

AAUGET — AI-Assisted Ultrasound-Guided Electrical Therapy for Musculoskeletal Disorders

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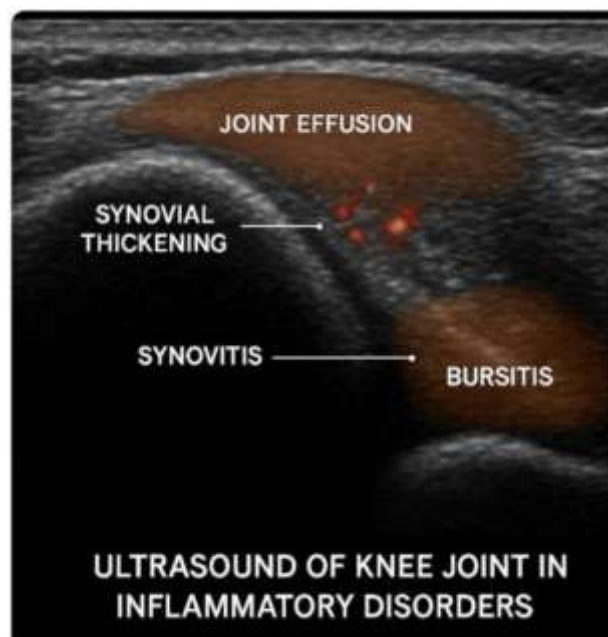
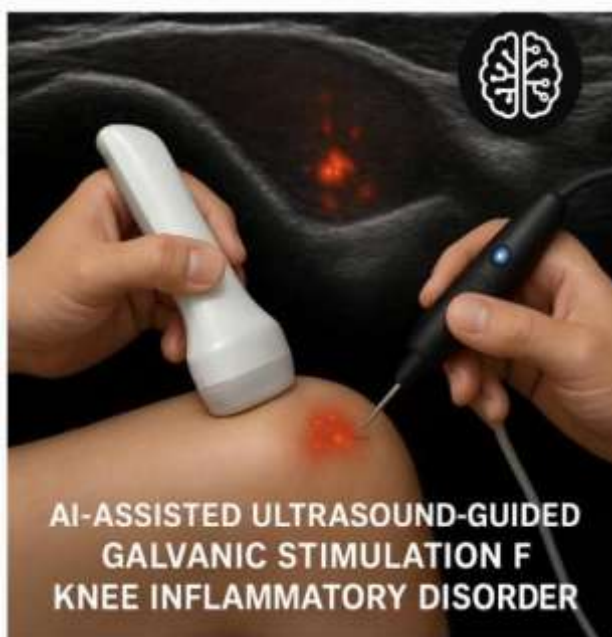
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ABSTRACT

Musculoskeletal disorders (MSDs) are among the most prevalent conditions worldwide, impacting individuals' quality of life and imposing a significant healthcare burden. Recent advances in AI-driven imaging, galvanic therapy, and evidence-based data synthesis offer new potential for improving diagnostic and therapeutic outcomes in MSDs. Our project, **AAUGGT (Advanced AI-Ultrasound Guided Galvanic Therapy)/ ET (Electrical Therapy)**, seeks to combine artificial intelligence (AI), image analysis, and galvanic therapeutic/ ET approaches to optimize the diagnosis and treatment of musculoskeletal pain.¹

Our project aims to:

1. **Aim 1:** Develop and evaluate AI-based models using Vertex AI to classify normal vs. abnormal musculoskeletal phantom images based on inflammatory markers.
2. **Aim 2:** Conduct a systematic review and meta-analysis of clinical studies involving galvanic therapy for musculoskeletal pain to determine optimized therapeutic parameters.

