Equipoise for Laminoplasty versus Fusion for Cervical Spondylotic Myelopathy

Is a randomized trial feasible?

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The paper in one sentence

The question

For patients with cervical spondylotic myelopathy (CSM), do expert spine surgeons **disagree enough** about which operation is best that it would be **ethical and feasible to randomize** patients between *laminoplasty* and *fusion* in a future trial?

The answer

Yes. Across 26 international experts judging 50 real cases, **92%** were suitable for randomization, with experts split about **40% laminoplasty / 57% fusion**. Preference for laminoplasty has also **risen from 18% to 40%** over the past decade.

What is the disease? (CSM)

Cervical spondylotic myelopathy (CSM) is age-related wear of the neck spine that narrows the spinal canal (*stenosis*) and compresses the spinal cord.

- The most common cause of spinal-cord dysfunction in adults, in the US and worldwide.
- Typical signs: clumsy hands, gait/balance trouble, hyperreflexia, a positive Hoffman's sign.
- Surgery is effective, but **complication rates are high** ($\sim$14% in a recent prospective study) and outcomes are unsatisfactory in up to 20% of cases.

In plain terms

The cord running through the neck gets pinched. Surgery relieves the pinch; the debate is *how*.

The competing operations

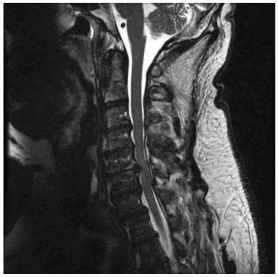
Figure Click here to access/download;Figure;Figure 1D.tif ±

Laminoplasty

Reshapes/hinges the bony arch (*lamina*) to make room for the cord **without fusing** the joints; motion is preserved. Lower complications, lower re-operation rate (5–7%), lower cost. **Least used in the US**; common in Europe & Asia.

Fusion (anterior/posterior)

Fuses vertebrae with hardware. Anterior = ACDF (from the front); posterior = laminectomy + instrumented fusion (from the back). Higher 5-year re-operation rate (12–18%).



Cord compression on sagittal T2 MRI (the problem surgery treats).

Why this matters: a puzzle of practice variation

- Laminoplasty use is ∼**4% in the US** vs ∼**43% in Japan**: a roughly **10-fold** gap not explained by anatomy alone.
- No randomized trial has *ever* directly compared laminoplasty to fusion for CSM.
- A prior US trial (CSM-S; Ghogawala et al., *JAMA* 2021) randomized patients between *ventral and dorsal* fusion (166 patients); laminoplasty, the least-used approach in the US, was *not* part of that randomization.

In plain terms

Same disease, very different treatment depending on where a patient lives. A gap this large with no anatomical explanation signals that surgeons genuinely disagree about the best option, which is what motivates a head-to-head randomized trial.

The key concept: clinical equipoise

Definition

Clinical equipoise = genuine uncertainty *within the expert community* about which of two treatments is better. It is the ethical pre-condition for randomizing patients: you may only flip a coin between A and B if experts honestly do not know which wins.

- If experts *overwhelmingly* preferred one option, randomizing would be unethical, and patients would refuse.
- So before proposing a trial, the authors **measured** whether equipoise exists, using an expert panel.

For an economist: it is close to asking whether the "experts' posterior" sits near 50/50, a revealed-preference test for decision uncertainty.

Design at a glance

- **26 international cervical-spine experts** reviewed **50 real CSM cases** drawn at random from the CSM-S trial.
- Each case = short clinical vignette + MRI + flexion/extension X-rays.
- Each expert did two things per case:
  1. Is this case **randomizable** (laminoplasty vs fusion)? (yes/no)
  2. Their **preferred approach**: A Laminoplasty, B ACDF, C Laminectomy+fusion, D Arthroplasty, E No surgery.
- Repeated at **two time points, 6 months apart**, giving $26 \times 50 \times 2 = 2{,}600$ votes.
- **12 of the 26** had also rated the same cases **10 years ago**, which lets the study measure change over a decade.

