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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 are compared against a range of values that are 13 equivalent 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 16 difference. We compare the behavior of the recently proposed second generation p-value (Blume, D'Agostino McGowan, Dupont, & Greevy, 2018) with the more established Two 18 One-Sided Tests (TOST) equivalence testing procedure (Schuirmann, 1987). We show that 19 the two approaches yield almost identical results under optimal conditions. Under 20 suboptimal conditions (e.g., when the confidence interval is wider than the equivalence range, 21 or when confidence intervals are asymmetric) the second generation p-value becomes difficult 22 to interpret. The second generation p-value is interpretable in a dichotomous manner (i.e., 23 when the SGPV equals 0 or 1 because the confidence intervals lies completely within or outside of the equivalence range), but this dichotomous interpretation does not require 25 calculations. We conclude that equivalence tests yield more consistent p-values, distinguish between datasets that yield the same second generation p-value, and allow for easier control 27 of Type I and Type II error rates.

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

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 are 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 as a 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 continuous data sampled from a bivariate normal distribution.

The TOST procedure also relies on the confidence interval around the effect. In the 61 TOST procedure the data are tested against the lower equivalence bound in the first one-sided test, and against the upper equivalence bound in the second one-sided test 63 (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" 81 (which will be discussed later) that comes into play whenever the confidence interval is more 82 than twice as wide as the equivalence range. To examine the relation between the TOST 83 p-value and the SGPV we can calculate both statistics across a range of observed effect sizes. Replicating the example by Blume et al. (2018), in Figure 1 p-values are plotted for the 85 TOST procedure and the SGPV. The statistics are calculated for hypothetical one-sample t-tests for observed means ranging from 140 to 150 (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 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 second generation *p*-values calculated from confidence intervals, and assuming data is sampled from a bivariate normal distribution. 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 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. We see that the p-value from the TOST procedure and the SGPV follow each other closely. When we discuss the relationship between the p-values from TOST and the SGPV, we focus 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. These three values are important for the SGPV because they indicate the values at which

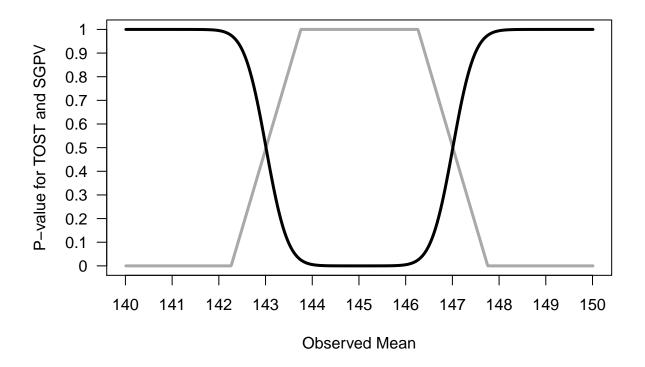


Figure 1. Comparison of p-values from TOST (black line) and SGPV (grey line) across a range of observed sample means (x-axis) tested against a mean of 145 in a one-sample t-test with a sample size of 30 and a standard deviation of 2, illustrating that when the TOST p-value = 0.5, the SGPV = 0.5, when the TOST p-value is 0.975, 1-SGPV = 1, and when the TOST p-value = 0.025, 1-SGPV = 0.

the SGPV indicates the data should be interpreted as compatible with the null hypothesis (SGPV = 1), or with the alternative hypothesis (SGPV = 0), or when the data are strictly inconclusive (SGPV = 0.5). These three points of overlap are indicated by the horizontal dotted lines in Figure 2 at TOST p-values of 0.975, 0.5, and 0.025.

When the observed sample mean is 145, the sample size is 30, and the standard deviation is 2, and we are testing against equivalence bounds of 143 and 147 using the TOST procedure for a one-sample t-test, the equivalence test is significant, t(29) = 5.48, p < .001.

