# Usefulness of Sealants for Dural Closure: Evaluation in an In Vitro Model

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**BACKGROUND:** Cerebrospinal fluid (CSF) leakage occurs in 4% to 32% of cranial surgeries and is associated with significant patient burden and expense. The use of sealant as an adjunct to primary dural closure is assumed to help prevent CSF leakage.

**OBJECTIVE:** To examine the utility of different sealants for dural closure using an in Vitro model.

**METHODS:** We evaluated 9 commonly used dural sealants, including Tachosil (Takeda Inc, Osaka, Japan), Adherus (Hyperbranch Inc, Durham, North Carolina), Duraform (Codman, Raynham, Massachusetts), Tissudura (Baxter, Deerfield, Illinois), Hemopatch (Baxter), TissuePatchDural (Tissuemed, Leeds, United Kingdom), Tisseel (Baxter), Duragen Secure (Integra, Plainsboro, New Jersey), and Duraseal, (Integra). Sealants were tested in 2 novel in Vitro setups using fresh porcine dura: the first tested the acute burst pressure of a sealed 3-mm gap, while the second examined resistance to a pressure wave mimicking intracranial pressure for 72 h.

**RESULTS:** Adherus showed the highest mean burst pressure (87 ± 47 mmHg) followed by Tachosil (71 ± 16 mmHg) and Duraseal (51 ± 42 mmHg); these were the only 3 sealants showing burst pressures above normal physiological intracranial pressure. In the 72-h setup, only Adherus and Duraseal maintained appropriate sealing for the duration of the experiment. Tachosil released from the dura after 1.4 h (95% confidence interval, −1.8-4.7).

**CONCLUSION:** Given the high cost of sealants and the results of this study, we advocate a critical attitude toward sealant application as an adjunct to classic dural closure.

**KEY WORDS:** Cerebrospinal fluid leakage, Dura mater, Dural closure

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Cerebrospinal fluid (CSF) leakage is one of the most common neurosurgical complications, occurring in 4% to 32% of surgical cases with a higher incidence in complicated skull base surgery, intradural spine surgery, and surgery of the posterior fossa.[1-2] The likelihood of CSF leakage as a surgical complication can also depend on age, indication, location of surgery, and underlying pathology. Most patients with CSF leakage necessitate a prolonged hospital stay, antibiotic treatment for meningitis, external lumbar drainage, reoperation, or a combination of these measures. CSF leakage leads to significant patient burden and expense, with an estimated cost of 10 000 to 15 000 US dollars per patient per leakage.[1]

The use of a dural sealant as an adjunct to primary dural closure is often assumed to have value for preventing CSF leakage; yet, few empirical reports describe such an effect. Moreover, objective evaluations of this approach in Vitro are rare.[3] Thus, the goal of this study was to perform an objective comparison of the 9 most commonly used intracranial dural sealants using an in Vitro paradigm.

**ABBREVIATIONS: CSF,** cerebrospinal fluid; **PIC,** programmable integrated circuit; **FDA,** Food and drug administration; **CE,** Conformité Européenne; **IFU,** Instructions for use

## METHODS

### Sealants

Nine dural sealants were tested in 2 different in Vitro assays. We included sealants that were Food and drug administration (FDA)- or Conformité Européenne (CE)-approved for dural

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application that had regular availability for surgical use in the United States or Europe. These sealants included Tachosil (Takeda Inc, Osaka, Japan), Adherus, (Hyperbranch Inc, Durham, North Carolina), Duraform (Codman, Raynham, Massachusetts), Tissudura (Baxter, Deerfield, Illinois), Hemopatch (Baxter), TissuePatchDural (Tissuemed, Leeds, United Kingdom), Tisseel (Baxter), Duragen Secure (Integra, Plainsboro, New Jersey), and Duraseal (Integra).

Before the start of the experiments, a representative from each company visited our laboratory to demonstrate and confirm the instructions for use (IFU) for each sealant. None of the companies officially approved or sponsored our study, or were involved in the actual experiments. All experiments were conducted by trained laboratory personnel in a randomized fashion. None of the authors has a financial relationship with any of the abovementioned companies.

## Dural Model

Human dura mater was not available in sufficient quantities for this study. We compared different species (cow, horse, goat, dog, sheep, cat, rabbit, pig, and rat) using histology. We selected porcine dura for the test model because of its close resemblance to the human dura and availability in large quantities (Figure 1). Cranial dura maters were harvested from 66 Dutch Landrace pigs (40-50 kg) just after they were slaughtered for consumption in a commercial abattoir. Therefore, animal care review board approval was not needed. The specimens were stored in physiological saline at 3°C to 4°C immediately after harvesting.

