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Equivalence Testing and the Second Generation P-Value

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Abstract

To move beyond the limitations of null-hypothesis tests, statistical approaches have been 12 developed where the observed data is compared against a range of values that are equivalent 13 to the absence of a meaningful effect. Specifying a range of values around zero allows researchers to statistically reject the presence of effects large enough to matter, and prevents practically insignificant effects from being interpreted as a statistically significant difference. 16 We compare the behavior of the recently proposed second generation p-value (Blume, D'Agostino McGowan, Dupont, & Greevy, 2018) with the more established Two One-Sided 18 Tests (TOST) equivalence testing procedure (Schuirmann, 1987). We show that the two 19 approaches yield almost identical results under optimal conditions. Under suboptimal 20 conditions (e.g., when the confidence interval is wider than the equivalence range, or when 21 confidence intervals are asymmetric) the second generation p-value becomes difficult to 22 interpret as a descriptive statistic. The second generation p-value is interpretable in a 23 dichotomous manner (i.e., when the SGPV equals 0 or 1 because the confidence intervals lies completely within or outside of the equivalence range), but this dichotomous interpretation 25 does not require calculations. We conclude that equivalence tests yield more consistent p-values, distinguish between datasets that yield the same second generation p-value, and 27 allow for easier control of Type I and Type II error rates. 28

- Keywords: equivalence testing, second generation *p*-values, hypothesis testing,
 TOST, statistical inference
- Word count:

Equivalence Testing and the Second Generation P-Value

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To test predictions researchers predominantly rely on null-hypothesis tests. This statistical approach can be used to examine whether observed data is sufficiently surprising under the null hypothesis to reject an effect that equals exactly zero. Null-hypothesis tests have an important limitation, in that this procedure can only reject the hypothesis that there is no effect, while scientists should also be able to provide statistical support for equivalence. When testing for equivalence researchers aim to examine whether an observed effect is too small to be considered meaningful, and therefore is practically equivalent to zero. By specifying a range around the null hypothesis of values that are deemed practically equivalent to the absence of an effect (i.e., 0 ± 0.3) the observed data can be compared against an equivalence range and researchers can test if a meaningful effect is absent (Hauck & Anderson, 1984; Kruschke, 2018; Rogers, Howard, & Vessey, 1993; Serlin & Lapsley, 1985; Spiegelhalter, Freedman, & Parmar, 1994; Wellek, 2010; Westlake, 1972).

Second generation p-values (SGPV) were recently proposed to as a descriptive statistic
that represents "the proportion of data-supported hypotheses that are also null hypotheses"
(Blume et al., 2018). The researcher specifies an equivalence range around a null hypothesis
of values that are considered practically equivalent to the null hypothesis. The SGPV
measures the degree to which a set of data-supported parameter values falls within the
interval null hypothesis. If the estimation interval falls completely within the equivalence
range, the SGPV is 1. If the confidence interval falls completely outside of the equivalence
range, the SGPV is 0. Otherwise the SGPV is a value between 0 and 1 that expresses the
overlap of data-supported hypotheses and the equivalence range. When calculating the
SGPV the set of data-supported parameter values can be represented by a confidence
interval (CI), although one could also choose to use credible intervals or Likelihood support
intervals (SI). When a confidence interval is used, the SGPV and equivalence tests such as
the Two One-Sided Tests (TOST) procedure (Lakens, 2017; Meyners, 2012; Quertemont,

2011; Schuirmann, 1987) appear to have close ties, because both tests compare a confidence interval against an equivalence range. Here, we aim to examine the similarities and differences between the TOST procedure and the SGPV. We limit our analysis to normally distributed continuous data.

The TOST procedure also relies on the confidence interval around the effect. In the TOST procedure the data is tested against the lower equivalence bound in the first one-sided test, and against the upper equivalence bound in the second one-sided test (Lakens, Scheel, & Isager, 2018). For an excellent discussion of the strengths and weaknesses of different frequentist equivalence tests, including alternatives to the TOST procedure, see (Meyners, 2012). If both tests statistically reject an effect as extreme or more extreme than the equivalence bound, you can conclude the observed effect is practically equivalent to zero from a Neyman-Pearson approach to statistical inferences. Because one-sided tests are performed, one can also conclude equivalence by checking whether the $1-2\times\alpha$ confidence interval (e.g., when the alpha level is 0.05, a 90% CI) falls completely within the equivalence bounds. Because both equivalence tests as the SGPV are based on whether and how much a confidence interval overlaps with equivalence bounds, it seems worthwhile to compare the behavior of the newly proposed SGPV to equivalence tests to examine the unique contribution of the SGPV to the statistical toolbox.