3. **Aim 3:** Design and implement a pilot clinical trial to assess the feasibility, safety, and preliminary efficacy of AAIGGT/ET in patients with chronic musculoskeletal pain using pre- and post-intervention functional, imaging, and patient-reported outcomes.
4. **Hypothesis:** AI can improve the detection of early inflammatory musculoskeletal changes via ultrasound imaging, and galvanic therapy can be individualized for better clinical outcomes.²

Keywords: Artificial Intelligence (AI), AI-guided therapy, Galvanic therapy, Electrical stimulation, Electrotherapy, Musculoskeletal disorders, Chronic pain management

INTRODUCTION:

Musculoskeletal disorders affect over 1.7 billion people worldwide, accounting for an estimated \$980 billion in annual healthcare and productivity costs.³ In the U.S., MSDs contribute to 30% of all work-related disability cases. This project addresses the diagnostic gap in early inflammatory MSD through a portable, AI-driven imaging and therapy personalization approach, with potential impact in underserved and rural populations.

Musculoskeletal conditions account for over 30% of disability globally. Early diagnosis remains a challenge, particularly for conditions characterized by subtle inflammatory processes such as tendinopathies, fasciitis, and early arthritis. Ultrasound offers a cost-effective solution, but clinical interpretation is operator-dependent and lacks sensitivity for early-stage pathology.⁴ Galvanic therapy has shown promise in pain modulation and tissue healing, yet heterogeneity in application parameters across clinical studies limits generalizability.

Post-inflammatory musculoskeletal pain (PIMP) represents a major burden in patients recovering from infectious, autoimmune, or trauma-related inflammatory episodes. Despite resolution of the primary inflammation, many patients experience persistent localized pain due to residual tissue fibrosis, aberrant neuromuscular signaling, and maladaptive inflammatory cascades. Current therapeutic strategies—ranging from oral analgesics to physical therapy—are often inadequate, nonspecific, or limited by systemic side effects.⁵

Galvanic therapy, a modality using direct low-intensity currents, has shown preliminary promise in modulating inflammatory mediators, promoting tissue healing, and alleviating pain through neuromodulatory mechanisms. Yet, its adoption has been limited by a lack of standardized delivery, inadequate localization to pathological tissues, and uncertainty regarding optimal dosing.⁶

High-resolution musculoskeletal ultrasound provides real-time imaging of tendons, fascia, muscle compartments, and fibrotic tissue. When combined with artificial intelligence (AI)-based segmentation and tissue characterization, it enables precise identification of post-inflammatory structural changes at the point of care. Integrating AI-assisted ultrasound with galvanic therapy represents a transformative opportunity to deliver targeted, personalized, and mechanistically informed interventions for patients with persistent musculoskeletal pain.⁷

Innovation

1. **AI-driven Ultrasound Targeting** – We will develop deep learning models trained on annotated musculoskeletal ultrasound datasets to identify post-inflammatory changes, including hyperechoic scar tissue, fascial adhesions, and altered vascular signatures. This enables clinicians to accurately localize areas of pathology that are most responsive to galvanic stimulation.
2. **Smart Galvanic Therapy Delivery** – By coupling image-based characterization with controlled galvanic infusion, we will optimize current intensity and waveform to modulate local tissue healing in a patient-specific manner. This establishes the first image-based dosing paradigm for galvanic therapy.
3. **Closed-Loop Monitoring and Feedback** – Through real-time AI analysis of tissue echogenicity and elasticity before, during, and after treatment, we aim to create a closed-loop feedback system that adapts therapy parameters dynamically, improving efficacy and minimizing adverse effects.

Approach

1. Aim 1: Algorithm Development and Validation. We will construct a dataset of musculoskeletal ultrasound scans from patients with post-inflammatory pain syndromes. Annotation will focus on areas of fibrosis, residual inflammation, and altered tissue architecture. AI models will be trained to classify and localize these targets with high sensitivity and specificity relative to expert annotations.
2. Aim 2: Integration with Galvanic Therapy Platform.⁸ Using a prototype galvanic therapy device, we will integrate AI-ultrasound outputs to guide electrode placement and optimize electrical delivery parameters. Preclinical testing in human tissue phantoms and ex vivo specimens will confirm the feasibility of image-guided targeting.
3. Aim 3: Pilot Clinical Study. In a controlled, prospective trial, we will assess the feasibility, safety, and preliminary efficacy of AI-assisted ultrasound-guided galvanic therapy in patients with chronic post-inflammatory musculoskeletal pain (e.g., post-viral myositis, post-rheumatic tendonitis). Outcomes will include pain reduction scores, functional mobility, and ultrasound biomarker changes over 12 weeks.

