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Keywords: Urogenital overuse injuries; Urogenital disorders; Pelvic floor; Female Sexual Dysfunction; Pudendal nerve

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Abstract: Purpose. Female cyclists undergo a perineal compression of the pudendal nerve and genital-perineal area, with underexplored effects on genital injuries and sexual dysfunctions. This study tests the effects of a new geometric bicycle saddle (SMP) on perineal compression, blood perfusion, genital sensation and sexual function.

Methods. 33 professional female athletes were monitored when using both the new saddle and a traditional professional saddle, in a randomized order. Short-term effects are estimated by measuring the partial pressure of vagina transcutaneous oxygen (PtcO2) before using the saddle, after 10 minutes of static sitting, after riding 20 minutes. Long-term effects are estimated by measuring athletes Female Sexual Distress Scale (FSDS) before using the new saddle and after 6 months using it.

Results. From an initial average of 70 mmHg, PtcO2 decreases by 30 mmHg after riding on a traditional saddle, 10 mmHg on the new saddle (respectively 20 and 7 after just sitting). When using the traditional saddle all FSDS scores are well over the 12 "normality" threshold, with an average of 41, while after using the new saddle the average falls to 12. All differences between the saddles are strongly significant: paired t-tests>6; p-value=0; 95% confidence intervals respectively 13±3 mmHg after sitting, 20±3 mmHg after riding, 29±2 FSDS scores.

Conclusion. Traditional saddles have strong negative effects on the vascular perfusion of the vulva, with possible consequences on female sexual functions. The SMP saddle reduces the compression on the pelvic floor and can help reducing the incidence of urogenital pathologies for female cyclists.

Heading page

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Titre: L'effet de la nouvelle selle de vélo géométrique sur la perfusion vasculaire vaginale et périnéale des femmes cyclistes.

Short title: Effects of a new saddle on genital perfusion of female cyclists

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The effect of a new geometric bicycle saddle on the genital-perineal vascular perfusion of female cyclists

Summary

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L'effet de la nouvelle selle de vélo géométrique sur la perfusion vasculaire vaginale et périnéale des femmes cyclistes

Résumé

Objectifs. Les femmes cyclistes subissent une compression périnéale du nerf pudendal et de la zone genito-périnéale, avec des effets sous-estimés de lésions génitales et de dysfonctionnements sexuels. Cette étude teste les effets d'une nouvelle selle géométrique (SMP) sur la compression périnéale, la perfusion sanguine, la sensation génitale et la fonction sexuelle.

Méthodes. 33 femmes athlètes professionnelles ont été observées lors de l'utilisation d'une selle professionnelle traditionnelle et une nouvelle, en ordre aléatoire. Des effets à court terme sont estimés en mesurant la pression partielle de l'oxygène transcutané vaginal (PtcO2) avant d'utiliser la selle, après 10 minutes de session statique et après 20 minutes de course. Des effets long terme sont estimés en mesurant l'échelle Female Sexual Distress Scale (FSDS) avant d'utiliser la nouvelle selle et après 6 mois de son utilisation.

Résultats. À partir d'une moyenne initiale de 70 mmHg, PtcO2 diminue de 30 mmHg après l'utilisation d'une selle traditionnelle et 10 mmHg avec la nouvelle selle (respectivement 20 et 7 après l'utilisation assise). Lors de l'utilisation de selle traditionnelle tous les scores FSDS sont bien au-dessus du plafond de “normalité” de 12, avec une moyenne de 41, par contre, après l'usage de la nouvelle selle, la moyenne précipite au 12. Toutes les différences entre les selles sont fortement significatives: test-t pour données appariées >6; p-value=0; 95% intervalle de confiance respectivement 13±3 mmHg après séance assise, 20±3 mmHg après course, 29±2 score FSDS.

Conclusion. Les selles traditionnelles ont de forts effets négatifs sur la perfusion vasculaire de la vulve, avec des possibles conséquences sur les fonctions sexuelles féminines. La selle SMP réduit la compression du plancher pelvien et peut aider à réduire l'incidence de pathologies urogénitales des femmes cyclistes.