The relationship between p-values from TOST and SGPV when confidence intervals are symmetrical

The second generation p-value (SGPV) is calculated as:

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$$p_{\delta} = \frac{|I \cap H_0|}{|I|} \times \max\left\{\frac{|I|}{2|H_0|}, 1\right\}$$

where I is the interval based on the data (e.g., a 95% confidence interval) and H_0 is the equivalence range. The first term of this formula implies that the second generation p-value

is the width of the confidence interval that overlaps with the equivalence range, divided by the total width of the confidence interval. The second term is a "small sample correction" 82 (which will be discussed later) that comes into play whenever the confidence interval is more 83 than twice as wide as the equivalence range. To examine the relation between the TOST p-value and the SGPV we can calculate both statistics across a range of observed effect sizes. In Figure 1 p-values are plotted for the TOST procedure and the SGPV. The statistics are calculated for hypothetical one-sample t-tests for observed means ranging from 140 to 150 87 (on the x-axis). The equivalence range is set to 145 ± 2 (i.e., an equivalence range from 143 to 147), the observed standard deviation is assumed to be 2, and the sample size is 30. For example, for the left-most point in Figure 1 the SGPV and the TOST p-value is calculated for a hypothetical study with a sample size of 30, an observed standard deviation of 2, and 91 an observed mean of 140, where the p-value for the equivalence test is 1, and the SGPV is 0. Our conclusions about the relationship between TOST p-values and SGPV hold for an SGPV calculated from confidence intervals, and assuming continuous normally distributed data. Readers can explore the relationship between TOST p-values and SGPV for themselves in an online Shiny app: http://shiny.ieis.tue.nl/TOST vs SGPV/.

The SGPV treats the equivalence range as the null-hypothesis, while the TOST 97 procedure treats the values outside of the equivalence range as the null-hypothesis. For ease of comparison we can plot 1-SGPV (see Figure 2) to make the values more easily comparable. 99 We see that the p-value from the TOST procedure and the SGPV follow each other closely. 100 When we discuss the relationship between the p-values from TOST and the SGPV, we focus 101 on their correspondence at three values, namely where the TOST p = 0.025 and SGPV is 1, where the TOST p = 0.5 and SGPV = 0.5, and where the TOST p = 0.975 and SGPV = 1. 103 These three values are important for the SGPV because they indicate the values at which 104 the SGPV indicates the data should be interpreted as compatible with the null hypothesis 105 (SGPV = 1), or with the alternative hypothesis (SGPV = 0), or when the data are strictly 106 inconclusive (SGPV = 0.5). These three points of overlap are indicated by the horizontal 107

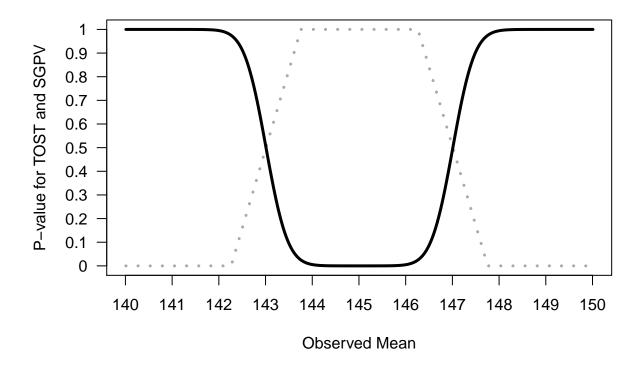


Figure 1. Comparison of p-values from TOST (black line) and SGPV (dotted grey line) across a range of observed sample means (x-axis) tested against a mean of 145 in a one-sample t-test with a sample size of 30 and a standard deviation of 2.

os dotted lines in Figure 2.

When the observed sample mean is 145, the sample size is 30, and the standard 109 deviation is 2, and we are testing against equivalence bounds of 143 and 147 using the TOST 110 procedure for a one-sample t-test, the equivalence test is significant, t(29) = 5.48, p < .001. 111 Because the 95% CI falls completely within the equivalence bounds, the SGPV is 1 (see 112 Figure 1). On the other hand, when the observed mean is 140, the equivalence test is not 113 significant (the observed mean is far outside the equivalence range of 143 to 147), t(29) =114 -8.22, p = 1 (or more accurately, p > .999 as p-values are bounded between 0 and 1). Because 115 the 95% CI falls completely outside the equivalence bounds, the SGPV is 0 (see Figure 1). 116

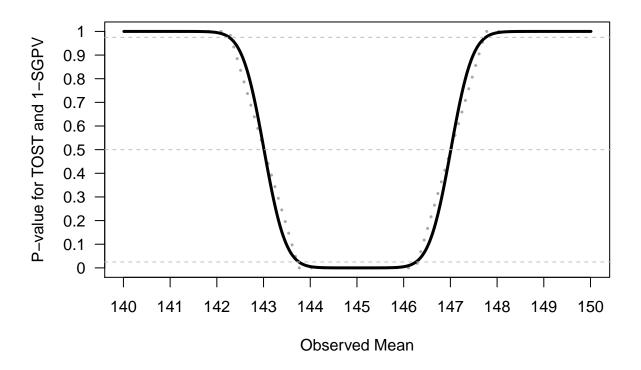


Figure 2. Comparison of p-values from TOST (black line) and 1-SGPV (dotted grey line) across a range of observed sample means (x-axis) tested against a mean of 145 in a one-sample t-test with a sample size of 30 and a standard deviation of 2.

