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Laparoscopic sacrocolpopexy (LSCP) using an ultra-lightweight polypropylene mesh[☆]

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ABSTRACT

Objectives: Since 2005 the preferred method for surgical treatment of vaginal vault prolapse within the department has been laparoscopic sacrocolpopexy with an ultra-lightweight polypropylene mesh. The study aimed to explore the functional and anatomical outcomes and mesh adverse events of women following this procedure.

Study design: All women who had a Laparoscopic Sacrocolpopexy (LSCP) using an ultra-lightweight (19 g/m²) polypropylene mesh in two units in the North West of England between March 2005 and January 2013 (*n* = 238) were invited to participate in the study.

Functional outcome data was collected using the Patient Global Impression Questionnaire (PGI-I), the Pelvic Floor Distress Inventory (PFDI-20) and the Electronic Personal Assessment Questionnaire (EPAQ) post-operatively. Anatomical outcome was assessed by Pelvic Organ Prolapse Quantification System (POP-Q) measurement. A mesh palpability assessment was performed and any mesh complications were recorded using the International Continence Society/International Urogynecology Association (ICS/IUGA) classification system. The results were compared to those in our previously published series using the same surgical technique but a standard weight mesh (82.5 g/m²).

Results: 89% of participants reported that they felt their post-operative condition had improved. POP-Q results revealed that the median position of C changed from -3 pre-op to -7 post-operatively. Mesh was palpable during vaginal examination in only 3 women (3%). No mesh extrusion was identified during the study.

Conclusions: The study demonstrates that LSCP performed with an ultra-lightweight polypropylene mesh improves women's functional and anatomical symptoms and appears to have a low risk of mesh extrusion.

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Introduction

Abdominal sacrocolpopexy has been shown to be an effective treatment for pelvic organ prolapse. However, in a 7 year follow-up study of over 200 cases, failure rates increased with time and the

overall risk of mesh extrusion was 10.5% [1]. The laparoscopic approach to sacrocolpopexy has also been shown to be effective in terms of anatomical and functional success at long term follow-up and mesh extrusion was seen in 6% cases [2]. Mesh complications can vary from a small thread of mesh protruding through the vaginal epithelium to infection of the whole mesh, requiring complete removal. Increasing concern about the problem of mesh extrusion and exposure has led to the development of meshes with a different structure and weight. However there is no evidence to determine whether the reduction in density has an impact on efficacy or risk of extrusion.

Materials and methods

This study is a retrospective review of the outcome of a consecutive series of women treated with a laparoscopic

Abbreviations: LSCP, laparoscopic sacrocolpopexy; PGI-I, Patient Global Impression Questionnaire; PFDI-20, Pelvic Floor Distress Inventory; EPAQ, Electronic Personal Assessment Questionnaire; POP-Q, Pelvic Organ Prolapse Quantification System; ICS/IUGA, International Continence Society/International Urogynecology Association.

[☆] The preliminary findings of this study were presented as a poster at The 34th Annual Scientific Meeting of The American Urogynecology Society (AUGS), Las Vegas, Nevada, October 16–19, 2013.

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sacrocolpopexy (LSCP) since 2005 using the same techniques we published in a previous study [2], but employing an ultra-lightweight polypropylene mesh (Restorelle[®], Coloplast A/S, Denmark, acquired from Mpathy Medical Devices in 2010). The objectives of the study were to explore the functional and anatomical outcomes of women following LSCP using an ultra-lightweight polypropylene mesh including subjective and objective recurrence of prolapse and mesh adverse events.

Restorelle is a Type I monofilament polypropylene mesh with a density of 19 g/m [3]. It is therefore considered an ultra-lightweight mesh [4]. Restorelle has been used exclusively at our institution for LSCP since 2005. Prior to this Prolene[®] (Ethicon, Johnson & Johnson Medical Limited, USA) was used, which is classified as a Standard mesh, with a density of 82.5 g/m² [5].

LSCP has been the preferred method for surgical treatment of vaginal vault prolapse in the department since 1993. Patients are not excluded on account of obesity or previous surgery (unless complicated) and several patients have had a previous open sacrocolpopexy.

The cohort included all women who underwent LSCP using Restorelle mesh at either St Mary's Hospital, Central Manchester University Hospitals NHS Foundation Trust, Manchester ($n = 189$) or BMI The Alexandra Hospital, Manchester ($n = 49$) between March 2005 and January 2013. These women were subsequently invited to attend a follow-up examination and complete a number of self-report questionnaires between August 2012 and August 2013.

Women willing to participate were invited to attend an appointment during which a pelvic examination was performed to assess vaginal support using the POPQ assessment and mesh palpability. The pelvic examination was performed by a member of the research team rather than a member of the surgical team who had performed the LSCP in an attempt to reduce the potential for information bias.