MOTS CLÉS. Blessures urogenitale pour abus; Dysfonctionnement urogénital; Plancher pelvien; Dysfonctionnement sexuel féminin; Nerf pudendal

1. Introduction

Cycling is a popular sport among women and men; both health and quality of life benefits have been reported on riders [1-2]. However, bicycle riding is also associated with a number of health risks including pelvic neurovascular compromise. The primary mechanisms leading to these symptoms in both genders are perineal compression of the pudendal nerve and genital-perineal area [3].

In contrast to men [4-5], literature on genital overuse injuries and sexual dysfunctions in female cyclists is scarce, in spite of genital complaints including pain, numbness and edema of pelvic floor, dysuria, stranguria, vulvar discomfort, dyspareunia [6]. Studies have found that in female cyclists the rider's position on the bicycle, as well as the type of saddle used, have more effect on resultant sexual dysfunctions than simply participation in cycling [7]. Prevailing results suggest that neurovascular damage occurs during cycling as a result of chronic compression of the genital area against the saddle [8-9]. Therefore, the symptoms were attributed to a compression of the pudendal nerve in Alcock's canal and from stretching the nerve during pedaling, as it spans between the sacrospinous and sacrotuberous ligaments, as well as the compression of the nerve against the saddle where it innervates the perineum and symphysis [10]. Altered nerve conduction and reduced blood flow to the vagina and clitoris can result in delayed vaginal engorgement, pain or discomfort with intercourse, less vaginal lubrication, reduced vaginal and clitoral sensation and may lead to FSD [11-13].

There are significant anatomical differences that affect how the bodies of females and males interact with the bicycle [14]. When compared to men, women have a wider pelvis, a lower center of gravity, a greater pelvic tilt when riding and a higher peak saddle pressure in the anterior region of the saddle when they move from the tops to the drops [15-17]. To date, few studies have evaluated the associations between saddle design, seat pressure and neurovascular compromise in women [6].

The aim of this study is to test the effects of two different kinds of saddle on perineal compression, blood perfusion, genital sensation and sexual function of female professional bikers. Specifically, we compare traditional saddles used by professional bikers to the SMP saddle (Figure 1), a new geometric bicycle saddle derived from a new conception saddle which was previously proved to be effective for men [18].

Figure 1 about here
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2. Materials and Methods

2.1. Subjects

Study subjects are 33 professional female cyclists from 6 Italian top teams running in the UCI Women's World Tour. All athletes signed an informed consent before being involved in the tests. Their average age is 24 (standard deviation 4.8; range 19-36), average weight is 57 kg (4.8; 50-69), average height is 167 cm (4.9; 159-179) and average BMI 20 (1.8; 18-24).

2.2. Design and methodology

We tested the effectiveness of the new SMP saddle by comparing it with standard saddles used by professional cyclists, flat and with a narrow protruding nose. The new saddle is the result of in-depth ergonomics studies. It supports the cyclist’s weight precisely distributing it over pelvic bones and buttocks and keeps the perineal area free from compression. It protects the coccyx from bruises and shocks caused by the roughness of the terrain.

In order to test short-term effects of using different kinds of saddle, the outcome of main interest is the change in blood perfusion of genital-perineal area caused by the compression on the perineal structures. Each of the 33 athletes used both her own saddle and the new saddle in two sessions separated by a lag of about 30 minutes. The choice of which saddle they used first was randomized. In both sessions the main measurements were repeated in three different moments: standing before using the saddle, after sitting on the saddle for 10 minutes, after riding for 20 minutes over the rollers with a constant gear ratio of 53:19. The athletes wore shorts without padding to show the direct compressive effect of the saddle, and they used their own bicycle, in order to not interfere in their habitual kinematic characteristics.