17 SGPV as a uniform measure of overlap

It is clear the SGPV and the p-value from TOST are closely related. When confidence intervals are symmetric we can think of the SGPV as a straight line that is directly related to the p-value from an equivalence test for three values. When the TOST p-value is 0.5, the SGPV is also 0.5 (note that the reverse is not true). The SGPV is 50% when the observed mean falls exactly on the lower or upper equivalence bound, because 50% of the symmetrical confidence interval overlaps with the equivalence range. When the observed mean equals the equivalence bound, the difference between the mean in the data and the equivalence bound is 0, the t-value for the equivalence test is also 0, and thus the p-value is 0.5 (situation A,

126 Figure 3).

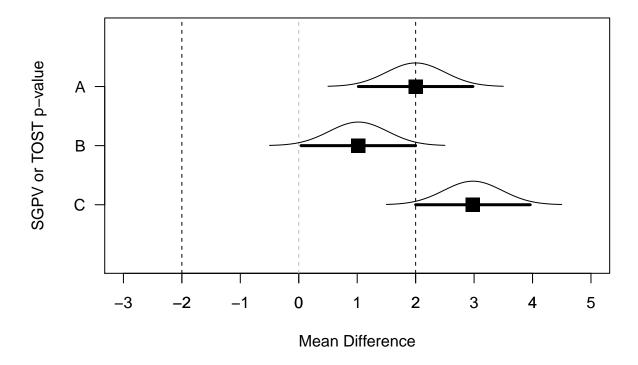


Figure 3. Means, normal distribution, and 95% CI for three example datasets that illustrate the relationship between p-values from TOST and SGPV.

Two other points always have to overlap. When the 95% CI falls completely inside the 127 equivalence region, and one endpoint of the confidence interval is exactly equal to one of the 128 equivalence bounds (see situation B in Figure 3) the TOST p-value (which relies on a 129 one-sided test) is always 0.025, and the SGPV is 1. The third point where the SGPV and 130 the p-value from the TOST procedure should overlap is where the 95% CI falls completely 131 outside of the equivalence range, but one endpoint of the confidence interval is equal to the 132 equivalence bound (see situation C in Figure 3), when the p-value will always be 0.975, and 133 the SGPV is 0. Note that this situation is in essence a minimum-effect test (Murphy, Myors, 134 & Wolach, 2014). The goal of a minimum-effect is not just to reject a difference of zero, but 135

to reject the smallest effect size of interest (i.e., the equivalence bounds). An equivalence test 136 and minimum effect test against the same equivalence bound are complementary, and when 137 a TOST p-value is larger than 0.975, the p-value for the minimum effect test is smaller than 138 0.05, and the minimum effect test provides no additional information that can not be derived 139 from the p-value from the equivalence test. The SGPV summarizes the information from an 140 equivalence test and a minimum-effect test. These can be two relevant questions to ask, 141 although it often makes sense to combine an equivalence test and a null-hypothesis test 142 instead (Lakens et al., 2018). 143

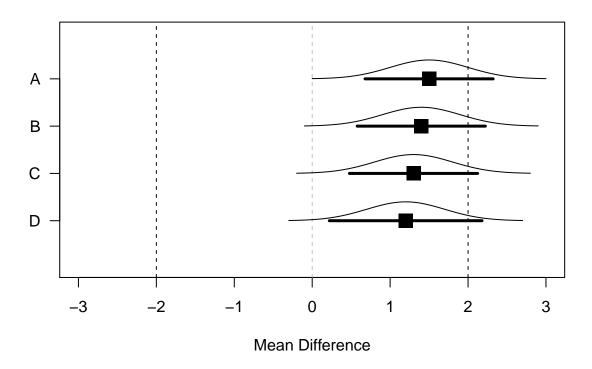


Figure 4. Means, normal distribution, and 95% CI for samples where the observed population mean is 1.5, 1.4, 1.3, and 1.2.

For example, in Figure 4 we have plotted four SGPV's. From A to D the SGPV is 0.76, 0.81, 0.86, and 0.91. The difference in the percentage of overlap between A and B (-0.05) is

identical to the difference in the percentage of overlap between C and D as the mean gets 0.1 146 closer to the test value (-0.05). As the observed mean in a one-sample t-test lies closer to the 147 test value, from situation A to D, the mean gets closer to the test value by 0.1) the difference 148 in the overlap changes uniformly. As we move the observed mean closer to the test value in 149 steps of 0.1 across A to D the p-value calculated for normally distributed data is not 150 uniformly distributed. The probability of observing data more extreme than the upper 151 bound of 2 is (from A to D) 0.16, 0.12, 0.08, and 0.06. As we can see, the difference between 152 A and B (0.04) is not the same as the difference between C and D (0.03). Indeed, the 153 difference in p-values is the largest as you start at p=0.5 (when the observed mean falls on 154 the test value), which is why the line in Figure 1 is the steepest at p = 0.5. Note that where 155 the SGPV reaches 1 or 0, p-values closely approximate 0 and 1, but never reach these values.