## Acute Burst Pressure Test

The setup (Figure 2) was based on the ASTM F2392-04 (Standard Test Method for Burst Strength of Surgical Sealants, www.astm.org) but improved upon the ASTM test in 4 ways: (1) the use of porcine dura instead of an artificial collagen; (2) the use of artificial CSF (EcoCyte Bioscience, Austin, Texas) instead of saline; (3) the use of a regulated constant temperature of 37°C for the experimental setup; and (4) the use of a computer with software designed to determine burst pressure (as opposed to visual inspection alone).

First, 132 circular cutouts of exactly 30 mm in diameter were cut from the 66 pieces of dura. Circles were taken from the right and left sides of the superior sagittal sinus. The thickness of each tissue cutout was measured at its center. A disc of 3 mm was then punched out from the middle of the dura cutout using a dedicated perforator. The dura was positioned flat on a nonstick plastic surface in a lightly moist environment. Subsequently, we prepared the sealants. It the tested sealant was a patch, a circle of exactly 15 mm in diameter was cut out of this patch. If the tested sealant was a gel, a dedicated polytetrafluoroethylene mold was used to apply the sealant in a circle shape of exact 15 mm in diameter and 1 mm in thickness. Sealants were applied according to the up-to-date IFU for each sealant. If pressure application was necessary, a standardized weight of 1 kg was applied for the time interval indicated in the IFU. Then, dural cutouts including sealant were then clamped in a watertight fashion between a container and a lid with a hole in the center with the sealant facing up (Figures 3A-3C). The container was filled with artificial CSF at a temperature of 37°C. The pressure chamber was connected to a fluid pump and a pressure probe. All air was removed from the pressure chamber, syringe, and lines before the start of testing. The fluid pump was started thereafter to provide a constant flow of 2.0 mL/min artificial CSF into to the pressure chamber. The resultant pressure was measured continuously via the pressure probe connected to a computer and determined to be approximately 7 mmHg/sec, depending on rigidity of the dura/sealant combination. This is relatively fast, and therefore according to clinical situation. We designed a simple software program to generate a real-time graph from pressure probe data that directly calculated the maximum output pressure just prior to an eventual pressure drop. This pressure was defined as the burst pressure (Figure 2B). We also tested the acute burst pressure of intact dura to analyze water tightness and the maximum pressure of the system.

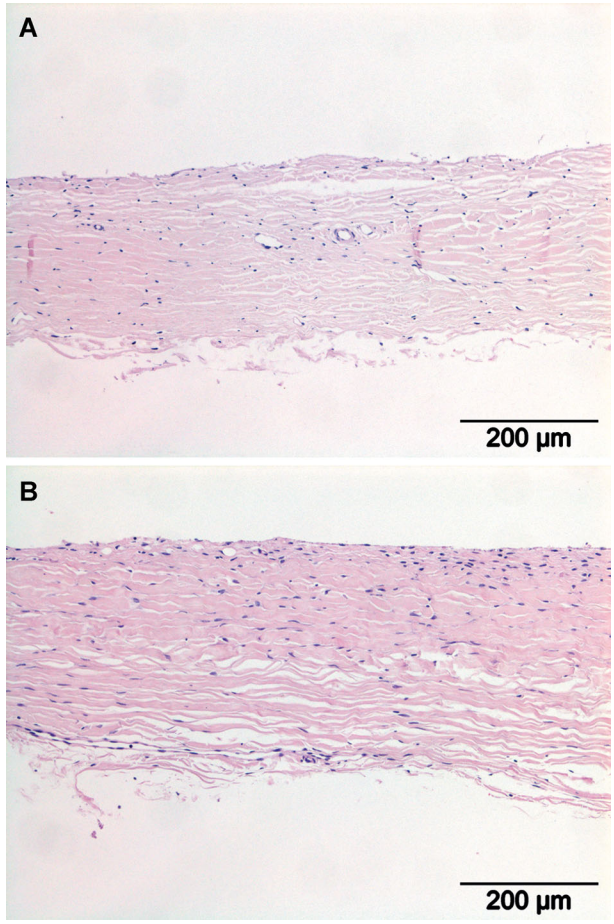


**FIGURE 1.** *Hematoxylin and eosin staining.* **A**, *Human cranial supratentorial dura.* **B**, *Porcine cranial supratentorial dura. It is noteworthy that both samples are composed of identical layers of fibrovascular, collagen rich connective tissue with the same amount of collagen and the same orientation of the fibroblasts and collagen fibers. The dura's of these 2 species are approximately of the same thickness and show nearly the same distribution, number, and size of blood vessels.*