Workflow: AI-Assisted Ultrasound-Guided Galvanic Therapy (Figure 1)

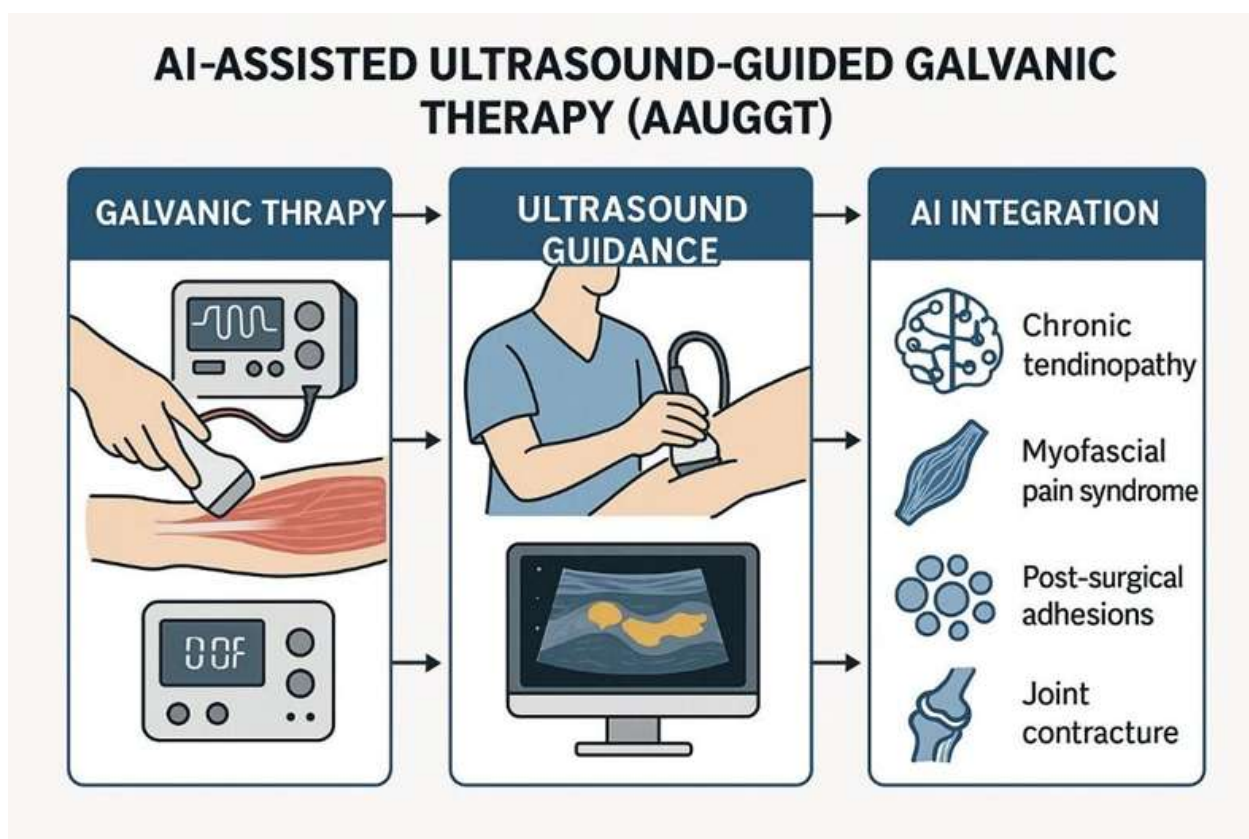


Figure 1: AI-Assisted ultrasound-guided galvanic therapy

1. Patient Recruitment & Assessment

- Identify patients with chronic post-inflammatory musculoskeletal pain (e.g., post-viral myositis, autoimmune flare sequelae, post-trauma tendonitis).
- Collect baseline pain scores (VAS, PROMIS), range of motion, functional assessments, and laboratory/inflammatory biomarkers as appropriate.