When different p-values for equivalence tests yield the same SGPV

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There are three situations where p-values for TOST differentiate between observed 158 results, while the SGPV does not differentiate. The first two situations were discussed before 159 and can be seen in Figure 1. When the SGPV is either 0 or 1, p-values from the equivalence 160 test fall between 0.975 and 1 or between 0 and 0.025. While the SGPV is 1 as long as the 161 confidence interval falls completely within the equivalence bounds, the p-value for the TOST 162 continues to differentiate between results as a function of how far the confidence interval lies within the equivalence bounds (the further the confidence interval is from both bounds, the 164 lower the p-value). The easiest way to see this is by plotting the SGPV against the p-value 165 from the TOST procedure. The situations where the p-values from the TOST procedure 166 continue to differentiate based on how extreme the results are, but the SGPV is a fixed value 167 are indicated by the parts of the curve where there are vertical straight lines at second 168 generation p-values of 0 and 1. 169

A third situation in which the SGPV remains stable across a range of observed effects,

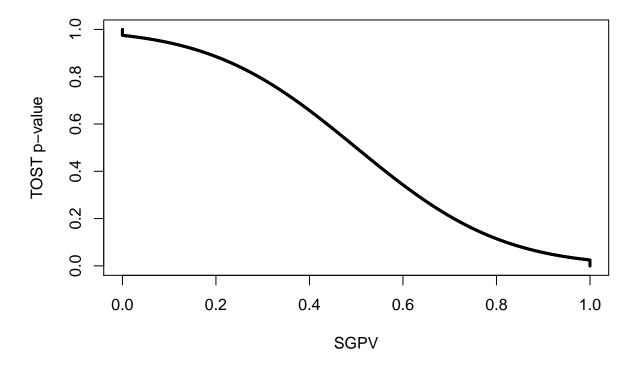


Figure 5. The relationship between p-values from the TOST procedure and the SGPV for the same scenario as in Figure 1.

while the TOST p-value continues to differentiate, is whenever the CI is wider than the 171 equivalence range, and the CI overlaps with the upper and lower equivalence bound. When 172 the confidence interval is more than twice as wide as the equivalence range the SGPV is set 173 to 0.5. Blume et al. (2018) call this the "small sample correction factor". However, it is not a 174 correction in the typical sense of the word, since the SGPV is not adjusted to any "correct" value. When the normal calculation would be "misleading" (i.e., the SGPV would be small, 176 which normally would suggest support for the alternative hypothesis, but at the same time 177 all values in the equivalence range are supported), the SGPV is set to 0.5 which according to 178 Blume and colleagues signals that the SGPV is "uninformative". Note that the CI can be 179 twice as wide as the equivalence range whenever the sample size is small (and the confidence 180

interval width is large) or when then equivalence range is narrow. It is therefore not so much a "small sample correction" as it is an exception to the typical calculation of the SGPV whenever the ratio of the confidence interval width to the equivalence range exceeds 2:1 and the CI overlaps with the upper and lower bounds.

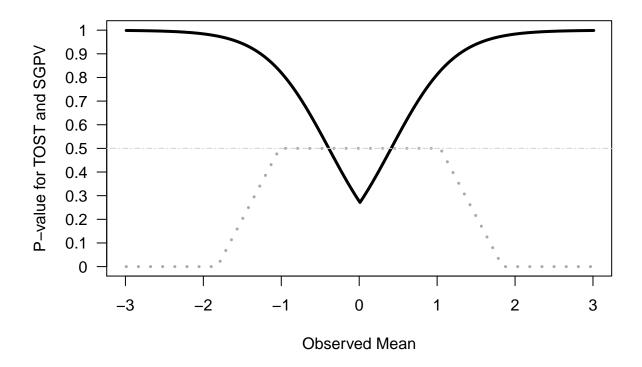


Figure 6. Comparison of p-values from TOST (black line) and SGPV (dotted grey line) across a range of observed sample means (x-axis). Because the sample size is small (n = 10) and the CI is more than twice as wide as the equivalence range (set to -0.4 to 0.4), the SGPV is set to 0.5 (horizontal lightgrey line) across a range of observed means.