## Three-Day Sustained Pressure Testing

To test the resistance of sealants to long-term physiological variations in pressure, we designed a 72-h pressure pulse assay (Figure 4A). In total, 9 dural circles of 30 mm with a 3-mm hole were prepared and sealant was applied as described above (the acute burst pressure experiment). The dura with sealant was subsequently clamped in a watertight fashion between a container and a lid with a hole in the center

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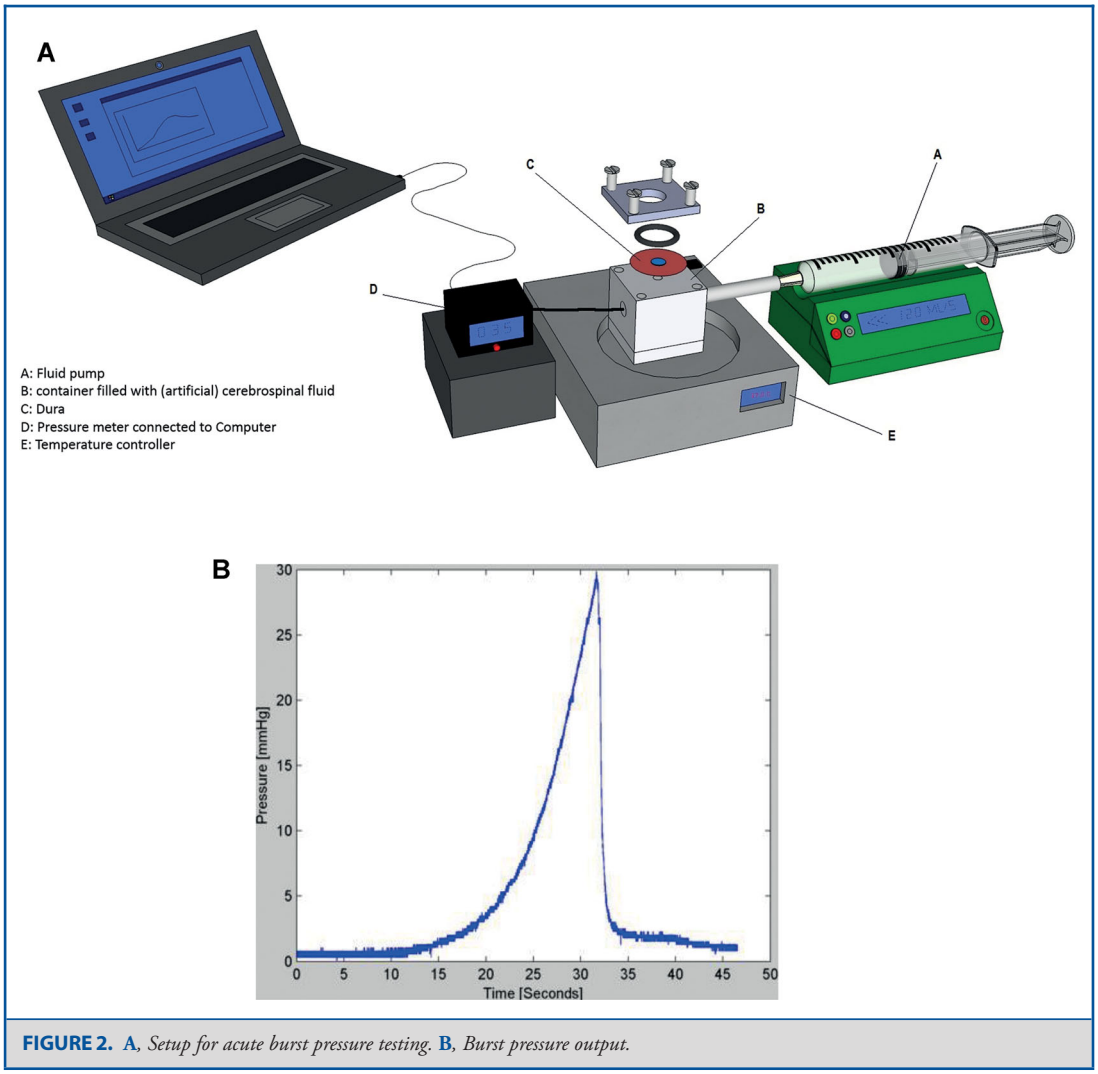


