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Conservative management versus systematic suture of isolated vaginal or first-degree perineal tears after delivery: A preliminary randomized efficacy trial

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► To cite this version:

Marine Lallemand, Aurélie d'Antona, Chrystelle Vidal, Aude Bourtembourg, Claire Toubin, et al.. Conservative management versus systematic suture of isolated vaginal or first-degree perineal tears after delivery: A preliminary randomized efficacy trial. Birth: Issues in Perinatal Care, 2022, 2022-00 (1-12), 10.1111/birt.12671 . hal-04079581

HAL Id: hal-04079581

<https://hal.science/hal-04079581>

Submitted on 24 Apr 2023

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31

32 **Funding**

33 This study is supported by University Hospital of Besançon, APICHU Ref: API/2015/60.

34

35 **Word account:** 3623 words

36

37 **Conflict of Interest and Financial Disclosure Statements**

38 The authors report no conflict of interest.

39

40 **Contributors**

41 All the authors contributed to the conception and design of the study. NM and RR provided
42 the idea for the research or article, created the hypothesis, and wrote the original proposal.

43 ML, NM, CV, LP and RR contributed to writing the paper. NM, CV, GB and LP wrote this
44 protocol paper. All the authors read and approved the final manuscript.

45

46 **Trial registration:**

- 47 - ClinicalTrials.gov Identifier: NCT02870712
- 48 - Date of registration: August 17, 2016
- 49 - Date the first patient/participant was enrolled: March 21, 2017
- 50 - [https://clinicaltrials.gov/ct2/show/NCT02870712?cond=Imsolence&cntry=FR&city=B](https://clinicaltrials.gov/ct2/show/NCT02870712?cond=Imsolence&cntry=FR&city=Besan%C3%A7on&draw=2&rank=1)
- 51 [esan%C3%A7on&draw=2&rank=1](https://clinicaltrials.gov/ct2/show/NCT02870712?cond=Imsolence&cntry=FR&city=Besan%C3%A7on&draw=2&rank=1)

52

53 **Funding**

54 This study is supported by University Hospital of Besançon, APICHU Ref: API/2015/60.

55

56 **Patient consent and approval**

57 Written patient consent was obtained for the research and publication.

58

59 **Ethics approval**

60 The Human Research Ethics Committee (Comité de Protection des Personnes EST II, process
61 number **15/494**).

62

63 **Acknowledgments**

64 We thank Grégory Tio for his help with the statical analyses.

65

66

67

68 **Structured Abstract**

69 **Background:** The objective of this study was to assess the preliminary efficacy and safety of
70 conservative management compared with systematic suture in isolated vaginal or first-
71 degree perineal tears after birth.

72 **Methods:** We conducted a preliminary efficacy, open-label, randomized, controlled and
73 prospective trial. This study implemented Simon's 2-step plan (interim analysis and final
74 analysis) to test the success rate of the digital compression strategy group. Primiparous
75 women aged ≥ 18 years with isolated vaginal or first-degree perineal tears after spontaneous
76 vaginal birth of a cephalic presenting term (≥ 37 weeks) neonate were randomly allocated
77 to the conservative management (CM) group (digital compression if bleeding followed by
78 suture if persistent bleeding) or a systematic suture (SS) group. The primary outcome was
79 the success of the intervention 10 days after delivery, defined by pain as evaluated using a
80 visual analog scale < 3 , satisfactory healing defined by a REEDA score ≤ 2 and no bleeding or
81 infection. Sexual well-being was assessed at two and six months postpartum.

82 **Results:** Among 861/2,209 eligible women, 143 consenting women with a superficial
83 perineal tear were randomized: 72 in the systematic suture group and 71 in the conservative
84 management group. Success rate was 87.8% (90% CI [70.5-93.54]) (42/55) in the systematic
85 suture group versus 90% (90% CI [78.3-93.8]) (53/61) in the conservative management
86 group. The REEDA score was significantly higher in the systematic suture group (1.4 versus
87 0.9; $p=0.036$). Perineal pain was significantly higher at day one in the systematic suture
88 group (2.38 vs 1.69; $p=0.034$). For the Female Sexual Functional Index score, no significant
89 difference was found between the two groups at inclusion or at 2 and 6 months postpartum.

90 **Conclusion:** Conservative management of superficial perineal tears shows an efficacy rate \geq
91 90%. Women in the conservative management group had less pain at the first-day follow-up
92 and lower REEDA scores at the 10th-day follow-up.