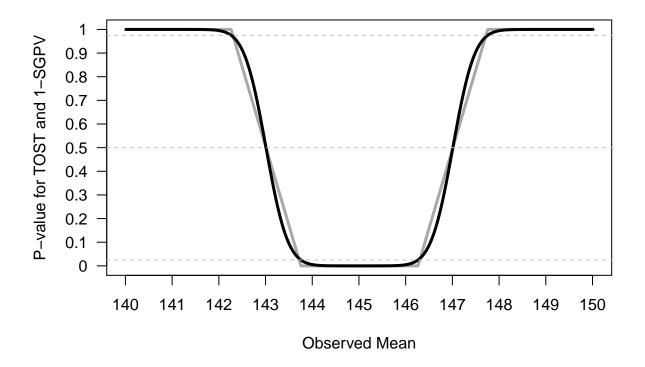


Figure 2. Comparison of p-values from TOST (black line) and 1-SGPV (grey line) across a range of observed sample means (x-axis) tested against a mean of 145 in a one-sample t-test with a sample size of 30 and a standard deviation of 2.

Because the 95% CI falls completely within the equivalence bounds, the SGPV is 1 (see Figure 1). On the other hand, when the observed mean is 140, the equivalence test is not significant (the observed mean is far outside the equivalence range of 143 to 147), t(29) = -8.22, p = 1 (or more accurately, p > .999 as p-values are bounded between 0 and 1). Because the 95% CI falls completely outside the equivalence bounds, the SGPV is 0 (see Figure 1).

118 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, Figure 3).

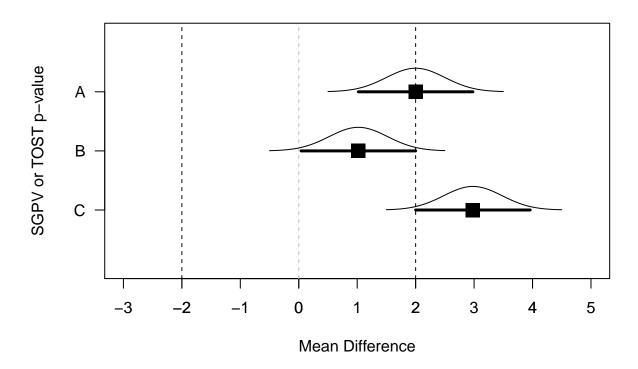


Figure 3. Means, normal distribution, and 95% CI for three example datasets that illustrate the relationship between p-values from TOST and SGPV.

Two other points always have to overlap. When the 95% CI falls completely inside the equivalence region, and one endpoint of the confidence interval is exactly equal to one of the equivalence bounds (see situation B in Figure 3) the TOST p-value (which relies on a

one-sided test) is always 0.025, and the SGPV is 1. Note that when sample sizes are small or 131 equivalence bounds are narrow, small p-values for the TOST or a SGPV = 1 might not be 132 observed in practice if too few observations are collected. The third point where the SGPV 133 and the p-value from the TOST procedure should overlap is where the 95% CI falls 134 completely outside of the equivalence range, but one endpoint of the confidence interval is 135 equal to the equivalence bound (see situation C in Figure 3), when the p-value will always be 136 0.975, and the SGPV is 0. Note that this situation is in essence a minimum-effect test 137 (Murphy, Myors, & Wolach, 2014). The goal of a minimum-effect is not just to reject a 138 difference of zero, but to reject the smallest effect size of interest (i.e., the equivalence 139 bounds). An equivalence test and minimum effect test against the same equivalence bound 140 are complementary, and when a TOST p-value is larger than 0.975, the p-value for the 141 minimum effect test is smaller than 0.05 (and therefore the minimum effect test provides no additional information that can not be derived from the p-value from the equivalence test). The SGPV summarizes the information from an equivalence test (and the complementary minimum-effect test). These can be two relevant questions to ask, although it often makes sense to combine an equivalence test and a null-hypothesis test instead (Lakens et al., 2018). 146