**FIGURE 2.** **A**, *Setup for acute burst pressure testing.* **B**, *Burst pressure output.*

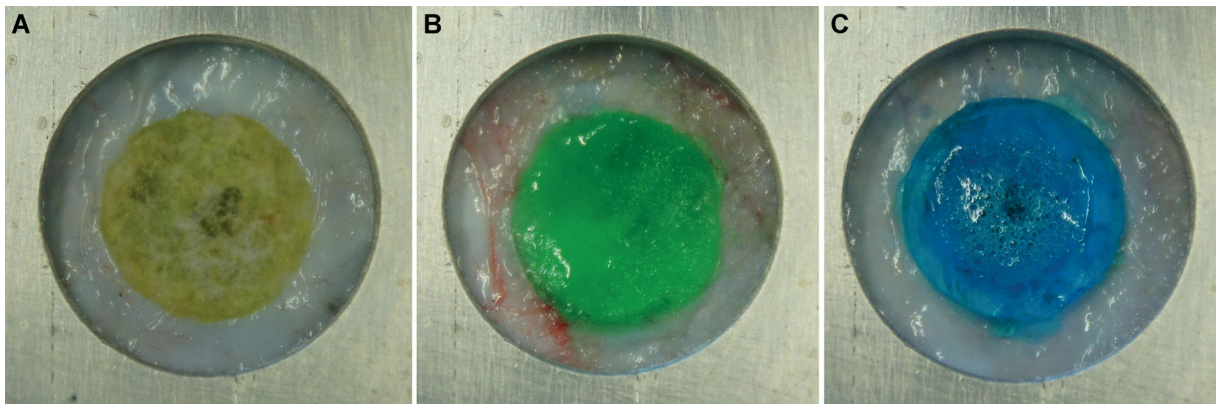


**FIGURE 3.** *Top view of the burst pressure setup.* **A**, *Tachosil.* **B**, *Adherus.* **C**, *Duraseal.*

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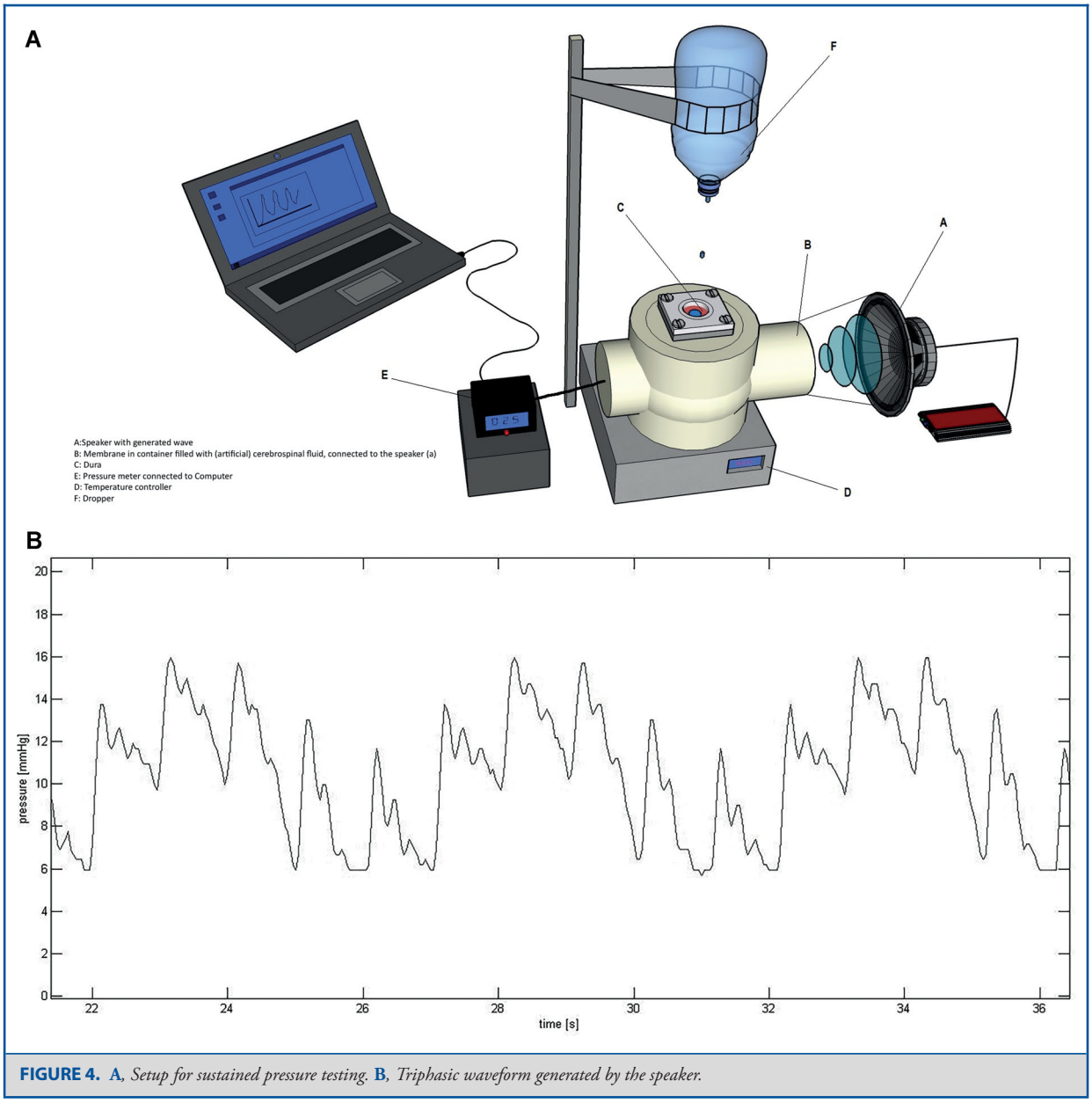