The blood perfusion was measured by means of the partial pressure of oxygen [18-20] in the vulva through the transcutaneous way (PtcO2), by using the TCM TOSCA/CombiM equipment with a Clark electrode. The electrode was applied through an adhesive ring to the labia majora of the cyclists' vulva, interposing a special electrolytic solution between membrane and vulva. As a general principle, PtcO2 depends on the oxygen content of the capillaries of the vulva and on the oxygen spread through the epidermis [20-21]. The oxygen content of the cutaneous capillaries depends on the local blood perfusion. In order to obtain the PaO2 from the PtcO2, the capillaries oxygen content has to be independent from the local blood flow. So, the increase in the local temperature is an essential factor that increases the cutaneous blood flow [18-20]. The temperature is routinely maintained to 43-44°C to avoid burning risks; therefore, we set up the machine at 44°C and the experiment was performed in a room with fresh air.

Finally, in order to evaluate long-term effects of using a different saddle we adopted a different strategy, by using the 12-items version of the Female Sexual Distress Scale (FSDS) questionnaire [22] as a diagnostic tool. Each item analyses an aspect of sexual distress on a 0-4 scale, thus the sum of the items has a 0-48 range, with 48 representing the maximum sexual distress and values under 12 as a "normality" threshold. All athletes were using traditional saddles before being involved in the project, while they used the new saddle for the following 6 months continuatively during their training and races. We asked each athlete to answer to the same FSDS questionnaire before and after the 6-months period.

2.3. Statistical analysis

Six different PtcO2 levels are available for each athlete, as in both sessions the measurements were repeated in three different moments: before using the saddle, after sitting for 10 minutes, after riding for 20 minutes. In order to test short-term effects of different saddles on oxygen levels, we focus on individual variations on time of PtcO2 levels. According to the timing of observations, we calculate for each athlete three different outcomes of interest:

1) "Sitting": PtcO2 after sitting *vs*. initial level;
2) "Riding": PtcO2 after riding *vs*. after sitting;
3) "Total": PtcO2 after riding *vs*. initial level (equivalent to "Sitting"+"Riding").

As a formal hypothesis test exploiting the design of our study, we compare the variations in PtcO2 occurring for the same athlete when using the two kinds of saddle. We first calculate for each athlete the difference between the two saddles separately for each outcome, and then test the null hypotheses that the mean differences between saddles are zero. Typical statistical methods fitting this study design are two-sided paired *t*-tests allowing for dependent observations. We also checked whether all results are independent on the order in which the saddles are tested, as expected due to the randomization. Finally, a two-sided paired *t*-test is also applied to test whether the mean FSDS score changed after the use of the new saddle.

As usual, *t*-statistics from the paired *t*-tests are compared with the Student *t* distribution in order to evaluate *p*-values and 95% confidence intervals. All analyses are carried on by using Stata software (Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC).

3. Results

Table 1 describes the observed distribution of the main outcomes. As regards PtcO2, from Table 1 and Figure 2 the average starting levels before sitting on any saddle are about 70 mmHg, with a range from 59 to 80. After sitting on a traditional saddle the whole distribution of oxygen levels shows a marked decline, with an average of 51 mmHg and a minimum value of 20; on the contrary, sitting on the new saddle takes to a lower decrease of oxygen levels, with a 66 mmHg average and all riders over 51. Similar evidence comes from oxygen levels after riding: average values are respectively 41 *vs*. 63, ranges are 16-62 *vs*. 40-75.

Table 1 and Figure 2 about here

Turning to variations on time for the same athlete, Figure 3 shows the distribution of the three outcomes of interest by using different saddles. Variations in PtcO2 levels with the new saddle are shrinked towards zero, while variations are much higher when using traditional saddles. Specifically, after "Sitting" on the new saddle almost all athletes (30 out of 33) show variations less than 10 mmHg, while with a traditional saddle mean and median are about 20, some athletes are close to 50 and only seven are under 10. The additional effect of "Riding" is negative for all athletes using a traditional saddle, while nine variations are positive when using the new saddle. Finally, while almost all "Total" variations are under 20 with the new saddle, the traditional saddle shows higher changes: all athletes are over 10, mean and median are close to 30 and some values are over 50.