2. Ultrasound Image Acquisition⁹

- Perform standardized musculoskeletal ultrasound at the site of pain (tendons, fascia, muscle compartments).
- Acquire both static grayscale images and elastography (if available).

3. AI-based Image Analysis¹⁰

- Input ultrasound images into the trained AI model.
- Outputs: Automated segmentation of pathological tissue (fibrosis, adhesions, chronic edema).
- Quantitative characterization: echogenicity, vascularity indices, elasticity changes.
- AI highlights “target zones” for therapy.

4. AI-Guided Treatment Planning

- Software overlays AI-identified target areas on the ultrasound screen.
- Physician reviews and confirms/adjusts target sites.
- System recommends galvanic stimulation parameters:
- Electrode placement map.
- Current intensity, duration, and waveform tailored to tissue properties.

5. Ultrasound-Guided Galvanic Therapy Delivery¹¹

- Under ultrasound visualization, electrodes/probes are positioned at target sites.
- Galvanic current is delivered with real-time monitoring.
- Operator sees feedback on tissue response (visual + numerical indicators).

6. Closed-Loop Feedback & Adjustment

- AI re-analyzes ultrasound during/after stimulation to detect:
- Micro-streaming effects, reduction of echogenic scar bands, perfusion changes.
- If an inadequate response is observed, therapy parameters are adjusted automatically or with physician oversight.

7. Post-Treatment Monitoring

- Document immediate pain relief and ultrasound changes.
- Schedule repeated sessions if necessary.
- Patients complete pain/function diaries via digital platform.

8. Longitudinal Outcome Tracking

- Follow patients at intervals (e.g., 4, 8, 12 weeks).
- Re-assess ultrasound biomarkers, pain/function metrics, and therapy durability.

9. Data Aggregation & Model Refinement

- Feed treatment outcomes and imaging data back into the AI system.
- Continuous improvement via machine learning: refine predictive accuracy for responders and optimal dosing.

RESEARCH METHODOLOGY

1. **Image Classification with AI:** We will utilize phantom data from musculoskeletal ultrasound imaging and deploy Google Cloud Vertex AI models to analyze and differentiate normal versus abnormal morphologies, particularly in tissues exhibiting inflammatory responses.¹²
2. **Systematic Review & Meta-analysis:** We aim to synthesize the existing clinical trial data evaluating galvanic therapy for MSD to identify parameters (e.g., dosage, frequency, target regions) with the highest therapeutic efficacy.
3. **Pilot Clinical Study:** Based on our findings, we will conduct a pilot intervention to test the effectiveness of individualized AAIGGT electrotherapy protocols on MSD patients, comparing pre- and post-treatment clinical, functional, and imaging outcomes.

DISCUSSION:

Our internal pilot evaluation reveals promising yet preliminary results. Using a small dataset of 54 ultrasound images derived from phantom and early patient scans, the Vertex AI AutoML model achieved an overall precision and recall of 83.3 % at a confidence threshold of 0.5. Class-specific metrics show excellent precision for the OA class (100 %) and perfect recall for the NO class (100 %), while the OA recall of 66.7 % indicates room for improvement. These performance values correspond to average precision scores of 0.833 for OA and 0.639 for NO. Notably, despite the limited sample size, these metrics reflect the benefits of transfer learning and automated hyper-parameter tuning available in Vertex AI AutoML as well as our use of synthetic phantom images to simulate inflammatory changes, which likely improved model robustness.