**FIGURE 4.** **A**, *Setup for sustained pressure testing.* **B**, *Triphasic waveform generated by the speaker.*

and the container was filled with artificial CSF at a temperature of 37°C. In this experiment, a pulsating triphasic intracranial pressure wave combined with respiratory pulsation was applied for 72 h. To create this wave, we plotted a standardized triphasic intracranial pressure wave resulting from a heartbeat of 60 beats per minute and a respiratory rate of 12 breaths per minute, oscillating between 6 and 16 mmHg, as previously described.[4] A formula for this wave was generated using a curve fitting tool (Matlab, Mathworks Inc, Natick, Massachusetts), and this formula was programmed into a programmable integrated circuit (PIC) to continually generate the function as output. A resistor–capacitor low-pass filter was used to convert the pulse-with-modulation signal of the PIC into an analog signal. A speaker, mechanically connected to the membrane of the container filled with artificial CSF, converted electric signal into movement to produce the programmed intracranial pressure wave in the liquid (Figure 4B).

The CSF container was connected to a pressure sensor and a computer recorded the pressure in the container (ie, pressure exerted on the dura). Saline was dripped at constant speed on top of the dura and sealant to prevent drying. Any leakage was characterized by a sudden decrease on the pressure-time graph.

In this setup, the programmed triphasic pressure wave had a maximum pressure of 16 mmHg. Therefore, only sealants with a 95% CI of burst pressure above 16 mmHg in the acute burst pressure test were included in the 72-h sustained pressure test (ie, Tachosil [Takeda], Duraseal

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[Hyperbranch], and Adherus [Integra]). A maximum duration of 72 h was selected based on the observation of a bacterial film forming on the dura when longer periods were utilized.

### Statistics

In the acute burst pressure test, we wanted to identify sealants with a minimum burst pressure of at least 16 mmHg (the approximate value of normal immediate postoperative intracranial pressure). We expected the standard deviation of measurements to be approximately 10 mmHg as per an earlier in Vitro study.[3] To calculate the minimum sample size required to identify significant differences with sufficient power, we used the using the online sample size calculator from the University of British Columbia. (http://stat.ubc.ca/~rollin/stats/ssize/n2.html). With an alpha of 5% and power at 90%, we calculated a minimal sample size of 9 measurements per subgroup; ultimately, we performed 14 measurements per subgroup to correct for large standard deviations (except for Duraform [Codman]; because Duraform showed no dural adherence, we only performed 6 measurements). Therefore, we performed a total of 132 burst pressure measurements. An analysis of variance was used to compare mean burst pressures between subgroups and used the post hoc Bonferroni correction to adjust for multiple comparisons. We also corrected differences in mean burst pressure per subgroup for differences in dural thickness and time interval between dural harvesting in the slaughterhouse and testing, because these variables could influence dural properties and therefore burst pressure.

