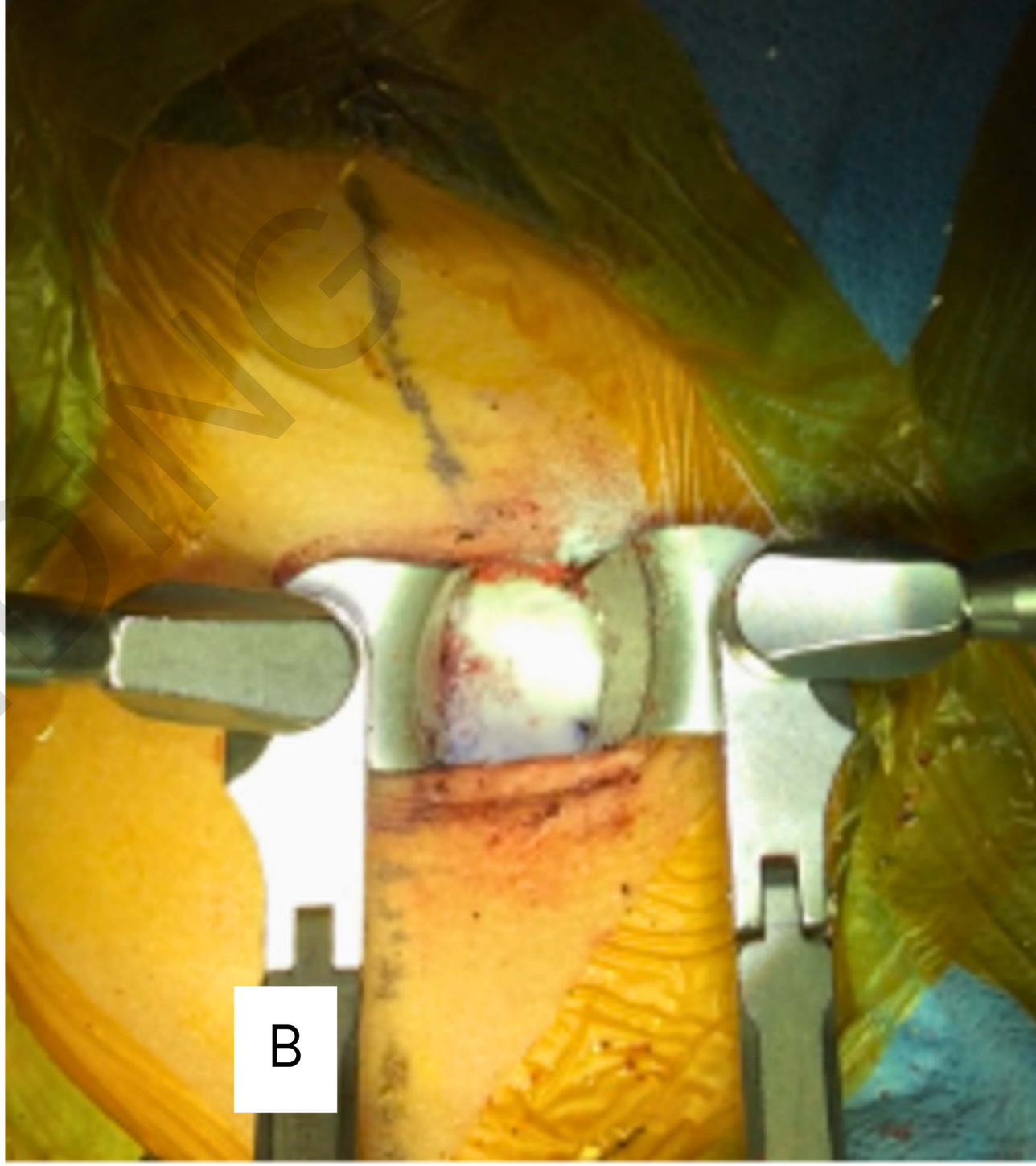

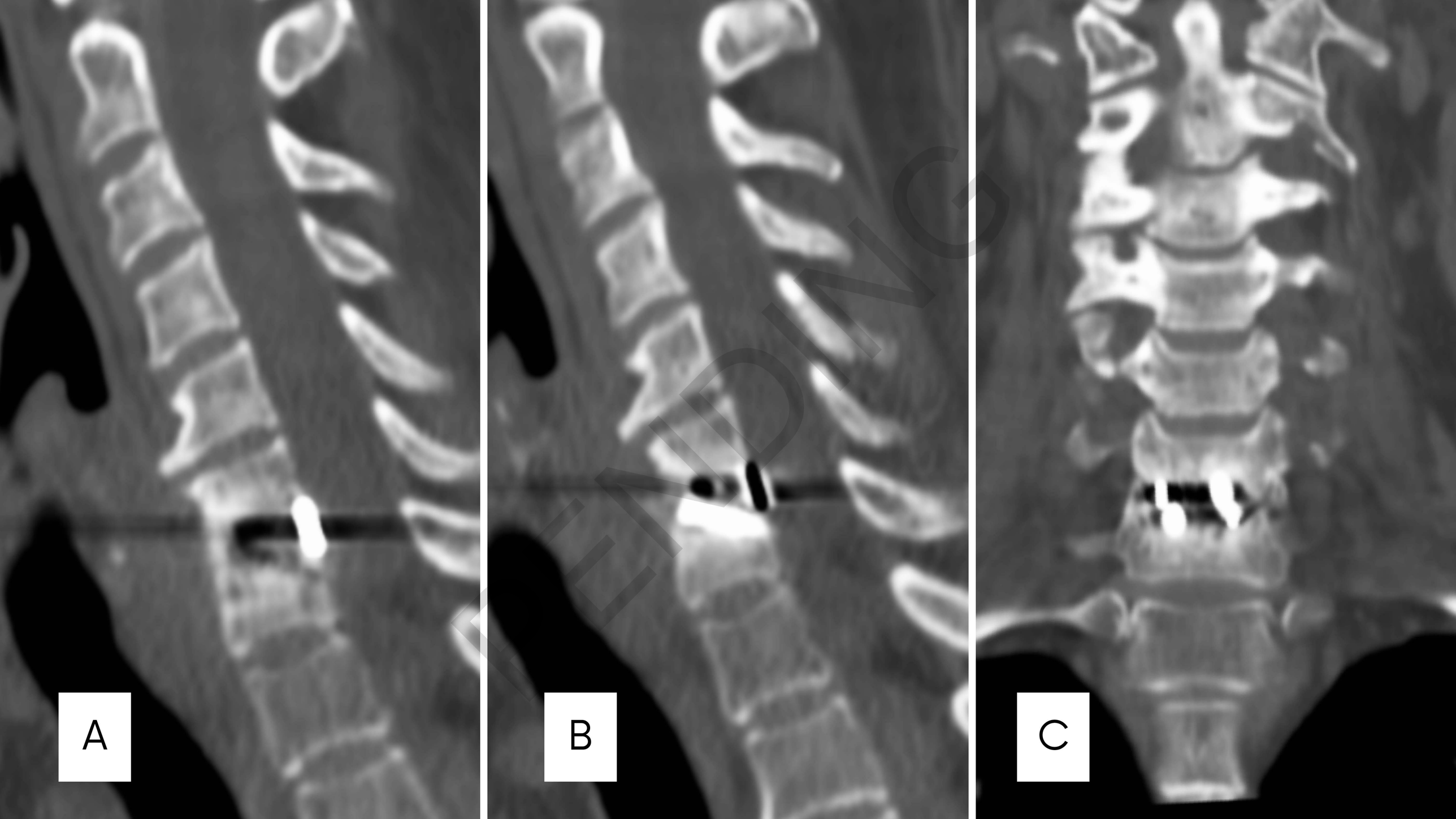
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Figure 5: Paired Samples