We can examine this situation by calculating the SGPV and performing the TOST for a situation where sample sizes are small and the equivalence range is narrow, such that the CI is more than twice as large as the equivalence range (see Figure 6). When the two statistics are plotted against each other we can see where they are unrelated (indicated by

straight lines in the curve, see Figure 7). We see the SGPV is 0.5 for a range of observed 189 means where the p-value from the equivalence test still varies. It should be noted that in 190 these calculations the p-values for the TOST procedure are never smaller than 0.05 (i.e., 191 they do not get below 0.05 on the y-axis). In other words, we cannot conclude equivalence 192 based on any of the observed means. This happens because the TOST p-value is smaller 193 than 0.05 only when the 90% CI falls completely between the upper and lower equivalence 194 bounds. However, we are examining a scenario where the 90% CI is so wide that it never 195 falls completely within the two equivalence bounds, and thus the equivalence test is never 196 significant. As Lakens (2017) notes: "in small samples (where CIs are wide), a study might 197 have no statistical power (i.e., the CI will always be so wide that it is necessarily wider than 198 the equivalence bounds)." None of the p-values based on the TOST procedure are below 0.05, 199 and thus, in the long run we have 0% power.

The *p*-value from the TOST procedure and the SGPV are also unrelated when the CI is wider than the equivalence range (so the precision is low) and overlaps with the upper and lower equivalence bound, but the CI is *not* twice as wide as the equivalence range. In the example below, we see that the CI is only 1.79 times as wide as the equivalence bounds, but the CI overlaps with the lower and upper equivalence bounds (Figure 8). This means the SGPV is not set to 0.5, but it is constant across a range of observed means.

If the observed mean would be somewhat closer to 0, or further away from 0, the
SGPV remains constant (the CI width does not change, and it completely overlaps with the
equivalence range) while the p-value for the TOST procedure does vary. We can see this in
Figure 9 below. The SGPV is not set to 0.5, but is slightly higher than 0.5 across a range of
means. How high the SGPV will be for a CI that is not twice as wide as the equivalence
range, but overlaps with the lower and upper equivalence bounds, depends on the width of
the CI and the equivalence range.

If we once more plot the two statistics against each other to see where they are

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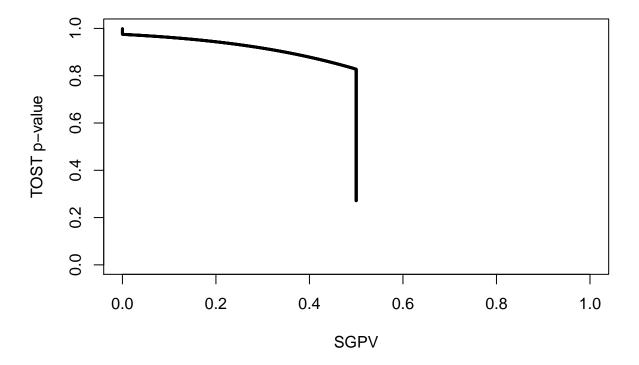


Figure 7. The relationship between p-values from the TOST procedure and the SGPV for the same scenario as in Figure 6.

unrelated (indicated by straight lines in the curve), we see the SGPV is 0.56 for a range of observed means where the p-value from the equivalence test still varies (Figure 10).

To conclude this section, there are three situations where the p-value from the TOST procedure is unrelated to the SGPV. In all these situations the p-value for the equivalence test differentiates tests with different means, but the SGPV does not. Therefore, as a purely continuous descriptive statistic, the SGPV is more limited than the p-value from the TOST procedure.

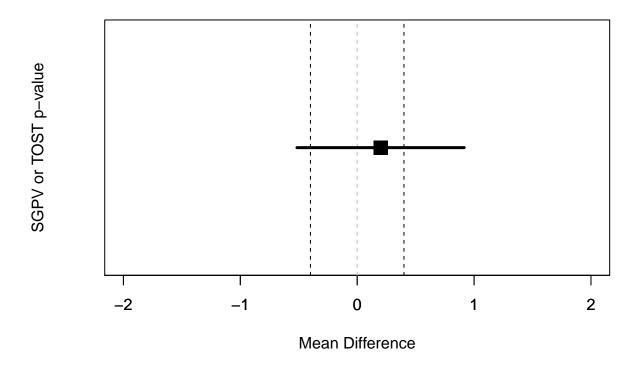


Figure 8. Example of a 95% CI that overlaps with the lower and upper equivalence bound (indicated by the vertical dotted lines).