For sealants tested in the sustained pressure test, we identified the minimum increase in time to burst from 0 h (no sealant) to 72 h (with sealant) with an estimated standard deviation of 24 h. With an alpha of 5% and power at 90%, we calculated a minimum sample size of 3 per group. All data were analyzed using IBM SPSS statistics (IBM Inc, Armonk, New York) version 22 and $P < .05$ was used as the threshold for statistical significance.

## RESULTS

### Acute Burst Pressure Test

The mean time interval between harvesting and use of the dura (use interval) was 3.4 ± 1.9 d, with a maximum interval of 6 d. The mean dural thickness at the time of testing was 350 ± 120 $\mu$m. There was no significant relationship between use interval and dural thickness ($r = -0.15$, $P = .87$), dural thickness and burst pressure ($r = 0.18$, $P = .44$), or use interval and burst pressure ($r = 0.09$, $P = .27$).

The mean maximum pressure of the dura in the control condition was 918 ± 94 mmHg; thereafter, the pump started to fail. In 3 measurements, the dura started to "sweat" (small droplets of CSF were observed without evident tearing). Table 1 shows the unadjusted values for burst pressure per subgroup. Out of the 9 sealant subgroups, Adherus (Integra) had the highest mean burst pressure (87 ± 47 mmHg), followed by Tachosil (Takeda; 71 ± 16 mmHg) and Duraseal (Hyperbranch; 51 ± 42 mmHg). Adherus, Tachosil, and Duraseal were the only 3 sealants with an adjusted 95% CI lower boundary of the burst pressure greater than 16 mmHg.

Table 2 shows the adjusted mean differences in burst pressure between these 3 sealants (I in Table 2) and the rest of the sealants (J in Table 2). The mean adjusted differences between Adherus, Duraseal, and Tachosil were nonsignificant. All sealants had significantly lower burst pressures compared to Tachosil and Adherus. Only Tissudura (Baxter) had a significantly lower burst pressure compared to Duraseal.

**TABLE 1. Results of Acute Burst Pressure Testing**

| Sealant | N | Mean burst pressure (mmHg) | Standard deviation |
|---|---|---|---|
| No opening | 14 | 918 | 94 |
| Adherus | 14 | 87 | 47 |
| Tachosil | 14 | 71 | 16 |
| Duraseal | 14 | 51 | 42 |
| Hemopatch | 14 | 19 | 5 |
| Tisseel | 14 | 12 | 9 |
| Duragen Secure | 14 | 10 | 3 |
| TissuePatchDural | 14 | 7 | 4 |
| TissueDura | 14 | 2 | 2 |
| Duraform* | 6 | 1 | 2 |
| Total | 132 | – | – |

*Experiment terminated due to a lack of dural adherence.

### Three-Day Sustained Pressure Testing

We only performed sustained pressure testing on Adherus (Integra), Tachosil (Takeda), and Duraseal (Hyperbranch) since these sealants showed sufficient burst pressures in the acute burst pressure test. Tachosil released from the dura after a mean of 1.4 h (95% confidence interval [CI], −1.8-4.7). In contrast, Adherus and Duraseal maintained full sealing capacities for 72 h in all tests (Table 3).

## DISCUSSION

In the present study, we performed an objective, standardized comparison of 9 commonly used dural sealants using 2 in Vitro assay paradigms.

### Model

This study employed a novel in Vitro assay model for dural burst pressure determination. We elected to develop a new model because the ASTM F2392-04 test method is too general for the dedicated evaluation of dural sealing. Yet, our model had some limitations; for example, we were unable to use human dura because of low availability. It is however noteworthy that the human and porcine dura are almost identical on a histological level. The model is obviously not suitable to make a statement on unintentional durotomies in the lumbar spine, since in that situation there is often a thin dura and no circumferential edge of dura to work with. Additionally, we did not incorporate dural substitutes, and we did not model contra-pressure provided by a bone flap, muscular layer, or fat in Vivo. Therefore, exact outcome values of this study cannot be perfectly translated to all clinical situations. Instead, we regard our model as a valid method for comparing burst pressure results. It could be interesting for the future to incorporate dural substitutes and contrapressure into