For example, in Figure 4 we have plotted four SGPV's. From A to D the SGPV is 0.76, 147 0.81, 0.86, and 0.91. The difference in the percentage of overlap between A and B (-0.05) is 148 identical to the difference in the percentage of overlap between C and D as the mean gets 0.1 149 closer to the test value (-0.05). As the observed mean in a one-sample t-test lies closer to the 150 test value, from situation A to D, the difference in the overlap changes uniformly. As we 151 move the observed mean closer to the test value in steps of 0.1 across A to D the p-value calculated for normally distributed data are not uniformly distributed. The probability of observing data more extreme than the upper bound of 2 is (from A to D) 0.16, 0.12, 0.08, 154 and 0.05. As we can see, the difference between A and B (0.04) is not the same as the 155 difference between C and D (0.03). Indeed, the difference in p-values is the largest as you 156 start at p = 0.5 (when the observed mean falls on the test value), which is why the line in 157

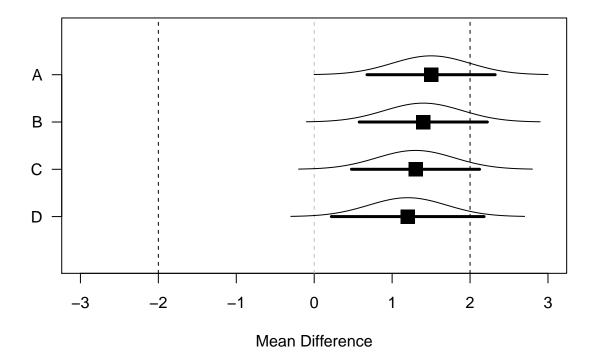


Figure 4. Means, normal distribution, and 95% CI for samples where the observed population mean is 1.5, 1.4, 1.3, and 1.2.

Figure 1 is the steepest at p=0.5. Note that where 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

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

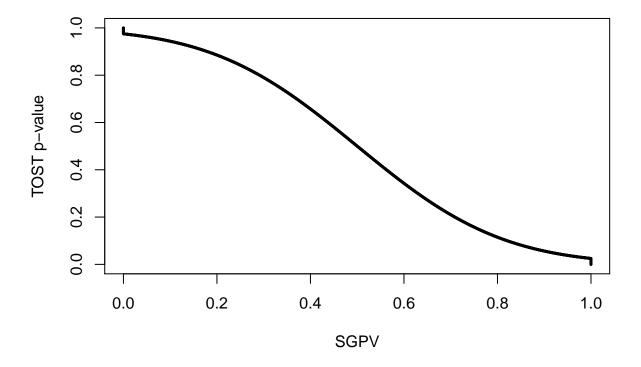


Figure 5. The relationship between p-values from the TOST procedure and the SGPV for the same scenario as in Figure 1.

A third situation in which the SGPV remains stable across a range of observed effects,
while the TOST p-value continues to differentiate, is whenever the CI is wider than the
equivalence range, and the CI overlaps with the upper and lower equivalence bound. When
the confidence interval is more than twice as wide as the equivalence range the SGPV is set

to 0.5. Blume et al. (2018) call this the "small sample correction factor". However, it is not a 177 correction in the typical sense of the word, since the SGPV is not adjusted to any "correct" 178 value. When the normal calculation would be "misleading" (i.e., the SGPV would be small, 179 which normally would suggest support for the alternative hypothesis, but at the same time 180 all values in the equivalence range are supported), the SGPV is set to 0.5 which according to 181 Blume and colleagues signals that the SGPV is "uninformative". Note that the CI can be 182 twice as wide as the equivalence range whenever the sample size is small (and the confidence 183 interval width is large) or when then equivalence range is narrow. It is therefore not so much 184 a "small sample correction" as it is an exception to the typical calculation of the SGPV 185 whenever the ratio of the confidence interval width to the equivalence range exceeds 2:1 and 186 the CI overlaps with the upper and lower bounds. 187