The first three rows in Table 2 show the results of paired t-tests for the three outcomes "Sitting", "Riding" and "Total" defined in the previous section. The mean differences are respectively around 13, 7 and 20 mmHg and they are highly significant at any traditional significance level: *t*-stats are all over 6 and all *p*-values are therefore very close to 0, thus rejecting all hypotheses of a null saddle effect. Moreover, when compared to initial distributions with standard deviations lower than 5 mmHg, all observed effect sizes are empirically very large from a substantial point of view.

As an additional robustness check, this empirical evidence is never significantly affected by the randomized order in which the athletes used the saddles. As an example, the overall total effect of 19.6 in Table 2 is respectively 19.3 when limiting the analysis to the 17 athletes using the new saddle during the first session, and 20.0 for the 16 ones who begun using the traditional one. Even with these lower sample sizes, all effects are still significantly positive in both groups.

Table 2 and Figure 3 about here

Finally, from Table 1 and Figure 4, when using traditional saddles the mean FSDS score was 41, very close to the maximum of 48, all scores were over 24 (average item response 2 on a 0-4 scale) and 88% were over 36 (average 3). On the contrary, after using the new saddle the mean was exactly at the "normality" threshold 12, and only 9 athletes out of 33 still showed values over this threshold, with a maximum value of 23 which is smaller than the minimum value observed just few months before. From the last row of Table 2, the average difference of 29 points is also statistically significant at any conventional level (t=26; p very close to 0).

Figure 4 about here
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4. Discussion

This study provides new insights about how using different saddles affects differently the blood perfusion of the vulva for female bikers. Thanks to its ergonomic characteristics, the new SMP saddle turns out to be more efficient for the protection of the blood perfusion of the vulva when compared to traditional saddles used by cyclists who cover long distances.

Our first key finding is that traditional saddles are associated to very high absolute changes in PtcO2 levels, and average variations are about 3 times higher than those observed when using the new saddle for every outcome of interest. Among the others, when compared to a common starting level about 70 mmHg, the average overall variation after riding is close to 30 for the traditional saddle, less than 10 for the new saddle.

The evidence about the short-term effects of using the two kinds of saddle is striking, and the randomized order of the sessions allows us to give a causal interpretation of these results. As the evidence is particularly clear for "Sitting" and "Total", it turns out that just sitting on a traditional saddle has immediate negative effects on blood perfusion, while riding has just an additional effect, even if this is still significantly higher when riding on traditional saddles.

A second key finding is that the higher local compression is associated to important long-term negative effects in sexual functions, while these effects are strongly lowered when using the new SMP saddle. All FSDS scores observed after using the new saddle are lower than those observed before its use, even when comparing different athletes, and the average difference of 29 points is highly significant and empirically very strong on a 0-48 range. Admittedly, the non-experimental before-after strategy for long-term effects is potentially weaker than the experimental one used for short-term ones, because of the absence of a control group which continued to use the traditional saddle over the same 6-months period. Still, we assume that there are no other reasons why the FSDS score should have changed so strongly in a relatively short time spell, in absence of a change of saddle. The only potential reason could be related to the 6-months aging of all athletes with time, but all our results turn out to be essentially the same for athletes at different ages. Thus we maintain that it is also possible to interpret changes in FSDS scores as an effect of using a different kind of saddle.

In order to understand the reasons of these strong effects, the geometric saddle was suggested as one of the main important factors in order to protect the blood perfusion of the genital-perineal area on female cyclists [14]. The absence of the nose of the saddle prevents a hard compression on the blood vessels, especially on women [23]. The geometry of the SMP saddle, by redistributing the body weight among the buttocks, the ischiatic tuberosity and the ischium, and thus freeing the perineal plane, prevents the squashing of the neurovascular structures that run medially to the ischiatic tuberosity. Furthermore, the depression in the rear part prevents the coccyx from touching the saddle, thus preventing repercussions caused by the unevenness of the ground that may affect the spine. Finally, the geometric shape of the saddle conforms to the shape of the thigh muscles [18]. As professional cyclists pedal with their knees medially toward the chassis of the bicycle to increase their power [24], these characteristics prevent the gracile muscle from rubbing with the adductor muscle that could annoyingly disturb the legs during cycling.