93

94

95 **Key words (5): perineal lacerations, suturing, pain, sexual well-being**

96

97

Main text

98 INTRODUCTION

99 In the United Kingdom in 2013, the rate of vaginal tears varied with patient age from
100 30% to 40%¹. In a study published in 2000, Lundquist et al. found 75% of women sustain any
101 perineal or vulvar lesion after vaginal delivery². The viewpoint of health professionals
102 regarding perineal repair has evolved, and women desire perineal protection at birth. To
103 reduce the medicalization of childbirth and adverse outcomes of surgical repair, a new
104 debate concerning whether to suture has emerged. In 1998, Gordon et al. showed a
105 decrease in immediate postpartum pain and dyspareunia at 3 months and 1 year when the
106 skin was not sutured during second-degree perineal tears^{3,4}. A Cochrane meta-analysis
107 found only two relevant studies⁵, which showed no differences in clinical outcomes up to
108 eight weeks postpartum between surgical and nonsurgical repair of first- and second-degree
109 perineal tears. Although the distribution of perineal tears has changed following decreases in
110 episiotomy rates, no study has attempted to replicate these findings since 2003.

111 The presence of sutures can reactive edema, and the resorption of suture material
112 may contribute to perineal pain. Digital compression to achieve hemostasis has been
113 proposed as an option for managing perineal tears. We hypothesized that bleeding vessels in
114 superficial tears during delivery could be digitally compressed, avoiding unnecessary sutures.

115 The first objective of this study was to evaluate the efficacy and safety of
116 conservative management compared with systematic suture in isolated vaginal or first-
117 degree perineal tears after birth. The secondary objective was to compare sexual well-being
118 at two and six months postpartum.

119

120 MATERIALS AND METHODS

121 **Design and setting**

122 We conducted a prospective preliminary efficacy study at a level III maternity unit between
123 March 2017 and September 2018. This study implemented Simon's 2-step plan (interim
124 analysis and final analysis) to test the success rate of conservative management. A
125 randomized controlled group was added to estimate the efficacy of systematic suture. A
126 preliminary and nondefinitive comparison of the standard regimen and experimental
127 regimen was made for secondary criteria. The protocol was approved by the EST II Ethics
128 Committee (reference number 16/521) and was registered as a clinical trial before the
129 initiation of study recruitment.

130 All methods were performed in accordance with the relevant guidelines and regulations.

131 This study was registered on clinicaltrials.gov (NCT02870712).

132

133 **Participants**

134 Women were eligible and recruited into the study during the eighth-month prenatal visit if
135 all the following criteria applied: a primiparous woman, ≥ 18 years of age, singleton
136 pregnancy, and ≥ 32 weeks of gestation. Women were excluded if they did not consent to
137 participate in the study or if any of the following criteria applied: women that did not fulfill
138 all the inclusion criteria, suspicion of a bleeding disorder, anticoagulant treatment during
139 pregnancy, a history of perineal surgery or infibulation, women serving a prison sentence,
140 and woman unable to read or understand French.

141 Participants were randomized after delivery if the following criteria applied: occurrence of a
142 first-degree perineal tear or an isolated vaginal tear (without muscle involvement), birth at \geq
143 37 weeks gestation, and spontaneous, cephalic, vaginal delivery of a live born neonate.

144 Women were not randomized if one of the following criteria applied: withdrawal of
145 informed consent, episiotomy, cesarean delivery, assisted vaginal delivery, manual placental
146 delivery and/or uterine exploration, intact perineum, or a second-degree perineal tear or
147 higher.

148

149 **Randomization and allocation**

150 A computer-generated 1:1 simple randomization table was created using SAS software.
151 Treatment allocation was written on index cards and concealed in identical, sealed opaque
152 envelopes to ensure balance between the groups. Randomization was performed in blocks
153 of four. After creating the randomization cards, the computer-generated randomization
154 table was deleted. Study allocation envelopes remained sealed until an isolated vaginal or
155 first-degree perineal tear was confirmed by the physician investigator and a second oral
156 consent was obtained.

157

158 **Study procedures**

159 Eligible women between 32⁺⁰ and 36⁺⁶ weeks of gestation were approached and informed of
160 the study by obstetric physicians or midwives during antenatal visits. The schedules of
161 enrollment and interventions were described verbally to eligible patients, and a written
162 information was also given (Table 1). All participants provided signed consent after
163 completing the informed consent process. When a woman who had previously consented to
164 participate in the study arrived in the delivery room, her wish to continue the study was
165 orally reconfirmed. The quality of sexual activity was assessed using a self-assessment and
166 the French version of the Female Sexual Functional Index (FSFI) questionnaire⁶.