We can examine this situation by calculating the SGPV and performing the TOST for 188 a situation where sample sizes are small and the equivalence range is narrow, such that the 189 CI is more than twice as large as the equivalence range (see Figure 6). When the two 190 statistics are plotted against each other we can see where the SGPV is the same while the 191 TOST p-value still differentiates different observed means (indicated by straight lines in the 192 curve, see Figure 7). We see the SGPV is 0.5 for a range of observed means where the 193 p-value from the equivalence test still varies. It should be noted that in these calculations 194 the p-values for the TOST procedure are never smaller than 0.05 (i.e., they do not get below 195 0.05 on the y-axis). In other words, we cannot conclude equivalence based on any of the 196 observed means. This happens because the we are examining a scenario where the 90% CI is so wide that it never falls completely within the two equivalence bounds. As Lakens (2017) 198 notes: "in small samples (where CIs are wide), a study might have no statistical power (i.e., 199 the CI will always be so wide that it is necessarily wider than the equivalence bounds)." 200 None of the p-values based on the TOST procedure are below 0.05, and thus, in the long run 201 we have 0% power.

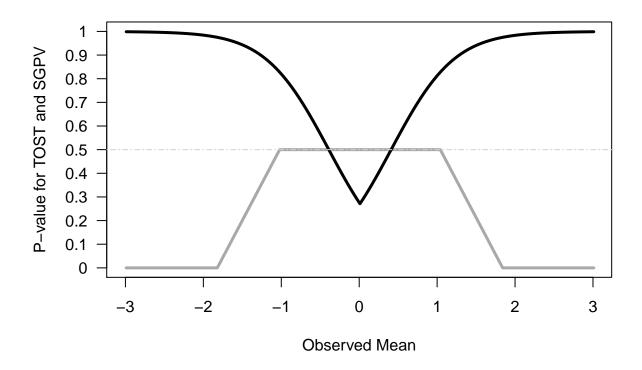


Figure 6. Comparison of p-values from TOST (black line) and SGPV (grey line) across a range of observed sample means (x-axis). Because the sample size is small (n = 10) and the CI is more than twice as wide as the equivalence range (set to -0.4 to 0.4), the SGPV is set to 0.5 (horizontal lightgrey line)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

The p-value from the TOST procedure still differentiates observed means, while the SGPV does not, 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, while the TOST p-value is not constant across this range.

If the observed mean would be somewhat closer to 0, or further away from 0, the

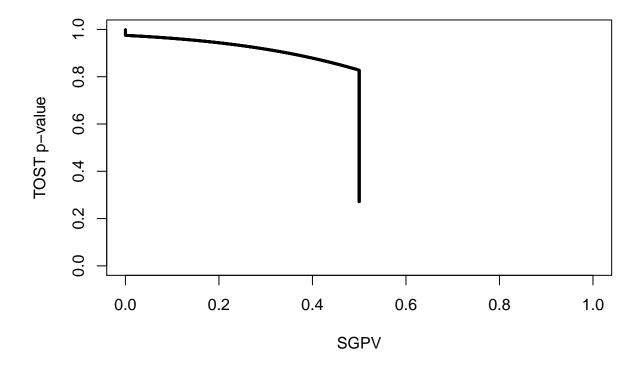


Figure 7. The relationship between p-values from the TOST procedure and the SGPV for the same scenario as in Figure 6.

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

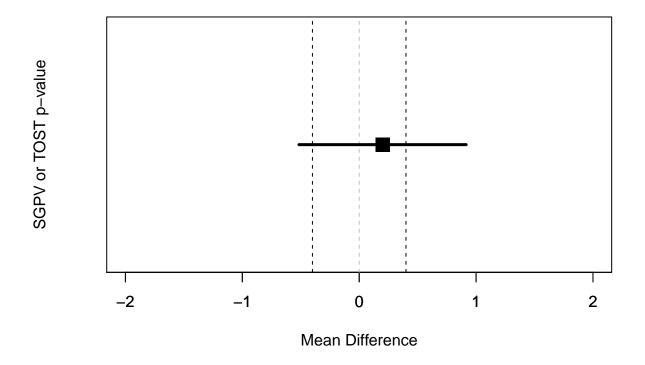


Figure 8. Example of a 95% CI that overlaps with the lower and upper equivalence bound (indicated by the vertical dotted lines).

To conclude this section, there are situations where the *p*-value from the TOST procedure continues to differentiate, while the SGPV does not. Therefore, interpreted as a continuous statistic, the SGPV is more limited than the *p*-value from the TOST procedure.