Case complexity and what was excluded

Complexity = number of stenotic levels:

- Low: 2 levels, **16 cases**
- Moderate: 3 levels, **27 cases**
- High: 4–5 levels, **7 cases**

Excluded by design:

- Cases with *kyphosis* / kyphotic deformity, which tilt the decision toward fusion and would break equipoise.

In plain terms

We deliberately kept the "coin-flip-able" cases so that any disagreement reflects real clinical uncertainty, not obvious anatomy.

How we analyzed the votes

Three questions, three tools

1. **What drives the choice?** Generalized estimating equations (GEE, logit link) relate "recommend randomization" to case complexity and time point, accounting for the fact that each surgeon votes many times (clustering) via a robust "sandwich" variance.
2. **Are surgeons consistent over 6 months?** Cohen's κ (agreement beyond chance), a switching rate, and a within-case **stability index** $= 1 - |T_1 - T_0|$.
3. **Do cases agree or split?** Stacked bar plots and heat maps of who chose what.

All in R 4.6.0 (`geepack`). GEE is a marginal / population-average model, econometrically close to a panel logit with cluster-robust SEs.

Result 1: Equipoise exists

- **46 / 50 cases (92%)** were randomizable by simple majority, at *both* time points.
- Panel response rate: **100%**.
- Of 2,600 votes: **laminoplasty 40%** (1,041), **fusion 57%** (1,479).
- Randomization was favored in **83.5%** of votes (2,172 / 2,600).

In plain terms

A near 40/60 split, with 92% of cases open to randomization, is the signature of genuine equipoise.

Table 1. Randomizability by preferred approach

Approach	Rand.	Votes	%
Laminoplasty	No	22	2.1
Laminoplasty	Yes	1019	97.9
Fusion	No	341	23.1
Fusion	Yes	1138	76.9
Arthroplasty	Yes	2	100
No surgery	No	65	83.3
No surgery	Yes	13	16.7

Result 2: What makes a case "randomizable"

- When an expert preferred **laminoplasty**, they called the case randomizable **98%** of the time; when they preferred fusion, **77%** ($P < 0.001$).
- **Harder cases were judged *more* randomizable.** Versus simple (low-complexity) cases: moderate **OR = 3.22** (95% CI 2.43–4.27) and high **OR = 2.46** (1.52–3.98), both $P < 0.001$.

Reading the odds ratio (OR)

OR compares the *odds* that a case is called randomizable in one group versus another. OR = 1 means no difference; OR > 1 means higher odds. So OR = 3.22 means moderate cases had about **3**× the odds of being called randomizable as low-complexity cases.

Both moderate and high exceed low because **simple cases usually have an obvious best operation** (experts agree, nothing to randomize), whereas **harder cases genuinely divide opinion**, exactly where a trial is justified. Moderate edges out high because the very hardest cases sometimes tip decisively toward fusion.

Result 3: Stable over 6 months

- Within-case **stability index = 0.85** (SD 0.09): surgeons largely repeat their own decisions.
- **Switching rate 15%**; Cohen's $\kappa = 0.44$ (moderate): some churn at the individual-case level.
- No time trend in the odds of randomizing (OR 1.18, $P = 0.20$): equipoise did not drift across the 6 months.
- Within-surgeon correlation was small: working correlation $\alpha = 0.11$ (95% CI 0.027–0.19).

Here α is the GEE *working correlation parameter*, i.e. the average correlation between any two votes by the same surgeon. It is *not* a significance level. A small α means one surgeon's repeated votes are only weakly related to each other.

In plain terms

The aggregate verdict ("randomizable") is rock-steady, even though a single surgeon may flip on a specific borderline case. Reassuring for trial planning.