167 Immediately after childbirth (D0), midwives performed standardized examination of the
168 perineum to define the degree of perineal tear. A physician investigator confirmed the type
169 of tear and confirmed eligibility for randomization. A second oral consent was obtained.
170 Randomization was performed only after a confirmation of an isolated vaginal or first-degree
171 perineal tear during a spontaneous term, cephalic, vaginal delivery.

172 In the intervention group (the conservative management group), no suture and no digital
173 compression were performed in the absence of bleeding. If bleeding occurred, the physician
174 investigators or midwives performed a 5-minute digital compression to obtain satisfactory
175 hemostasis without suturing. If bleeding persisted, a suture was performed to obtain
176 appropriate hemostasis with simple interrupted stiches using fast absorbable thread
177 (OptimR 0 and 3/0). In the control group (the systematic suture group), the physician
178 investigators or midwives performed the suture according to the usual practices in the
179 obstetric care unit—i.e., suture with simple interrupted stiches using absorbable suture
180 thread (OptimR 0 and 3/0).

181 During the 3-day postpartum period, the midwives assessed each morning for analgesic
182 consumption and perineal pain (Table 1). Pain was assessed using a visual analog scale (VAS)
183 presented horizontally to participants⁷. On the third postpartum day (D3), when leaving the
184 maternity ward, an assessment of perineal pain (VAS score), pain medication consumption
185 and perineal healing was performed. Postpartum healing of the perineum was evaluated
186 using the REEDA (Redness, Edema, Ecchymosis, Discharge and Approximation of skin
187 reparation) scale. A score of 0 to 3 was assigned to the five following components: redness,
188 edema, bruising, oozing, and appreciation of tear healing⁸ (Appendix 1). An appointment
189 was set for the tenth (D10) postpartum day (+/- 1 day) with one of the doctor investigators,
190 and a self-monitoring logbook was provided, enabling us to record medication consumption

191 and pain scores (VAS score). At D10, the investigator performed a clinical examination to
192 assess the progression of perineal healing using the REEDA scale, identified complications if
193 any, and evaluated the intensity of perineal pain using the VAS score.

194 The final follow-up visit occurred two months (\pm 2 weeks) after delivery, coinciding with the
195 systematic postnatal visit. During this consultation, the practitioner collected information on
196 the resumption of sexual intercourse as well as an assessment of perineal pain (VAS score)
197 and healing quality (REEDA scale). A postnatal FSFI questionnaire was given to the patient
198 for a new self-evaluation during this appointment, as well as for use at six months
199 postpartum.

200

201 **Data collection**

202 The data collected included maternal medical and obstetric history, maternal demographic
203 and clinical characteristics, details about delivery and perineal tearing, intervention
204 procedures, and maternal perceptions at 3 days, 10 days, and 2 months after childbirth.

205 Data collection was performed in a standardized manner with a paper case report form
206 (CRF). Next, the data were recorded in an electronic research database (CleanWEB[®]). An
207 outpatient follow-up booklet recorded pain, any medication taken (analgesic), and
208 notification of any consultations with a practitioner (gynecologist, midwife, general
209 practitioner) for two months.

210

211 **Outcomes**

212 The primary outcome was the success of the intervention 10 days after delivery defined as
213 pain evaluated by VAS $<$ 3, satisfactory healing defined as a REEDA score \leq 2 (and at each sub
214 score), and no bleeding or infection.

215

216 Secondary outcomes included:

217 - Success of the intervention on the third postpartum day with satisfactory wound healing
218 defined as a REEDA score ≤ 2 , perineal pain with VAS score < 5 , and no local complication
219 (bleeding or infection).

220 - Success of the intervention in the second month postpartum defined as the absence of
221 perineal pain (VAS equal to 0) and resumption of sexual intercourse without dyspareunia
222 (FSFI questionnaire).

223 - Sexual well-being (FSFI questionnaire) at six months postpartum

224 - Consumption of analgesics on the third day and second month postpartum

225 - Need for medical care during the first two months postpartum

226 We performed a per-protocol analysis to examine our results for consistency after removing
227 protocol violations that may have confounded our results.