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The relation between equivalence tests and SGPV 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

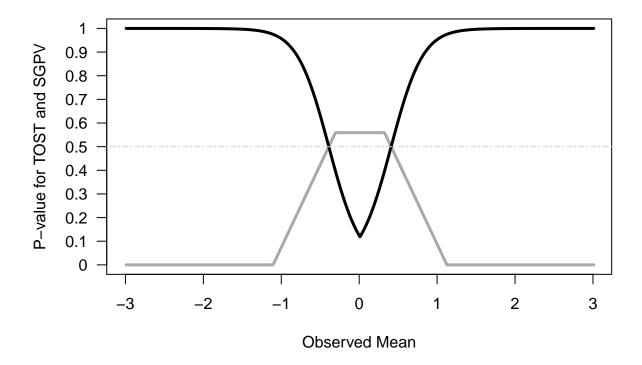


Figure 9. Comparison of p-values from TOST (black line) and SGPV (grey line) across a range of observed sample means (x-axis). The sample size is small (n = 10), but because the sd is half as big as in Figure 7 (1 instead of 2) the CI is less than twice as wide as the equivalence range (set to -0.4 to 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.

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 ranging from 0.126 to 0.993. Note that calculating confidence intervals for
a correlation involves a Fisher's z-transformation, which transforms values such that they are
approximately normally z-distributed, which allows one to compute symmetric confidence
intervals. These confidence intervals are then retransformed into a correlation, where the

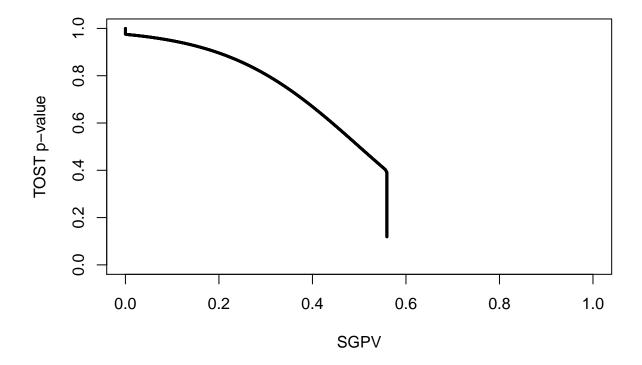


Figure 10. The relationship between p-values from the TOST procedure and the SGPV for the same scenario as in Figure 9.

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 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 related as discussed above, with TOST *p*-values of 0.975 and 0.025 corresponding to a 1-SGPV of 1 and 0, respectively. 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.

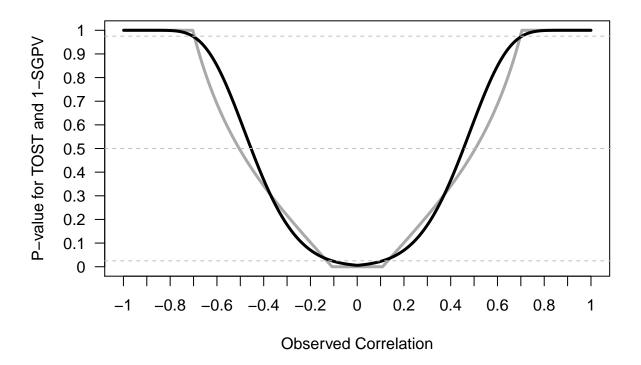


Figure 11. Comparison of p-values from TOST (black line) and 1-SGPV (grey curve) across a range of observed sample correlations (x-axis) tested against equivalence bounds of r = -0.45 and r = 0.45 with n = 30 and an alpha of 0.05.

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 bound the p-value for the equivalence test indicates that the probability of observing the observed or more extreme data, assuming the equivalence bound is the true effect size, is 50%. In other words, if the true effect size is the same as the equivalence bound, it is equally likely to find an effect more extreme than the equivalence bound, as it is to observe an effect

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that is less extreme than the equivalence bound. However, as can be seen in Figure 12, the two second generation p-values associated with the observed correlations at r = -0.45 and r = 0.45 are larger than 50%. Because the confidence intervals are asymmetric around the observed effect size of 0.45 (ranging from 0.11 to 0.70) according to Blume et al. (2018) 58.11% of the data-supported hypotheses are null hypotheses, and therefore 58.10% of the data-supported hypotheses are compatible with the null premise.