As a consequential practical implication, when considering the development of a new ergometric conception of seat designs, which have to be suitable for professional cyclists to whom this study is addressed, we must not forget their effect on pelvic and trunk angle and on comfort [23, 25, 26]. The true innovation brought about by the SMP saddle is its capacity of interfering scarcely on the blood perfusion of the genital-perineal area on female cyclists, maintaining limited dimensions, especially in width, which is considered as an essential factor in the protection of the compression on the perineal structures [18].

An additional contribution could be checking potential heterogeneous effects of the new saddle when comparing different athletes in terms of observable characteristics. In some robustness checks we allowed for heterogeneous effects by age, height, weight and BMI, but our main results are never affected. There is only a slight evidence that the two only athletes weighing more than 65 kg show the largest decrease in PtcO2 when sitting on the traditional saddle, while they face a variation in line with other athletes when sitting on the new saddle. As a potential future research, larger samples with more detailed information about the athletes could allow for more detailed analyses on potential heterogeneous effects of different seat designs.

As for the limitations of the study, the available sample is apparently small, but the 33 athletes involved in our tests represent a relevant quote of top female professional bikers and almost the whole population of riders from top teams located in Northern Italy; moreover, this sample size showed off to be sufficient in order to detect very significant effects on averages, without having to discuss potential problems of statistical power. Other potential limitations are related to our identification strategy: while our experimental strategy has a strong internal validity, there could be some concern about its external validity. As an example, results for professional athletes could be potentially different when applied to amateurs or everyday bikers. Thus, additional research is needed in order to test the effectiveness of the new kind of saddle for different populations of interest.

5. Conclusions

Traditional saddles have strong negative effects on the vascular perfusion of the vulva with possible consequences on female sexual function, while a new kind of saddle is able to strongly lower these effects. The SMP saddle avoids affecting the blood perfusion, while maintaining desirable dimensions, mainly in width, and protecting the cyclists against compression on the perineal structures. As an important practical implication, the geometry of a bicycle saddle is an important parameter to consider in the attempt to reduce the compression on neurovascular structures of the pelvic floor.

Disclosure of interest

The authors declare that they have no competing interest.

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Tables

Table 1: Descriptive statistics: PtcO2 levels and FSDS scores.

Variable	Mean	*S.D.*	Min.	25th	Med.	75th	Max
Initial PtcO2 level (mmHg)							
Compared saddle	70.33	5.13	59	68	70	73	80
New saddle	72.03	4.22	64	70	71	75	80
PtcO2 level after sitting (mmHg)							
Compared saddle	50.97	12.06	20	41	53	59	72
New saddle	65.61	6.10	51	62	65	70	79
PtcO2 level after riding (mmHg)							
Compared saddle	41.21	12.26	16	32	44	50	62
New saddle	62.52	7.54	40	59	63	68	75
Female Sexual Distress Scale (FSDS)							
Compared saddle	40.82	4.96	24	39	42	44	48
New saddle	12.09	3.80	7	10	11	13	23
Number of observations	33						

Table 2: Variations in PtcO2 levels and FSDS scores: average by saddle and paired t-test.

	Means		New saddle effect			
	Compared	New saddle	Diff.	*s.e.*	*t-stat*	95% CI
PtcO2 change after sitting	19.36	6.42	12.94	1.75	7.41	9.38-16.50
PtcO2 change after riding	9.76	3.09	6.67	1.03	6.48	4.57- 8.76
Total (Sitting+Riding)	29.12	9.51	19.61	1.62	12.14	16.32-22.90
FSDS score	40.82	12.09	28.73	1.09	26.41	26.55-30.90

Figure titles

Figure 1: The new geometric saddle.

Figure 2: Distribution of oxygen levels by time of observation and saddle.

Figure 3: Distribution of variations in oxygen levels, by time periods and saddle.

Figure 4: Distribution of Female Sexual Distress Score (FSDS), by saddle.

Figure 1: The new geometric saddle.