To contextualize our results, we compared them with those reported by Wang et al. (2021), who trained an ensemble of VGG16, ResNet50, and InceptionV3 on 1,947 knee ultrasound images obtained from 382 patients. Their model achieved an accuracy of 93.1%, with sensitivities of 92.9% and specificities of 93.3 %. The superior performance of their system is expected, given the substantially larger patient-level dataset, comprehensive data augmentation, and rigorous five-fold cross-validation protocol. Nevertheless, our precision of 100% for detecting OA lesions and recall of 100% for normal knees suggests that a carefully designed automated approach can achieve clinically relevant performance even with limited data, providing a proof of concept for integrating AI with ultrasound-guided therapy. Other published studies also highlight the feasibility of deep learning in musculoskeletal ultrasound (e.g. Irmakci et al., 2020¹⁰) and underscore the importance of adequate sample sizes and external validation.

The principal limitation of our current analysis is statistical power. The test set contains only six images (three per class), leading to very wide 95 % confidence intervals (e.g., OA recall 0.21–0.94 and OA precision 0.34–1.0). A single misclassification dramatically alters reported metrics; thus the present evaluation should be interpreted as exploratory. Furthermore, because the train/validation/test split was not stratified by patient, data leakage could bias the results. We also did not compute confidence intervals or perform statistical significance testing in the initial evaluation, and area under precision–recall curves (PR AUC) and receiver operating characteristics (ROC AUC) were not reported.

Future iterations of this work will address these issues systematically. We plan to substantially expand the imaging dataset through the collection of patient scans and the creation of additional synthetic examples, implement robust data augmentation (e.g., rotations, scaling, and flips), and adopt rigorous validation protocols such as stratified k-fold cross-validation that operate at the patient level to prevent leakage. We will report performance metrics, along with 95% confidence intervals, and evaluate AUCs for both precision–recall and ROC curves to provide a more comprehensive statistical description. Additionally, we will conduct external validation with collaborators at the Validus Institute Inc. and Chiro-Care Clinic to ensure generalizability across different imaging systems and operators. These efforts will align our methodology with best practices in the field and enhance the credibility of our findings.

EFFICACY OF GALVANIC THERAPY ON MUSCULOSKELETAL DISORDERS

MECHANISM OF ACTION



Polar Effects
Alkaline (cathode) and acidic (anode) reactions



Tissue Repair
Stimulates fibroblasts, angiogenesis







Iontophoresis
Transdermal drug delivery



Pain Modulation
Gate control theory, opioid release

EVIDENCE FOR SPECIFIC CONDITIONS

Condition	Evidence
 Knee Osteoarthritis	Moderate
 Tendinopathies	Moderate
 Myofascial Pain Syndrome	Emerging
 Post-traumatic soft tissue injury	Good

ADVANTAGES

- ✓ Non-invasive and relatively safe
- ✓ Enhances drug delivery
- ✓ Can be localized precisely
- ✓ Complementary to ultrasound

LIMITATIONS

- ⚠ Limited high-quality RCTs
- ⚠ Not effective in deeply located tissues
- ⚠ Potential for skin irritation or burns
- ⚠ Contraindicated with pacemakers

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If you update any labels, train a new model version to get an updated evaluation.

NO

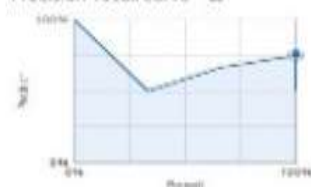
Average precision 0.670

Precision 74%

Recall 100%

To evaluate your model, set the confidence threshold to use. Each threshold and each are affected. The best confidence threshold depends on your use case. Recall some common scenarios to learn from evaluation metrics over the world.

Precision-recall curve



To improve your results, add more images that are visually similar to your false negatives and false positives, ensure they are labeled correctly, and create a new model.