228

229 **Sample size**

230 No former study has assessed the success rate of systematic suturing. Therefore, we
231 arbitrarily decided, according to our professional experience, a success percentage below
232 which conservative management would be rejected as 80% and a success percentage of
233 efficacy of 92%. With a power of 80% and an alpha risk of 5%, 56 women were included in
234 the experimental arm in two stages: a first stage with 22 women and a second stage with 34
235 additional patients. The size of the reference group (systematic suture) was the same as that
236 of the experimental group (conservative management)—i.e., 56 patients. Therefore, the
237 total number required was 112 patients.

238

239 **Statistical analysis**

240 The study was planned as an efficacy trial to assess the primary outcome. To verify the
241 absence of perineal non-healing, complications, and pain in the arm where tears were not
242 systematically sutured, an interim analysis was planned before the trial began and
243 performed by the statisticians after the inclusion of 22 women in the conservative
244 management arm and after collection of follow-up information from D10. This analysis
245 focused on the efficacy and safety of conservative management, integrated at the same
246 time: pain assessment (VAS score <3), perineal healing (all REEDA sub scores ≤ 2), and no
247 bleeding or local infection at D3. Of the first 22 women in the conservative management
248 group, according to Simon's plan, the trial could be stopped for ineffectiveness if the number
249 of successes on D10 was ≤ 18 . If the preliminary results were effective, 34 additional women
250 were included in this study arm.

251

252 Participant and delivery characteristics were compared between the groups using
253 appropriate tests (*t* test, Wilcoxon rank sum test, χ^2 test, or Fisher exact test). The
254 proportions of success with conservative management were described using a 90%
255 confidence interval. The calculation of the confidence interval considered the sequential
256 nature of the design. The individual components of the primary and secondary outcomes
257 were compared using X^2 and Fisher exact tests. Bonferroni corrections were performed for
258 multiple comparisons. Statistical analyses were performed using SAS® for Windows version
259 9.4.

260

261

262 **RESULTS**

263 **Recruitment**

264 During the inclusion period, we performed 2,209 antenatal visits at our center with women
265 between 32⁺⁰ and 36⁺⁶ weeks of gestation (Figure 1). In total, 861 women (39%) met the
266 eligibility criteria, and initial participation consent was obtained for 569 women (66%). After
267 exclusion, 143 women were randomized to the delivery room, with an inclusion rate of
268 143/170 (84.1%). Overall, 72 patients were allocated to systematic suture, and 71 were
269 allocated to conservative management. For both groups, the initial maternal and neonatal
270 characteristics were comparable (Table 2). A disparity in the distribution of perineal tears
271 between the groups was notable ($p=0.02$). In the systematic suture group, 28 women
272 (38.89%) and 44 women (61.11%) had a first-degree perineal tear and an isolated vaginal
273 tear, respectively. In the conservative management group, 15 women (21.13%) and 56
274 women (78.87%) had a first-degree perineal tear and an isolated vaginal tear, respectively.
275 Overall, 27/143 (18.8%) women were lost to follow-up on the 10th day postpartum: 17 in the
276 systematic suture group and 10 in the conservative management group. Outcomes were
277 compared between the two groups using a per-protocol analysis: 72 (at first and third day
278 follow-up) and 55 patients (at 10th day follow-up) in the systematic suture group and 71 (at
279 first and third day follow-up) and 61 patients (at 10th day follow-up) in the conservative
280 management group. In this last group, 5 (7%) women had no digital compression and no
281 suture, 33 (46.5%) women had digital compression without suture, and 33 (46.5%) women
282 had sutures because of the ineffectiveness of digital compression.

283

284 **Results of the interim analysis**

285 Among the 22 women examined on the 10th day postpartum, the success rate at D3 in the
286 conservative management group was 95.45% (n=21). The interim analysis showed that the
287 success rate was higher than 80%. Therefore, the study continued to reach 56 patients in
288 each group.

289

290 **Primary outcome of the final analysis**

291 The success rate at D10 was 87.8% (90% CI: [70.5-93.54] (42/55)) in the systematic suture
292 group versus 90% (90% CI: [78.3-93.8] (53/61)) in the conservative management group
293 (Table 3 and 4). Pain at D10 was similar in both groups. The REEDA score was significantly
294 higher in the systematic suture group (1.4 versus 0.9; p=0.036). A REEDA score >2 was
295 observed for 8 patients (14%) in the systematic suture group and 4 patients (6%) in the
296 conservative management group (p=0.2).