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Figure 2: Distribution of oxygen levels by time and saddle

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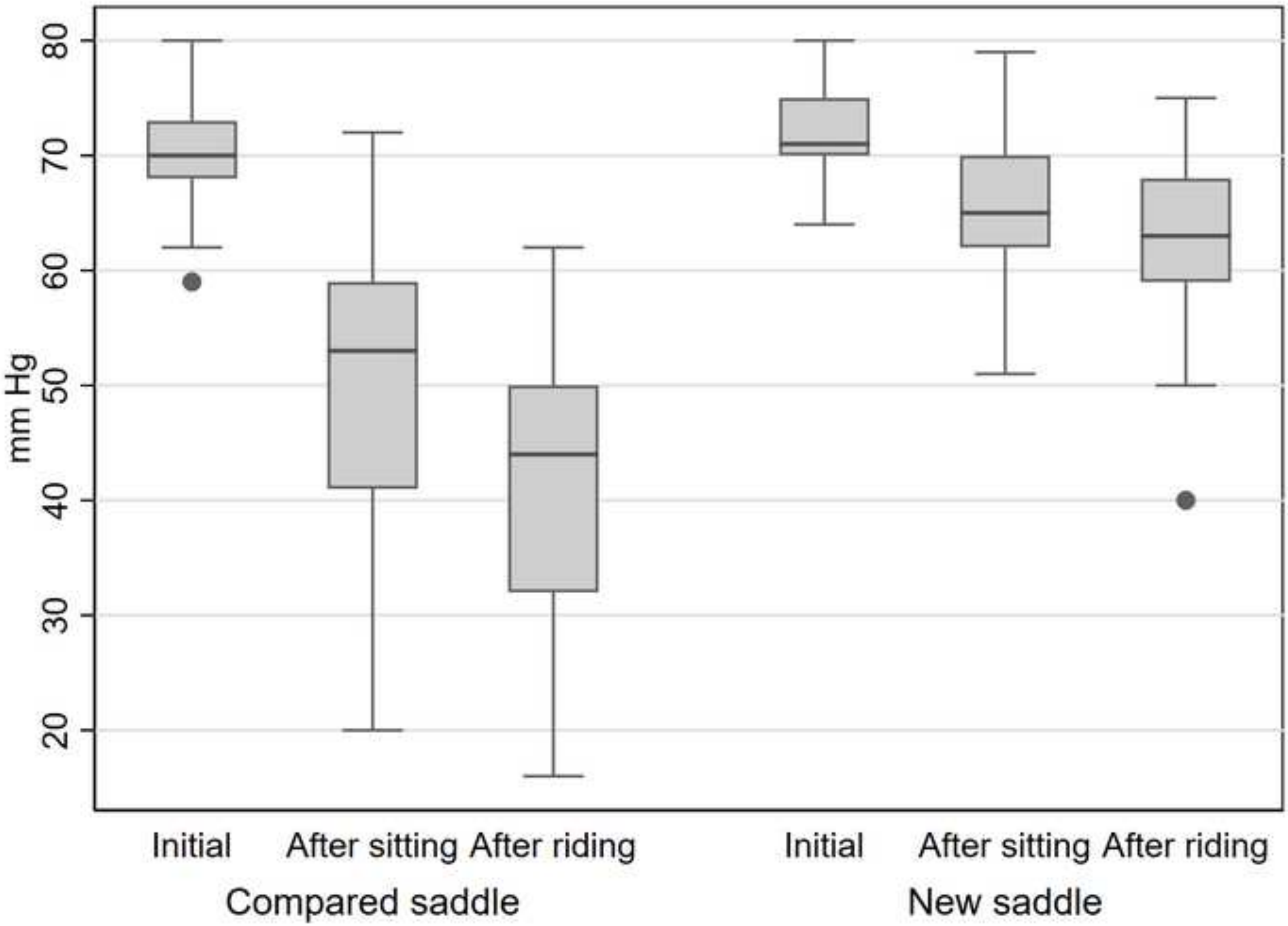