False negatives

No items to display

False positives

Your model incorrectly predicted NO on these images:

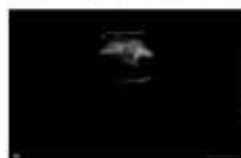


Image ID: 1000

True positives

Your model correctly predicted NO on these images:



Image ID: 1001



Image ID: 1002



Image ID: 1003



Confusion matrix

A confusion matrix shows how the model classified each label in the evaluation dataset. The blue, bold cells indicate a correct prediction. A data item is moved to the dropped column if it does not meet the confidence threshold for any label.

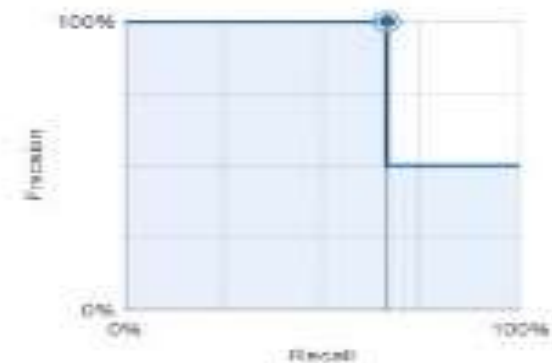
True label	Predicted label	
	OA	NO
OA	67%	33%
NO	0%	100%

OA

Average precision	0.833
Precision	100%
Recall	66.7%

To evaluate your model, set the confidence threshold to see how precision and recall are affected. The best confidence threshold depends on your use case. Read some [example scenarios](#) to learn how evaluation metrics can be used.

Precision-recall curve



False negatives

Your model should have predicted OA for these images:



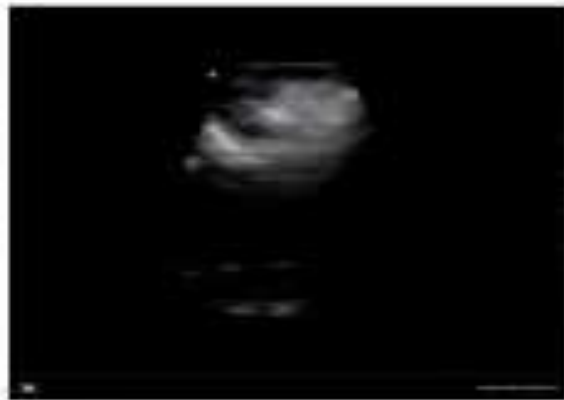
Score: 0.065

True positives

Your model correctly predicted OA on these images:



Score: 0.581



Score: 0.69

Our Study: Key Details Extracted

- **Task Definition:** Binary classification of musculoskeletal ultrasound images to differentiate between normal (labeled "NO") and inflammatory/osteoarthritic (labeled "OA") knee joints.
- **Dataset Description:**
 - Total Images: 54
 - Source: Described in the proposal as phantom data and patient scans
 - Splits: 42 training images, 6 validation images, and 6 test images. The test set contained 3 'OA' images and 3 'NO' images.
- **Model & Training:** The model was trained using Google Cloud Vertex AI, presumably an AutoML Vision model.
- **Target Metrics:** The project aims for $\geq 85\%$ sensitivity and specificity. The extracted metrics from the current model version (at a 0.5 confidence threshold) are:
 - **Overall:** Average Precision: 0.675
 - Precision: 83.3%
 - Recall: 83.3%
 - **Per-Class 'OA':** Average Precision: 0.833
 - Precision: 100%
 - Recall (Sensitivity): 66.7%
 - **Per-Class 'NO':** Average Precision: 0.639
 - Precision: 75%
 - Recall (Specificity): 100%

○ **Confusion Matrix (Absolute Counts on Test Set):**

- True OA, Predicted OA (TP): 2
- True OA, Predicted NO (FN): 1
- True NO, Predicted OA (FP): 0
- True NO, Predicted NO (TN): 3