Result 4: A decade of change

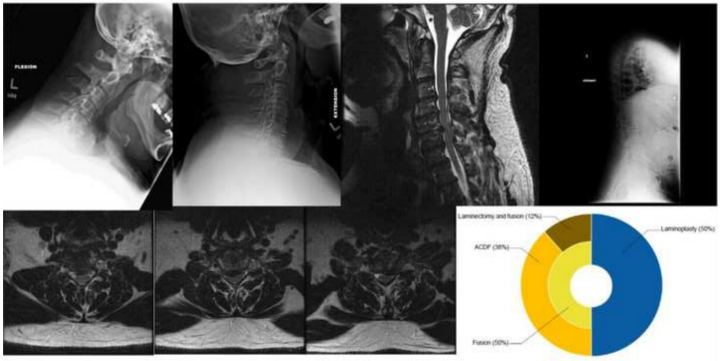
- Among the **12 experts** who also voted **10 years ago**, laminoplasty preference rose from **18% to 40%** ($P < 0.001$).
- The jump is significant for "10 years ago" vs later, but "current" vs "6 months ago" is flat ($P = 0.07$): the change happened, then plateaued.
- Case-level split: 25/26 experts preferred laminoplasty at both time points in **29%** of cases; all 26 chose fusion in **38%** of cases.

Reading the trend

Publication of high-quality trial data (CSM-S) appears to have *moved* expert practice toward laminoplasty, evidence that surgeons update when given good data.

A representative case: experts split down the middle

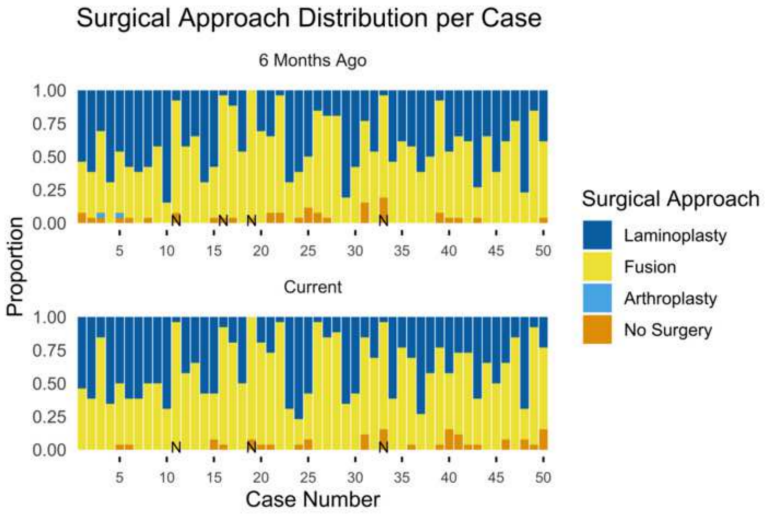
57-year-old male without radiculopathy but clumsy hands and gate disturbance with hyperreflexia and Hoffman's on exam. MR – stenosis at C4-C5 and C5-C6 and C6-C7.



57-year-old man: clumsy hands, gait disturbance, and a positive Hoffman's sign; stenosis at C4–C7.

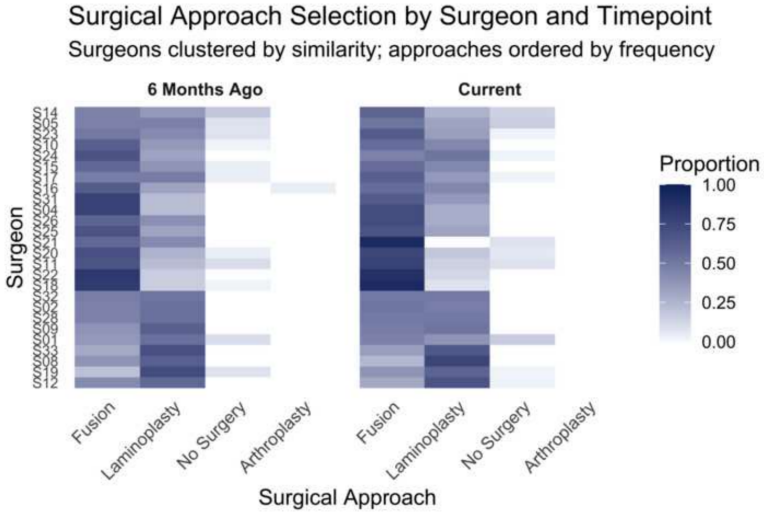
For this single patient the panel splits **50% laminoplasty / 50% fusion** (38% ACDF, 12% laminectomy+fusion). **How to read this:** The X-rays and MRI (top) define one real case; the donut (bottom right) shows how the experts voted on it. A near 50/50 donut is equipoise made visible.