Figure 3: Variations in oxygen levels, by time and saddle
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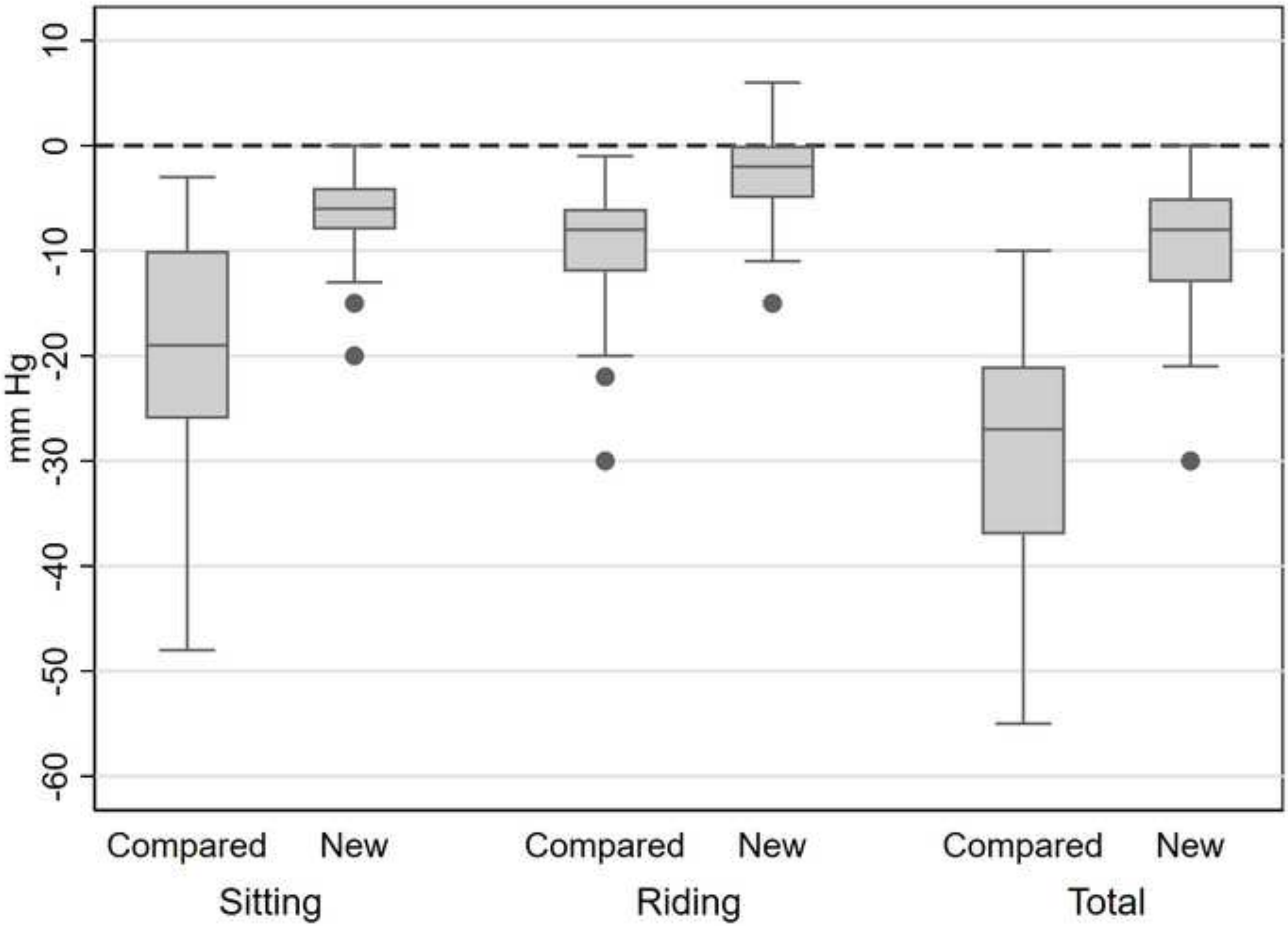

Figure 4: Female Sexual Distress Score (FSDS), by saddle

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