297

298 **Secondary outcomes of the final analysis**

299 Perineal pain was significantly higher at D1 in the systematic suture group (2.38 vs 1.69; p=
300 0.034). Beyond D3, D10 and M2, no significant difference was found in terms of pain.

301 The success rate at D3 was not significantly different between the two groups (65.28% vs
302 77.46%; p=NS). The success rate was higher at two months postpartum in the conservative
303 management group (35% vs 19%; p=NS). Thirty-seven of 42 women (88%) had an EVA = 0 at
304 two months postpartum in the conservative management strategy group.

305 Pain medications were first-level analgesics. No difference was found in their use at D3 (15%
306 vs 14%; p=NS), at D10 (4% vs 3%; p=NS) or at two months postpartum (0% in both groups)
307 between the two groups. No atypical healing progress, infection, or persistent bleeding
308 requiring a medical consultation occurred in either group.

309

310 FSFI questionnaires were completed for 106 women at inclusion and 82 (57%) at inclusion
311 and 2 months postpartum (39 in the systematic suture group and 43 in the conservative
312 management group). No significant difference was found between the two groups at
313 inclusion or 2 and 6 months postpartum. At inclusion, the total FSFI score was 23.52 (\pm 9.19)
314 in the conservative management group and 22.35 (\pm 8.43) in the systematic suture group.

315

316 At 2 months postpartum, 73 women had resumed sexual intercourse: 35 (64%) and 38 (66%)
317 women in the systematic suture and conservative management groups, respectively.
318 Concerning dyspareunia at 2 months postpartum, 11 of 31 women (35%) in the conservative
319 management group versus 6 of 32 women (19%) in the systematic suture group had almost
320 never or never experienced dyspareunia on penetration ($p=$ NS). By contrast, 10 of 32
321 women (31%) in the systematic suture group versus 3 of 31 women (10%) in the
322 conservative management group had almost always or always experienced dyspareunia
323 during penetration ($p=$ NS). Four patients (12%) in the systematic suture group versus none
324 in the conservative management group had almost always or always experienced
325 dyspareunia after penetration ($p=$ 0.113).

326 At 6 months postpartum, 97% of women in each group had sexual intercourse: 38/39
327 women in the systematic suturing group and 34/35 women in the conservative management
328 group.

329

330 **DISCUSSION**

331 With a success rate of 90% at the 10th-day follow-up, we demonstrated that conservative
332 management of superficial perineal tears after delivery was safe and efficient. Women from

333 the conservative management group had lower pain at the first-day follow-up and lower
334 REEDA scores at the 10th-day follow-up. Adverse events were not higher with conservative
335 management than with systematic suture. Whether or not the perineal tear was sutured, no
336 local bleeding or infection events were observed at follow-up.

337

338 In our study, the success rates of intervention were similar in both groups at 10 days
339 postpartum (pain evaluated by VAS < 3, satisfactory healing defined by a REEDA score \leq 2
340 (and at each sub score), and no bleeding or infection), suggesting that conservative
341 management could be a safe option for managing superficial perineal tears. Interestingly,
342 the REEDA score and edema were significantly higher in the systematic suture group at D10.
343 Lower REEDA scores were found in the conservative management group at two months.
344 These results contrast with those of Lundquist et al.² and Fleming et al. (SUNS trial)⁴.
345 Lundquist et al. recruited and randomized 80 women with minor perineal tears (grade I-II)
346 into two groups: non-suture versus systematic suture. They concluded there were no
347 significant differences in the healing process in the early postpartum period up to day three².
348 The SUNS trial examined the differences in outcomes between primiparous women (n=74)
349 with and without sutures for first- or second-degree tears during spontaneous vaginal birth⁴.
350 They reported significantly faster healing associated with better approximation of the
351 wound in the suture group at day ten. However, we noted the lack of measurement
352 standardization for healing in Lundquist et al., while Fleming et al. also used the REEDA
353 score. The inclusion of perineal muscle tears in these studies makes interpretation of the
354 results more complicated.

355 Perineal pain evaluated using the visual analog scale was significantly higher at day one in
356 the systematic suture group. However, no significant difference was found in terms of pain

357 evaluation beyond D3, D10 and M2. This difference at day one could be explained by the
358 lack of blindness and the patient's satisfaction at not having been sutured. This bias could
359 have faded over time, explaining why a significant difference was not found later in the
360 study. This possibility is consistent with the finding of no significant difference in the use of
361 analgesic medication between the groups. In the SUNS trial, Fleming et al. also found no
362 significant difference in pain between the groups⁴.