Most cases genuinely divide the experts



Each bar is one of the 50 cases (top: 6 mo ago; bottom: now). Most are strongly **mixed**: real disagreement.

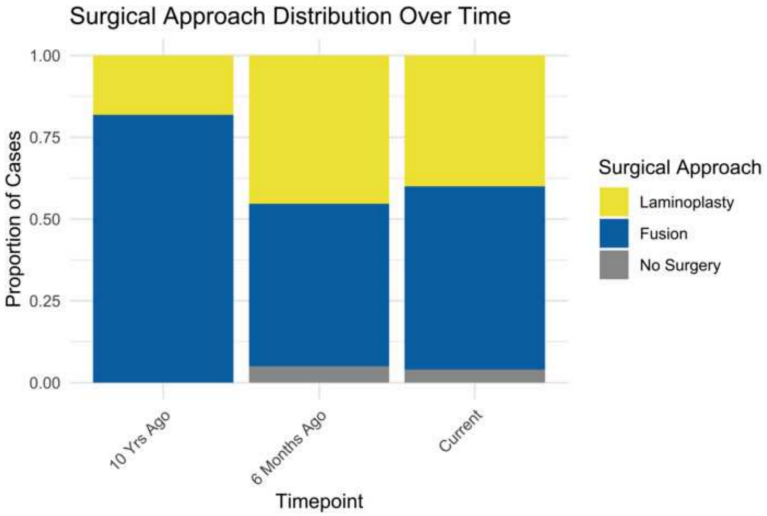
No stable surgeon "type," and no drift over time



Rows = surgeons, columns = approaches; the two panels are 6 mo ago vs now.

No clear clusters of "always-fusion" or "always-laminoplasty" appear, and the pattern is **stable**: variety but no drift.

Laminoplasty's use has climbed over a decade



Each bar is the mix of approaches at one time point. Laminoplasty climbs sharply from "10 yrs ago" to now; the two recent points look alike: the **18%** $\rightarrow$ **40%** rise that then plateaued.

Why a trial is justified now

- An **expert equipoise panel** has previously boosted patient consent to randomization (e.g. SLIP study: 40% to 80%).
- CSM surgery has **high complications** (especially age >74), **unsatisfactory outcomes** in ∼20%, and fusion re-operation rates (12–18%) well above laminoplasty (5–7%).
- **20 of the 26** experts will be site PIs in the planned RCT, so the panel is the trial's own recruiting base.
- Distinct from the ongoing English *MyRanC* trial, which compares laminectomy (*not* laminoplasty) with or without fusion.

Limitations

- Experts were chosen for **leadership**, each with their own surgical bias; a different panel might judge randomizability differently.
- An ideal equipoise panel would be **balanced** so pro-laminoplasty and pro-fusion biases offset.
- **Laminectomy alone** was not offered as an option (it is associated with delayed kyphosis in $\sim$30% and is not a guideline primary procedure).
- Panel opinion may not represent *all* spine surgeons, a generalizability caveat.

Conclusion

Bottom line

Among global cervical-spine experts there is **clinical equipoise** for laminoplasty vs. fusion in CSM: **92%** of unselected cases are randomizable, and preference for laminoplasty has **roughly doubled (18% to 40%) over a decade**.

A carefully defined randomized trial is **feasible** and its results would likely **change practice worldwide**. The paper also models a reusable *method*: use an expert panel to establish equipoise *before* launching a surgical RCT.

Cite as:

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