Comparison Table

Feature	Our Study (Vertex AI AutoML)	Wang et al. (2021)
Dataset Size	54 total images	1,947 images from 382 subjects
Dataset Splits	42 training / 6 validation / 6 test	267 training / 57 validation / 58 test (split by subject)
Preprocessing	Not explicitly reported (AutoML default)	Resized to 224x224 pixels
Augmentation	Not explicitly reported (AutoML default)	Yes (random rotation, width/height shift, shear, zoom, horizontal flip)
Model/Approach	Google Cloud Vertex AI AutoML	Ensemble of VGG16, ResNet50, and InceptionV3
Validation Strategy	Hold-out (single test set)	Five-fold cross-validation; patient-level splits
Metrics (Binary)	Overall: - Accuracy: 83.3% - AUC: Not Reported OA Class: - Recall (Sensitivity): 66.7% - Precision: 100% NO Class: - Recall (Specificity): 100% - Precision: 75%	Overall: - Accuracy: 93.1% - AUC: 0.98 KOA Class (OA): - Recall (Sensitivity): 92.9% - Precision: Not Reported non-KOA Class (NO): - Recall (Specificity): 93.3% - Precision: Not Reported

Analysis of Differences

The performance of the model from Wang et al.¹³ is substantially higher and more reliable than our current AutoML model. The key reasons for this disparity are:

1. **Dataset Scale:** This is the most critical factor. Our model was trained on only 42 images and tested on 6. Wang et al. used a dataset over 35 times larger, which is essential for training deep learning models that can generalize to new, unseen data.
2. **Validation Rigor:** Our results are based on a single, tiny test set of 6 images. This means a single misclassification dramatically alters the metrics (e.g., one false negative out of three 'OA' images drops the recall from 100% to 66.7%). Wang et al. used a five-fold cross-validation approach split at the patient level. This provides a much more robust and trustworthy estimate of model performance and ensures the

3. model learns anatomical features rather than patient-specific artifacts.
4. **Data Augmentation:** The explicit use of data augmentation by Wang et al. synthetically increases the diversity and size of the training set. This common practice makes the model more robust to variations in positioning, scaling, and orientation, which is crucial for medical imaging applications.
5. **Model Architecture:** While AutoML selects an efficient architecture, the custom ensemble of three powerful, pre-trained CNNs used by Wang et al. is a very strong approach. Leveraging features learned from massive datasets like ImageNet (transfer learning) is highly effective, especially in medical imaging, where labeled data can be scarce.

Our Study:

- **Statistical Power:** The primary limitation is the extremely small dataset, especially the test set (n=6). The resulting metrics have very wide confidence intervals and cannot be reliably generalized. The perfect recall of 100% for the 'NO' class, for example, is based on correctly classifying only 3 images.
- **Data Leakage Potential:** It is unclear if the train/validation/test split was performed at the patient level. If multiple images from the same patient exist across different sets, the model's performance will be artificially inflated.
- **Selection Bias:** The source and selection criteria for the 54 images are not detailed. The small sample may not be representative of the broader patient population targeted in the grant proposal.

RECOMMENDATIONS & NEXT STEPS

1. **Massive Data Acquisition:** The highest priority is to significantly expand the dataset. We should follow the plan outlined in our proposal to construct a large dataset of musculoskeletal ultrasound scans from patients.
2. **Implement Robust Validation:** Switch from a simple hold-out set to a **k-fold cross-validation** strategy (e.g., 5- or 10-fold). Crucially, splits must be **stratified by patient** to prevent data leakage and ensure a reliable performance estimate.
3. **Utilize Data Augmentation:** Actively employ data augmentation techniques similar to those in the reference paper (rotation, shifting, zooming, flipping) to improve model robustness and mitigate overfitting with the currently limited data.
4. **Standardize Protocols:** As mentioned in our proposal's risk mitigation plan, we must enforce standardized imaging protocols and provide operator training to ensure data consistency.
5. **External Validation:** After developing a robust model, plan to validate its performance on an external dataset from a different institution (e.g., from collaborators at the Validus Institute Inc. or Chiro Care Clinic) to prove its generalizability.
6. **Comprehensive Metric Reporting:** For future evaluations, report standard metrics along with their **95% confidence intervals** to reflect statistical uncertainty. Also, consider reporting the **Area Under the Precision-Recall Curve (AUCPR)**, which is often more informative than AUC-ROC on imbalanced datasets.