The relation between equivalence tests and SGPV when for asymmetrical confidence intervals around correlations

So far we have only looked at the relation between equivalence tests and the SGPV when confidence intervals are symmetric (e.g., for confidence intervals around mean differences). For correlations, which are bound between -1 and 1, confidence intervals are only symmetric for a correlation of exactly 0. The confidence interval for a correlation becomes increasingly asymmetric as the observed correlation nears -1 or 1. For example, with ten observations, an observed correlation of 0 has a symmetric 95% confidence interval ranging from -0.630 to 0.630, while and observed correlation of 0.7 has an asymmetric 95% confidence interval confidence interval ranging from 0.126 to 0.993. Note that calculating confidence intervals for

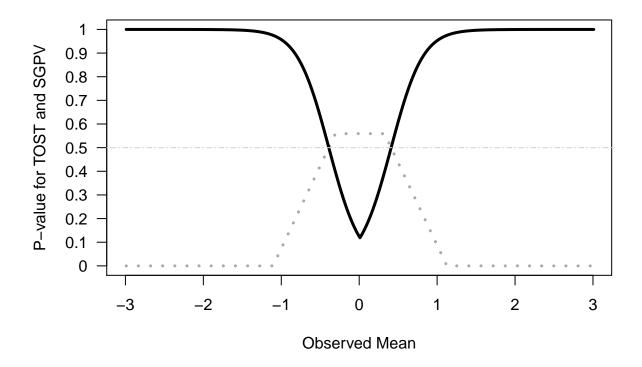


Figure 9. Comparison of p-values from TOST (black line) and SGPV (dotted grey line) across a range of observed sample means (x-axis). The sample size is small (n = 10), but because the sd is half as big as in Figure 7 (1 instead of 2) the CI is less than twice as wide as the equivalence range (set to -0.4 to 0.4). The SGPV is not set to 0.5 (horizontal light grey line) but reaches a maximum slightly above 0.5 across a range of observed means.

a correlation involves a Fisher's z-transformation, which transforms values such that they are approximately normally distributed, which allows one to compute symmetric confidence intervals, which are then retransformed into a correlation, where the confidence intervals are asymmetric if the correlation is not exactly zero.

The effect of asymmetric confidence intervals around correlations is most noticeable at smaller sample sizes. In Figure 11 we plot the p-values from equivalence tests and the SGPV (again plotted as 1-SGPV for ease of comparison) for correlations. The sample size is 30 pairs

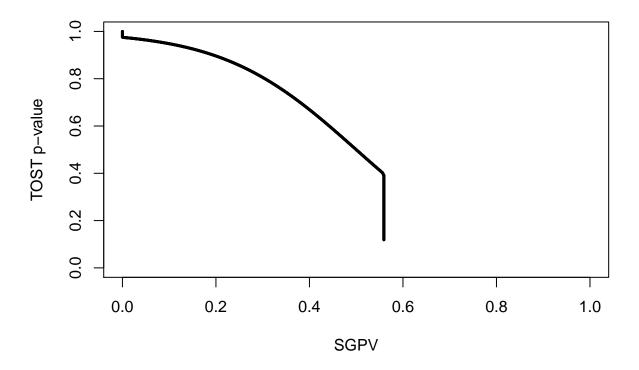


Figure 10. The relationship between p-values from the TOST procedure and the SGPV for the same scenario as in Figure 9.

of observations, and the lower and upper equivalence bounds are set to -0.45 and 0.45, with an alpha of 0.05. As the observed correlation in the sample moves from -1 to 0 the p-value from the equivalence test becomes smaller, as does 1-SGPV. The pattern is quite similar to that in Figure 2. The p-value for the TOST procedure and 1-SGPV are still identical when p-values are 0.975 and 0.025 (indicated by the upper and lower horizontal dotted lines). There are two important differences, however. First of all, the SGPV is no longer a straight line, but a curve, due to the asymmetry in the 95% CI. Second, and most importantly, the p-value for the equivalence test and the SGPV do no longer overlap at p = 0.5.

The reason that the equivalence test and SGPV no longer overlap is also because of asymmetric confidence intervals. If the observed correlation falls exactly on the equivalence

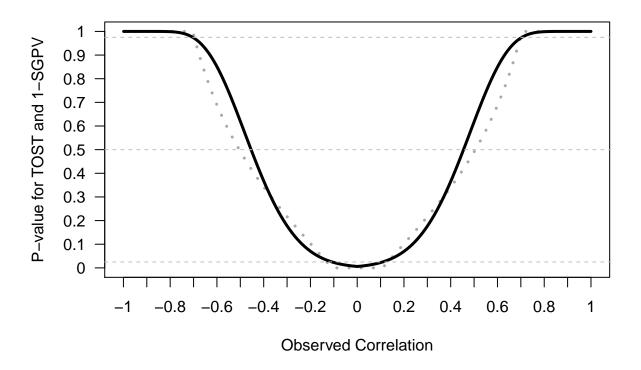


Figure 11. Comparison of p-values from TOST (black line) and 1-SGPV (dotted grey curve) across a range of observed sample correlations (x-axis) tested against equivalence bounds of r = -0.45 and r = 0.45 with r = 30 and an alpha of 0.05.

bound the p-value for the equivalence test indicates that the probability of observing the 249 observed or more extreme data, assuming the equivalence bound is the true effect size, is 250 50%. In other words, if the true effect size is the same as the equivalence bound, it is equally 251 likely to find an effect more extreme than the equivalence bound, as it is to observe an effect that is less extreme than the equivalence bound. However, as can be seen in Figure 12, the 253 two second generation p-values associated with the observed correlations at r = -0.45 and r 254 = 0.45 are larger than 50%. Because the confidence intervals are asymmetric around the 255 observed effect size of 0.45 (ranging from 0.11 to 0.70) according to Blume et al. (2018) 256 58.11% of the data-supported hypotheses are null hypotheses, and therefore 58.10% of the 257

data-supported hypotheses are compatible with the null premise.