363 At six months postpartum, 97% of women in each group had sexual intercourse. In our
364 study, 31% of women (n =10) in the systematic suture group had dyspareunia during
365 penetration compared with 10% (n=3) in the conservative management group (p=NS).
366 Lundquist et al. found similar results: 18% in the suture group versus 8% in the non-suture
367 group².

368

369 Superficial perineal tears are frequent (more than 50% of primiparous women). After the
370 exclusion of noneligible women after delivery, the randomization rate for our study was
371 84.1% (143/170). In the SUNS trial, only 74 of 1,314 eligible (6%) women were randomized.
372 The main reason given for this low randomization rate was nonadherence by the midwives'
373 team to the study protocol. Our high randomization rate can be explained by our using
374 several training sessions and our regular involvement of our team members in research
375 protocols evaluating the prevention of perineal tears with restrictive use of episiotomy and
376 careful delivery of shoulders with active delivery of the anterior arm using Couder's
377 maneuver^{9,10}.

378 Our study showed a higher REEDA score and edema in the systematic suture group at day 10
379 and a lower REEDA score in the conservative management group at two months
380 postpartum. These results align with our hypothesis that less reactional edema occurs in the

381 absence of sutures. However, no difference was found in perineal pain or the consumption
382 of analgesics after day one. Women reported less dyspareunia at two months postpartum in
383 the conservative management group.

384 For ethical reasons, we chose not to include second-degree perineal tears in our research
385 protocol because the existing literature concerning the prognosis for more extensive tears
386 are contradictory. The degree of morbidity after muscular tears could directly influence
387 urinary and anorectal functions.

388

389 Our study is limited by a lack of blindness to the treatment assignment of patients and the
390 clinical staff that assessed the pain, REEDA scores, and FSFI questionnaire. However, blinding
391 was not possible because the allocated interventions could easily be observed. Despite
392 randomization, isolated vaginal tears were higher and first-degree perineal tears were lower
393 in the conservative management group. Nineteen percent of women were lost to follow-up
394 because the 30-day examination was unusual and considered a burden by women. However,
395 the choice of this postnatal visit seemed essential to carefully monitor healing within a
396 reasonable timeframe and to identify possible complications of each intervention. Its
397 monocentric nature and our policy of the restrictive use of episiotomy limit the external
398 validity of our results. Because of a double examination of the perineal tear by the
399 midwife/doctor pair, we believe that we have limited misidentification of tear degree. Long-
400 term follow-up concerning incontinency and psychological well-being is missing. Finally, a
401 lack of power likely caused the failure to detect meaningful differences between the two
402 groups.

403 The implementation of our protocol in a single center limits the external validity of the
404 results, which must be confirmed in a larger, multicenter trial. We did not include long-term

405 follow-up, including urinary and fecal incontinences and psychological well-being. Additional
406 studies are required to confirm that digital compression without suturing can be used safely
407 in maternity wards.

408 This study is currently the largest trial evaluating the efficacy and safety of conservative
409 management compared to systematic suture in cases of superficial perineal tears following
410 spontaneous vaginal delivery. Women easily adhered to the study concept. More than 2,220
411 pregnant women were screened, and only 5% declined to participate (n= 107) during
412 screening. One percent (n=8) of women declined to participate in the study after delivery.
413 The number of women included was calculated before the beginning of recruitment (112
414 patients), and the Simon 2-step plan minimized ineffective interventions. The follow-up was
415 long enough, allowing us to have sufficient hindsight and robust results.

416

417

418 **Conclusion**

419 Although systematic suturing remains our usual technique to manage superficial perineal
420 tears, this study suggests that conservative management according to the quality of
421 hemostasis could be a safe and efficient option. Superficial perineal tears may heal
422 spontaneously without affecting the quality and resumption of sexual intercourse. Women
423 often welcome the option of not suturing. We showed that the success of digital
424 compression without suturing is sufficient ($\geq 90\%$) to continue investigation in a controlled
425 randomized multicenter phase 3 study.

426

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460 **Figure Legends:**

461 **Figure 1.** Flow chart

462 n: number of cases, D10: 10th day postpartum, REEDA: Redness, Edema, Ecchymosis,

463 Discharge and Approximation of skin reparation; VAS: Visual Analogic scale; FSFI: Female

464 Sexual Functional Index

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