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**TABLE 2. Differences in Burst Pressure Corrected for Dural Thickness[a] and Use Interval[b]**

| (I) Sealant | (J) Sealant | Mean difference (I − J) | Std. error | Sig.[c] | 95% Confidence interval for difference[c] | |
|---|---|---|---|---|---|---|
| | | | | | Lower bound | Upper bound |
| Adherus | None | −833.938* | 14.453 | .000 | −882.225 | −785.651 |
| | TissuePatchDural | 84.672* | 15.368 | .000 | 33.330 | 136.013 |
| | Tachosil | 11.984 | 15.254 | 1.000 | −38.979 | 62.946 |
| | Duraform | 87.018* | 18.476 | .000 | 25.294 | 148.743 |
| | Hemopatch | 66.885* | 14.251 | .000 | 19.273 | 114.496 |
| | TissueDural | 81.223* | 14.697 | .000 | 32.123 | 130.323 |
| | Duraseal | 31.566 | 15.272 | 1.000 | −19.454 | 82.587 |
| | Tisseel | 75.846* | 14.032 | .000 | 28.966 | 122.727 |
| | Duragen Secure | 83.134* | 16.762 | .000 | 27.136 | 139.133 |
| Tachosil | None | −845.922* | 14.813 | .000 | −895.409 | −796.434 |
| | TissuePatchDural | 72.688* | 17.768 | .003 | 13.329 | 132.047 |
| | Adherus | −11.984 | 15.254 | 1.000 | −62.946 | 38.979 |
| | Duraform | 75.035* | 19.523 | .009 | 9.811 | 140.259 |
| | Hemopatch | 54.901* | 15.403 | .024 | 3.440 | 106.362 |
| | TissueDural | 69.240* | 14.713 | .000 | 20.086 | 118.393 |
| | Duraseal | 19.583 | 14.764 | 1.000 | −29.741 | 68.906 |
| | Tisseel | 63.863* | 15.475 | .003 | 12.161 | 115.564 |
| | Duragen Secure | 71.151* | 20.259 | .028 | 3.467 | 138.834 |
| Duraseal | None | −865.505* | 14.493 | .000 | −913.924 | −817.085 |
| | TissuePatchDural | 53.105 | 18.283 | .197 | −7.976 | 114.187 |
| | Adherus | −31.566 | 15.272 | 1.000 | −82.587 | 19.454 |
| | Tachosil | −19.583 | 14.764 | 1.000 | −68.906 | 29.741 |
| | Duraform | 55.452 | 19.910 | .280 | −11.065 | 121.970 |
| | Hemopatch | 35.318 | 15.086 | .939 | −15.081 | 85.717 |
| | TissueDural | 49.657* | 14.311 | .033 | 1.844 | 97.469 |
| | Tisseel | 44.280 | 15.657 | .247 | −8.027 | 96.587 |
| | Duragen Secure | 51.568 | 19.923 | .487 | −14.992 | 118.128 |

Differences based on estimated marginal means.
[a]Thickness of the circular cutout of dura measured in mm at its center.
[b] Time interval from dura harvesting in the slaughterhouse until the performance of the test in hours.
[c]Bonferonni-corrected for multiple comparisons.
* $P < .05$ level.

**TABLE 3. Results of 3-d Sustained Pressure Testing**

| Sealant | N | Mean time to burst (h) | 95% Confidence interval |
|---|---|---|---|
| TachoSil | 3 | 1.4 | −1.8-4.6 |
| Duraseal | 3 | 72 | – |
| Adherus | 3 | 72 | – |

the model. Moreover, a spinal variant of the model could be made, incorporating the curvature and different dural thickness at this location.

Standard deviations in the acute burst pressure test were relatively large. This may have been related to dural variations, although thickness and use interval were relatively consistent and did not appear to affect the results. We tried to eliminate human sources of variability in the experiments by training laboratory personnel for dural sealant application and randomizing the experiments among different experimenters. An alternative hypothesis is that the quality of some dural sealants may not have been perfectly consistent. Indeed, sealants requiring preparation or mixing just prior to application introduced a significant source of variability.

## Literature

There is no literature consensus regarding a superior method for dural closure after neurosurgery. Megyesi et al[5] demonstrated in Vitro that an interrupted simple suturing technique seemed to afford the most watertight dural closure for linear incisions. Yet, this observation is controversial for supratentorial craniotomy.[6] Chauvet et al[3] reported that the use of different sealants improved primary dural closure in an in Vitro setting; Bioglue (Cryolife, Kennesaw, Georgia), Duraseal (Integra), Tachosil (Takeda), and Tisseel were tested in this study. Of note, there are important differences between the present study and that by Chauvet et al.[3] First, Chauvet examined burst pressure in dural samples closed with both suturing and sealant reinforcement, whereas we examined sealants alone. Second, Chauvet et al[3] pressurized