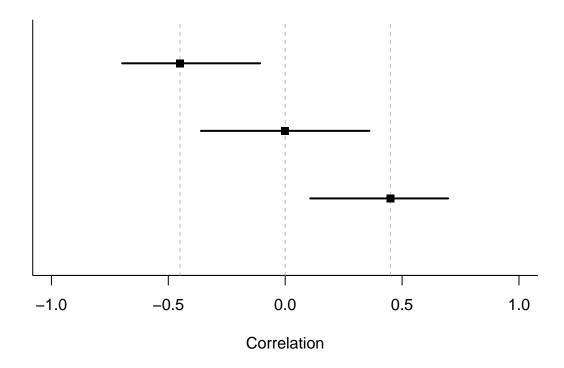


Figure 12. Three 95% confidence intervals for observed effect sizes of r = -0.45, r = 0, and r = 0.45 for n = 30. Only the confidence interval for r = 0 is symmetric.

This example illustrates the difference between a proportion and a probability. As long 259 as data is normally distributed, there is always a 50% probability of observing a correlation 260 smaller or larger than the true correlation, but the SGPV for this situation depends on how 261 far away the observed correlation is from 0. The further away from 0, the larger the SGPV when the observed mean falls on the equivalence bound. The SGPV is the proportion of values in a 95% confidence interval that overlap with the equivalence range, but not the 264 probability that these values will be observed. In the most extreme case (i.e., a sample size 265 of 4, and equivalence bounds set to r = -0.99 and 0.99, with an observed correlation of 0.99) 266 58.10% of the confidence interval overlaps with the equivalence range, even though in the 267

long run only 50% of the correlations observed in the future will fall in this range. It should be noted that in larger sample sizes the SGPV is closer to 0.5 whenever the observed 269 correlation falls on the equivalence bound, but this extreme example nevertheless clearly 270 illustrates the difference between question the SGPV answers, and the question a p-value 271 answers. The conclusion of this section on asymmetric confidence intervals is that a SGPV of 272 1 or 0 can still be interpreted as a p < 0.025 or p > 0.975 in an equivalence test, since the 273 SGPV and p-value for the TOST procedure are always directly related at the values p =274 0.025 and p = 0.975. Although Blume et al. (2018) state that "the degree of overlap conveys 275 how compatible the data are with the null premise" this definition of what the SGPV 276 provides does not hold for asymmetric confidence intervals. Although a SGPV of 1 or 0 can 277 be directly interpreted, a SGPV between 0 and 1 is not interpretable as "compatibility with 278 the null hypothesis" under the assumption of normally distributed data, and the generalizability of this statement needs to be examined beyond normally distributed data. Indeed, Blume and colleagues write in the supplemental material that "The magnitude of an inconclusive second-generation p-value can vary slightly when the effect size scale is 282 transformed. However definitive findings, i.e. a p-value of 0 or 1 are not affected by the scale 283 changes."

What are the Relative Strengths and Weaknesses of Equivalence Testing and the SGPV?

When introducing a new statistical method, it is important to compare it to existing
approaches and specify its relative strengths and weaknesses. First of all, even though a
SGPV of 1 or 0 has a clear interpretation (we can reject effects outside or inside the
equivalence range), intermediate values are not as easy to interpret (especially for effects that
have asymmetric confidence intervals). In one sense, they are what they are (the proportion
of overlap), but it can be unclear what this number tells us about the data we have collected.

This is not too problematic, since the main use of the SGPV (e.g., in all examples provided 293 by Blume and colleagues) seems to be to examine whether the SGPV is 0, 1, or inconclusive. 294 As already mentioned, this interpretation of a SGPV as is very similar to the 295 Neyman-Pearson interpretation of an equivalence test and a minimum effect tests (which are 296 complementary). The difference is that where a SGPV of 1 can be interpreted as p < .025, 297 equivalence tests provide exact p-values, and they continue to differentiate between for 298 example p = 0.048 and p = 0.002. Whether this is desirable depends on the perspective that 290 is used. From a Neyman-Pearson perspective on statistical inferences the main conclusion is 300 based on whether or not $p < \alpha$, and thus an equivalence test and SGPV can be performed by 301 simply checking whether the confidence interval falls within the equivalence range, just as a 302 null-hypothesis test can be performed by checking whether the confidence interval contains 303 zero or not. At the same time, it is recommended to report exact p-values (American Psychological Association, 2010), and exact p-values might provide information of interest to 305 readers about how precisely how surprising the data, or more extreme data, is under the null model. Some researchers might be interested in combining an equivalence tests with a 307 null-hypothesis significance test. This allows a researcher to ask whether there is an effect 308 that is statistically different from zero, and whether effect sizes that are considered 309 meaningful can be rejected. Equivalence tests combined with null-hypothesis tests classify 310 results into four possible categories, and for example allow researchers to conclude an effect 311 is significant and equivalent (i.e., statistically different from zero, but also too small to be 312 considered meaningful, see (Lakens et al., 2018)). 313