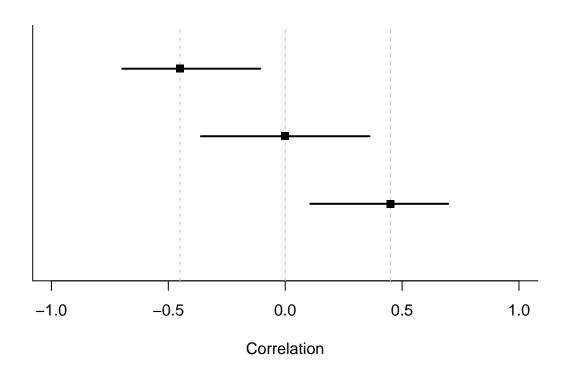


Figure 12. Three 95% confidence intervals for observed effect sizes of r = -0.45, r = 0, and r = 0.45 for n = 30. Only the confidence interval for r = 0 is symmetric.

This example illustrates the difference between a proportion and a probability. As long as data are sampled from a bivariate normal distribution, there is always a 50% probability of observing a correlation smaller or larger than the true correlation, but the SGPV for this situation depends on how 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 265 is the proportion of values in a 95\% confidence interval that overlap with the equivalence 266 range, but not the probability that these values will be observed. In the most extreme case 267 (i.e., a sample size of 4, and equivalence bounds set to r = -0.99 and 0.99, with an observed 268 correlation of 0.99) 58.10% of the confidence interval overlaps with the equivalence range, 269 even though in the long run only 50% of the correlations observed in the future will fall in 270 this range. It should be noted that in larger sample sizes the SGPV is closer to 0.5 whenever 271 the observed correlation falls on the equivalence bound, but this extreme example 272 nevertheless clearly illustrates the difference between question the SGPV answers, and the 273 question a p-value answers. The conclusion of this section on asymmetric confidence 274 intervals is that a SGPV of 1 or 0 can still be interpreted as a p < 0.025 or p > 0.975 in an 275 equivalence test, since the SGPV and p-value for the TOST procedure are always directly related at the values p = 0.025 and p = 0.975. Although Blume et al. (2018) state that "the 277 degree of overlap conveys how compatible the data are with the null premise" this definition 278 of what the SGPV provides does not hold for asymmetric confidence intervals. Although a 279 SGPV of 1 or 0 can be directly interpreted, a SGPV between 0 and 1 is not interpretable as 280 "compatibility with the null hypothesis" under the assumption of a bivariate normal 281 distribution, and the generalizability of this statement needs to be examined beyond normal 282 bivariate distributions. Indeed, Blume and colleagues write in the supplemental material 283 that "The magnitude of an inconclusive second-generation p-value can vary slightly when the 284 effect size scale is transformed. However definitive findings, i.e. a p-value of 0 or 1 are not 285 affected by the scale changes." 286

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 289 approaches and specify its relative strengths and weaknesses. Here, we aimed to compare the SGPV against equivalence tests based on the TOST procedure. 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 293 have asymmetric confidence intervals). In one sense, they are what they are (the proportion 294 of overlap), but it can be unclear what this number tells us about the data we have collected. 295 This is not too problematic, since the main use of the SGPV (e.g., in all examples provided 296 by Blume and colleagues) seems to be to examine whether the SGPV is 0, 1, or inconclusive. 297 As already mentioned, this interpretation of a SGPV is very similar to the Neyman-Pearson 298 interpretation of an equivalence test and a minimum effect tests (which are complementary). 299 The difference is that where a SGPV of 1 can be interpreted as p < .025, equivalence tests 300 provide exact p-values, and they continue to differentiate between for example p = 0.024 and 301 p = 0.002. Whether this is desirable depends on the perspective that is used. From a 302 Neyman-Pearson perspective on statistical inferences the main conclusion is based on 303 whether or not $p < \alpha$, and thus an equivalence test and SGPV can be performed by simply 304 checking whether the confidence interval falls within the equivalence range, just as a 305 null-hypothesis test can be performed by checking whether the confidence interval contains 306 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 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 310 null-hypothesis significance test. This allows a researcher to ask whether there is an effect 311 that is statistically different from zero, and whether effect sizes that are considered 312

meaningful can be rejected. Equivalence tests combined with null-hypothesis tests classify results into four possible categories, and for example allow researchers to conclude an effect is significant *and* equivalent (i.e., statistically different from zero, but also too small to be considered meaningful, see Lakens et al. (2018)).