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samples prior to sealing so that each sample served as its own control. Mean burst pressure values were 17 mmHg for Bioglue, 28 mmHg for Duraseal, 27 mmHg for Tachosil, and 10 mmHg for Tisseel (Baxter). We did not examine Bioglue in our study because this product contains glutaraldehyde and can therefore only be used off-label for dural closure in the United States and Europe; yet, we observed higher mean burst pressures of 51 mmHg for Duraseal, 71 mmHg for Tachosil, and 12 mmHg for Tisseel. A possible explanation for this discrepancy is the use of multiple sutures and a long incision in the Chauvet study, which likely increased the number of dural gaps. A second possible explanation is that the Chauvet suture line was first exposed to high pressure in a slower pressure build-up before sealing, leading to dural microrupture formation and a larger area requiring sealant.

### Clinical Implication

Tachosil (Takeda), Adherus (Integra), and Duraseal (Hyperbranch) showed acceptable burst pressure results in the acute burst pressure assay. However, the other 6 tested commonly used and FDA and/or CE approved dural sealants showed a mean burst pressure below 20 mmHg in acute testing. The average cost of 1 sealant is typically greater than 300 US dollars, and often more than 1 package is used per patient, amounting to an estimated 300 000 to 400 000 US dollars per year for a general neurosurgical department. At present, the general use of these high-cost sealants for the prevention of dural leakage therefore appears unjustified. Tachosil subsequently detached from dura after less than 2 h in the sustained pressure test, while Adherus and Duraseal remained attached. These results are disquieting since Tachosil is currently the most widely used CE-approved dural sealant in Europe. These results could theoretically explain the results of a recent randomized controlled trial showing no statistically significant reduction of postoperative CSF leakage with the use of Tachosil as an adjunct to classic dural suturing.[7]

## CONCLUSION

The results of our study warrant a critical attitude toward sealant application as an adjunct to classic dural closure techniques. The development of more effective sealants that provide prolonged dural adherence and improved cost efficiency will ultimately facilitate the correct use of sealants to decrease the likelihood of CSF leakage as a neurosurgical complication.

### Disclosure

This study was partially funded by Polyganics bv, Groningen, The Netherlands.

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## COMMENTS

The reviewers wish to congratulate the authors on an interesting paper for a much-needed topic. The paper is mechanically sound and well-constructed. The authors do a nice job looking at the limitations of the in vitro versus in vivo model. They are careful to indicate the reality that bone placement, fat, muscle, etc will change flow dynamics. The focus is always on operative technique and water tight closure whenever possible. The paper is a wonderful adjunct. More exploratory research is warranted to document how different sealants work in different clinical scenarios. What is the impact or can it be modeled in the future to look at dural substitutes patch grafting with sealant or at incomplete primary closure with sealant? Do small suture based holes or a central small defect change the pressure flow dynamics?

The authors are performing interesting and much needed work.

**Richard Menger**
*Shreveport, Louisiana*

The authors have done a detailed and through testing of dural sealants and confirmed what has long been suspected, many dural sealants do not satisfactorily seal. Only 2 of 9 tested passed the burst and adherence testing.

Is there a need to routinely use dural sealants? As the dura mater is rarely leaking CSF preoperatively it seems logical to make it so once again postoperatively. Thus, the goal of a "water tight" closure following an operative procedure would appear to be important. But is it?

If the intracranial pressure is normal, CSF leakage is rarely a problem. If there is substantial increased resistance to CSF drainage, no matter how "water tight" one makes the dural closure CSF leakage will occur.

For supratentorial procedures I approximate the dura mater but often a gap exists at some point. As the dural edges are cauterized to stop bleeding with posterior fossa procedures it is not possible to even approximate the dura mater. I leave it open and just overlay a sheet of oxidized cellulose.

I have not used dural substitutes nor sealants. When reviewing our posterior fossa procedures our CSF leak rate has not been higher when compared with substitutes and sealants usage. Operative time is also reduced.

**J. Gordon McComb**
*Los Angeles, California*

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The authors have provided a useful in vitro model comparison of a series of dural sealant products and showed the relative strengths of each under increasing pressure. This should provide practicing neurosurgeons a guide not just to the product comparison, but also to the limits of these sealants under elevated water pressure. It seems logical that no matter what sealant is used, monitoring for communicating hydrocephalus, using temporary CSF diversion, and avoiding maneuvers that temporarily elevate intracranial pressure may be necessary and useful in most cases.

**Richard W. Byrne**
*Chicago, Illinois*

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