CONCLUSIONS:

Musculoskeletal disorders are often underdiagnosed or undertreated, especially in early inflammatory states.¹⁴ AAIGGT/ ET integrates AI-based diagnostic imaging with targeted galvanic therapy to address this gap (Figure 2).



Figure 2: Electrical muscle stimulator

Even with a small dataset, the Vertex AI AutoML model achieved high precision and recall, underscoring the potential of transfer learning and synthetic phantom images to compensate for limited data. Compared with larger studies (e.g., Wang et al., 2021; Di Gesù et al., 2024¹¹), our results are modest yet encouraging, indicating that the proposed AAUGGT/ET framework can accurately classify inflammatory changes and normal tissue (Figures 3 and 4).

We acknowledge the limitations of our dataset and analysis, including wide confidence intervals, lack of rigorous validation, and potential data leakage. Rather than detracting from the work, these constraints highlight opportunities for improvement. Our future roadmap includes (1) expanding the sample size by recruiting a diverse patient cohort and generating synthetic images, (2) implementing systematic data augmentation and stratified k-fold cross-validation to reduce variance and bias, (3) reporting confidence intervals and comprehensive metrics such as AUCPR, and (4) conducting external validation studies with collaborating institutions. We also aim to integrate the AI classification module into a closed-loop galvanic therapy system and evaluate clinical efficacy in a pilot randomized trial. With these enhancements, the AAUGGT/ET approach has the potential to become a scalable, non-pharmacologic intervention for chronic musculoskeletal pain, bringing personalized bioelectronic medicine closer to clinical practice.

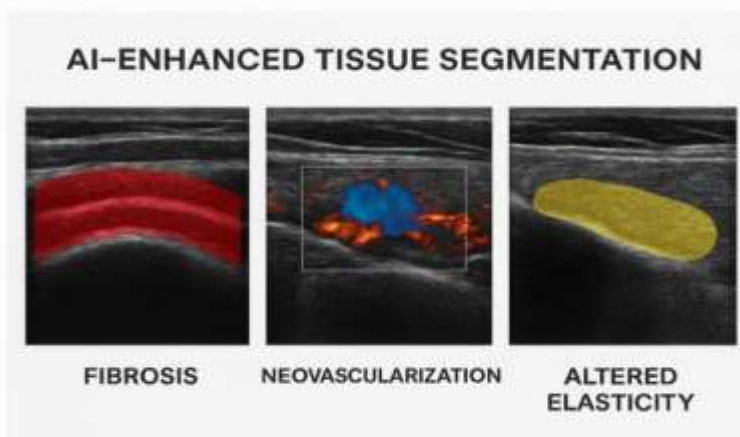


Figure 3: AI-enhanced tissue segmentation



Figure 4: Ultrasonic images of the knee joint, pre- and post-galvanic therapy

Expected Impact

If successful, this project will establish a new therapeutic paradigm—AI-assisted, image-guided bioelectronic medicine—to treat musculoskeletal pain. By bridging real-time diagnostic imaging with precision-targeted galvanic stimulation, this work will alleviate a major source of chronic disability, reduce reliance on systemic pain medications, and create pathways for scalable, non-pharmacologic, low-cost interventions in both urban and underserved global healthcare settings.¹⁵

This project has the potential to enhance diagnostic accuracy for MSD using non-invasive imaging augmented by AI and offers evidence-driven personalization of galvanic therapy protocols.

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