An important issue when calculating the SGPV is its reliance on the "small sample 317 correction", where the SGPV is set to 0.5 whenever the ratio of the confidence interval width 318 to the equivalence range exceeds 2:1 and the CI overlaps with the upper and lower bounds. 319 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 323 data favor alternative hypotheses", even when a better interpretation would be that there is 324 not enough data to accurately estimate the true effect compared to the width of the 325 equivalence range. Although it is necessary to set the SGPV to 0.5 whenever the ratio of the 326 confidence interval width to the equivalence range exceeds 2:1, it leads to a range of 327 situations where the SGPV is set to 0.5, while the p-value from the TOST procedure 328 continues to differentiate (see for example Figure 6). An important benefit of equivalence 329 tests is that it does not need such a correction to prevent misleading results. 330

As a more extreme example of the peculiar behavior of the "small sample correction" 331 as currently implemented in the calculation of the SGPV see Figure 13. In this figure 332 observed correlations (from a sample size of 10) from -1 to 1 are tested against an 333 equivalence range from r = 0.4 to r = 0.8. We can see the SGPV has a peculiar shape 334 because it is set to 0.5 for certain observed correlations, even though there is no risk of a 335 "misleading" SGPV in this range. This example suggests that the current implementation of 336 the "small sample correction" could be improved. If, on the other hand, the SGPV is mainly 337 meant to be interpreted when it is 0 or 1, it might be preferable to simply never apply the 338

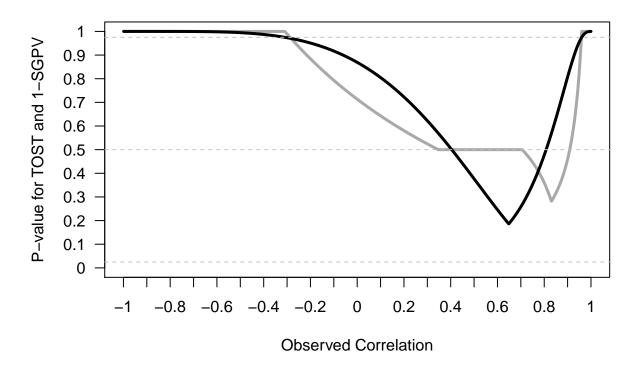


Figure 13. Comparison of p-values from TOST (black line) and 1-SGPV (grey curve) across a range of observed sample correlations (x-axis) tested against equivalence bounds of r = 0.4 and r = 0.8 with n = 10 and an alpha of 0.05.

"small sample correction".

Blume et al. (2018) claim that when using the SGPV "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 a TOST p = 0.025 equals SGPV = 1, as long as the SGPV is calculated based on confidence intervals, and assuming data are sampled from a continuous bivariate normal distribution), 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 it will 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.

350 Conclusion

We believe that our explanation of the similarities between the TOST procedure and 351 the SGPV provides context to interpret the contribution of second generation p-values to the 352 statistical toolbox. The novelty of the SGPV can be limited when confidence intervals are 353 asymmetrical or wider than the equivalence range. There are strong similarities with 354 p-values from the TOST procedure, and in all situations where the statistics yield different 355 results, the behavior of the p-value from the TOST procedure is more consistent and easier 356 to interpret. We hope this overview of the relationship between the SGPV and equivalence 357 tests will help researchers to make an informed decision about which statistical approach 358 provides the best answer to their question. Our comparisons show that when proposing 359 alternatives to null-hypothesis tests, it is important to compare new proposals to already 360 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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