T-Test of Preoperative vs. Postoperative (24 Months) VAS Scores for NF and DBM

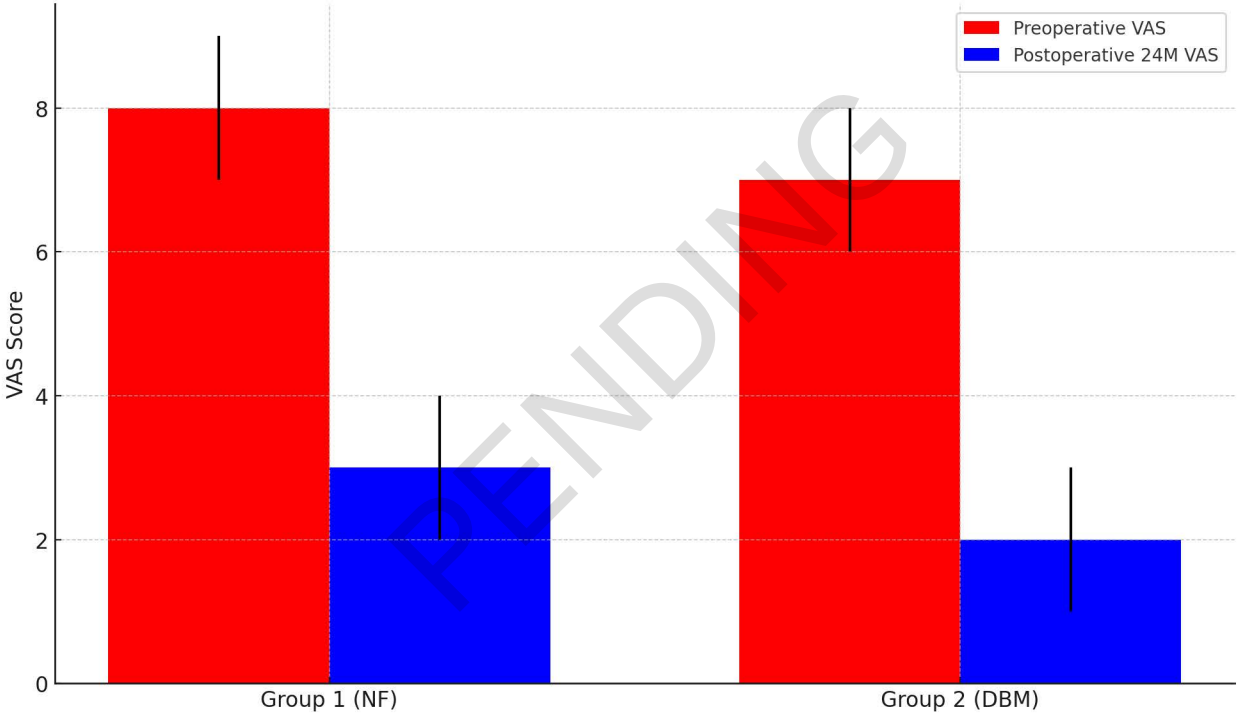
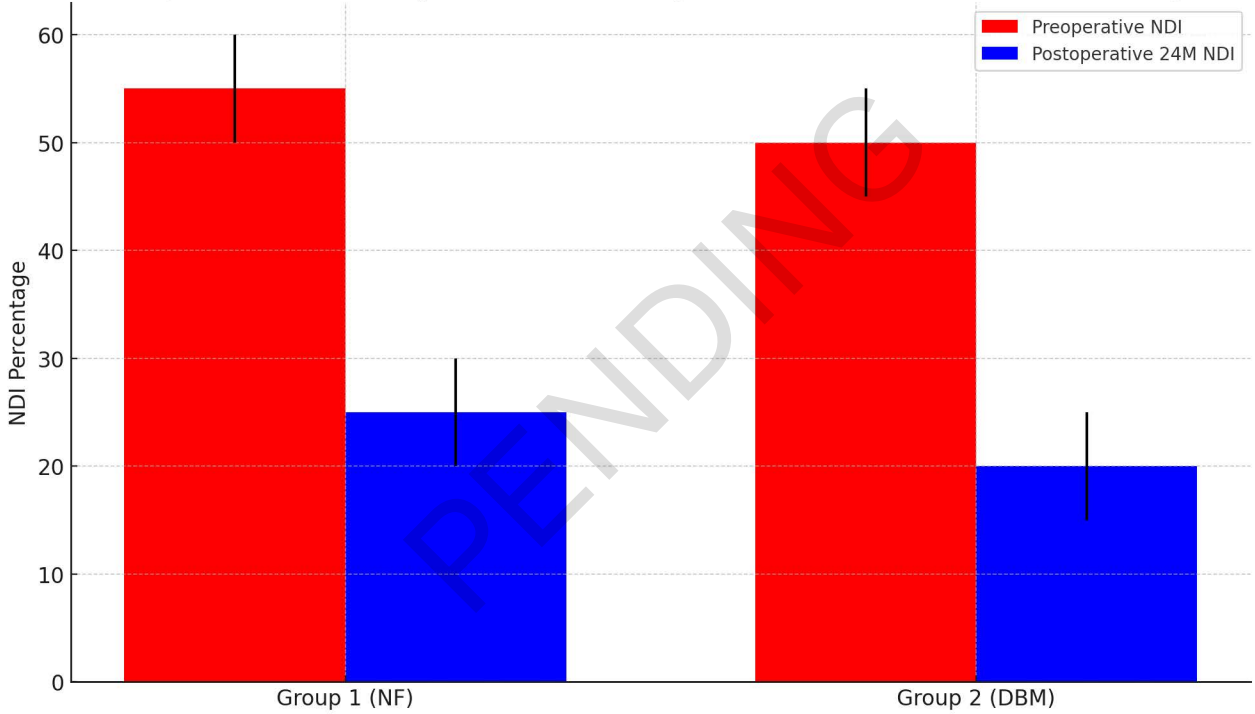