An important issue when calculating the SGPV is its reliance on the "small sample correction", where the SGPV is set to 0.5 whenever the ratio of the confidence interval width to the equivalence range exceeds 2:1 and the CI overlaps with the upper and lower bounds. This exception to the normal calculation of the SGPV is introduced to prevent misleading values. Without this correction it is possible that a confidence interval is extremely wide, and an equivalence range is extremely narrow, which without the correction would lead to a

very low value for the SGPV. Blume et al. (2018) suggest that under such a scenario "the 320 data favor alternative hypotheses", even when a better interpretation would be that there is 321 not enough data to accurately estimate the true effect compared to the width of the 322 equivalence range. Although it is necessary to set the SGPV to 0.5 whenever the ratio of the 323 confidence interval width to the equivalence range exceeds 2:1, it leads to a range of 324 situations where the SGPV is set to 0.5, while the p-value from the TOST procedure 325 continues to differentiate (see for example Figure 6). An important benefit of equivalence 326 tests is that it does not need such a correction to prevent misleading results. 327

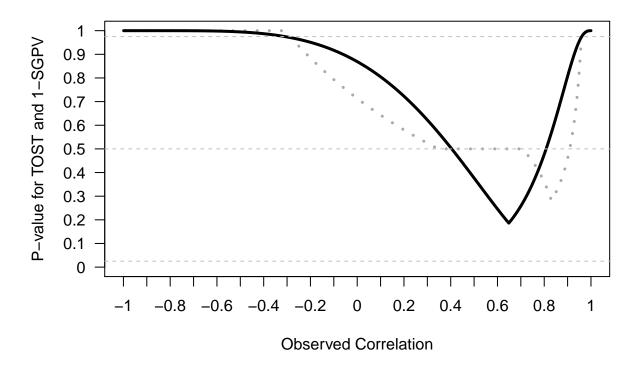


Figure 13. Comparison of p-values from TOST (black line) and 1-SGPV (dotted grey curve) across a range of observed sample correlations (x-axis) tested against equivalence bounds of r = 0.4 and r = 0.8 with r = 10 and an alpha of 0.05.

As a more extreme example of the peculiar behavior of the "small sample correction"

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as currently implemented in the calculation of the SGPV see Figure 13. In this figure 329 observed correlations (from a sample size of 10) from -1 to 1 are tested against an 330 equivalence range from r = 0.4 to r = 0.8. We can see the SGPV has a peculiar shape 331 because it is set to 0.5 for certain observed correlations, even though there is no risk of a 332 "misleading" SGPV in this range. This example suggests that the current implementation of 333 the "small sample correction" could be improved. If, on the other hand, the SGPV is mainly 334 meant to be interpreted when it is 0 or 1, it might be preferable to simply never apply the 335 "small sample correction". 336

Blume et al. (2018) claim that "Adjustments for multiple comparisons are obviated" (p. 15). However, this is not correct. Given the direct relationship between TOST and SGPV highlighted in this manuscript (where to TOST p = 0.025 equals SGPV = 1, as long as the SGPV is calculated based on confidence intervals, and assuming continuous and normally distributed data), not correcting for multiple comparisons will inflate the probability of concluding the absence of a meaningful effect based on the SGPV in exactly the same way as for equivalence tests. Whenever statistical tests are interpreted as support for a hypothesis (e.g., SPGV = 0 or SGPV =1), it is possible do so erroneously, and if researchers want to control error rates, they need to correct for multiple comparisons.

346 Conclusion

We believe that our explanation of the similarities between the TOST procedure and
the SGPV provides context to interpret the contribution of second generation p-values to the
statistical toolbox. The novelty of the SGPV can be limited when confidence intervals are
asymmetrical or wider than the equivalence range. There are strong similarities with
p-values from the TOST procedure, and in all situations where the statistics yield different
results, the behavior of the p-value from the TOST procedure is more consistent and easier
to interpret. We hope this overview of the relationship between the SGPV and equivalence

tests will help researchers to make an informed decision about which statistical approach
provides the best answer to their question. Our comparisons show that when proposing
alternatives to null-hypothesis tests, it is important to compare new proposals to already
existing procedures. We believe equivalence tests achieve the goals of the second generation
p-value while allowing users to easily control error rates, and while yielding more consistent
statistical outcomes.

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