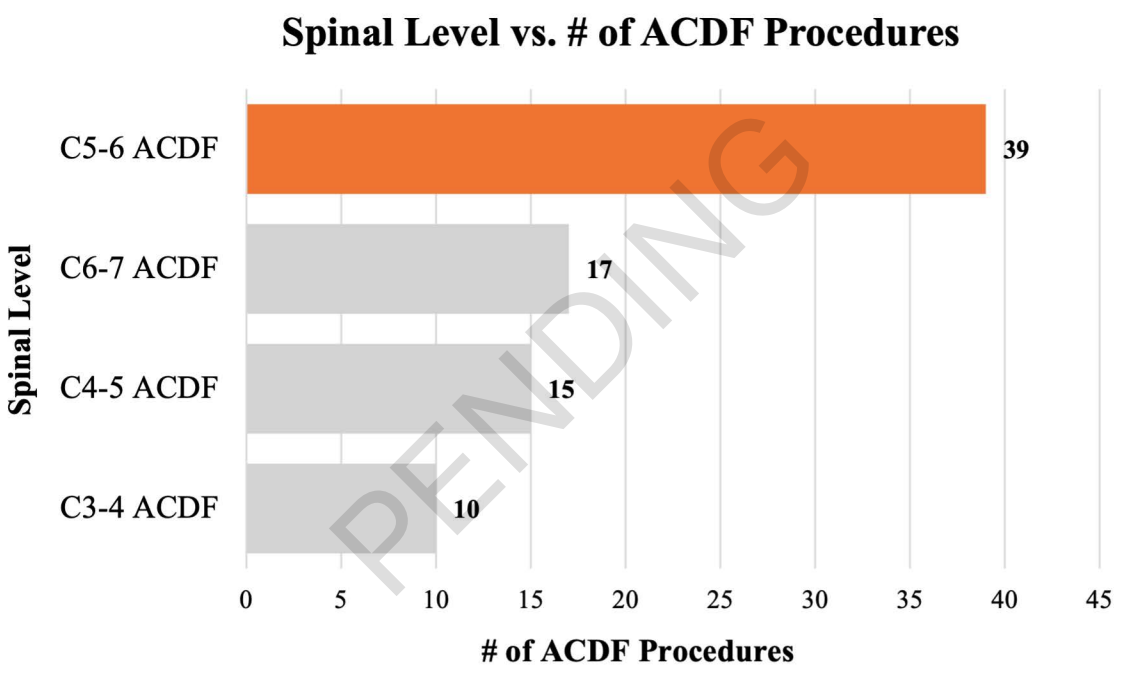


Figure 6: Paired Samples T-Test of Preoperative vs. Postoperative (24 Months) NDI Percentages for NF and DBM




Spinal Level vs. # of ACDF Procedures
C5-6 ACDF
C6-7 ACDF
C4-5 ACDF
C3-4 ACDF
39
17
15
10
Spinal Level
0
5
10
15
20
25
30
35
40
45
# of ACDF Procedures
PENDING