The women were asked to complete the following questionnaires; the Patient Global Impression of Improvement questionnaire for urogenital prolapse (PGI-I)-a validated questionnaire which asks the participant to describe how their post-operative condition is now compared with prior to their surgery; The Electronic Personal Assessment Questionnaire (EPAQ)-a validated patient-focused symptom and quality of life questionnaire exploring the frequency, severity and impact of symptoms related to bladder, bowel, vaginal and sexual domains; The Pelvic Floor Distress Inventory (PFDI-20)-a validated questionnaire in which the participant is asked to consider bowel, bladder and pelvic symptoms over the past 3 months and if present to report how bothersome the symptom is for them.

Women unable or unwilling to attend a follow-up appointment were invited to complete the study questionnaires at home and give written permission for the study team to collect relevant data from their medical records. 7 patients had died since surgery, 6 of these deaths were unrelated to the procedure, therefore approval was obtained to allow access to the deceased patients' medical records wherever possible.

The surgical technique used Restorelle as a flat mesh which was attached to the posterior and anterior surface of the vagina. It is sutured to the vagina with 6–12 vicryl sutures and secured to the anterior aspect of the 5th lumbar vertebrae with titanium helical screws.

Results

231 women were identified; however 75 women declined to participate or failed to respond, leaving the remaining sample of

156 women. 101 women (65%) attended a follow-up appointment and 147 (94%) completed study questionnaires. Median follow-up time was 34 months post-operatively (range 1–94 months). 25 (16%) study participants had their surgery more than 5 years prior to follow-up. At the time of surgery the mean age was 61 (range: 38–85 SD: 10.3), mean BMI was 27 (range: 19–38 SD: 3.9) and the median parity was 2 (range 0–7). 87 (58%) of the sample had previously had a laparotomy. The number of participants with comorbidities at the time of surgery was low with 6 (4%) having diabetes, 19 (13%) receiving cardiovascular treatment (primarily for hypertension) and 2 (1%) receiving long-term anti-coagulation therapy.

28 (18%) of the women had a history of previous vault support surgery. All women presented with vault prolapse; none of the LCSP were performed at the same time as hysterectomy. The route of previous hysterectomy was evenly distributed between the women, with 77 (51%) having had an abdominal hysterectomy and 75 (49%) a vaginal hysterectomy. The number of previous prolapse operations amongst the sample ranged between 0–5 (median = 1 SD: 0.9). Further details of participants' history of prolapse surgery are documented within Table 1.

Adverse events during or immediately following surgery are detailed in Table 2. There was one death 16 days following surgery due to port site hernia complications (patient included within bowel injury data).

Global outcome

147 women completed the PGI-I; 75% of participants reported that they felt their post-operative condition was "very much better" or "much better". 7% reported that their condition was now "worse". The patients who felt that their post-operative condition had worsened ranged between 1–57 months post-operatively (Median: 28 SD: 17.1). Further analysis of the anatomical outcome of the 10 women who felt that their post-operative condition had worsened, revealed that of the 7 who had been re-examined as part of the study, only one woman (14%) had a failure of apical support (defined as stage 2 or more) with point C at +5 (Stage 3). This same degree of recurrent apical prolapse was also

Table 1
Previous gynaecological surgery.

	n=	%
LSCP	6	4%
Open SCP	9	6%
SSF	13	8%
Vaginal repair	90	58%
TVT	6	4%
TOT	5	3.2%
Colposuspension	14	9%
Abdominal hysterectomy	77	50%
Vaginal hysterectomy	75	49%

Table 2
Adverse Events.

Adverse event	n =	Percentage
Bladder injury	2	1.3%
Ureter injury	1	0.6%
Vaginal injury	2	1.3%
Rectal injury	1	0.6%
Bowel injury	2	1.3%
Blood transfusion	2	1.3%
Death	1	0.6%

noted at the woman's routine 6 month post-operative follow-up appointment 51 months previously. Of the remaining women who felt that their condition had deteriorated, 71% ($n=5$) had an apical stage of 0 and 14% ($n=1$) an apical stage of 1. When comparing pre and post-operative EPAQ scores for this group of women, an improvement was seen in the mean scores for bladder, bowel, vaginal and sexual symptoms.

Anatomical outcome

As detailed in Table 3, the median position of C changed from -3 pre-op (IQR = -4 to 1) to -7 post-operatively (IQR = -8 to -6). Similar improvements were noted in the other points. 2 women (2%) had a failure of apical support, both being beyond the hymen.

Functional outcome

It is acknowledged that a patient's functional outcome may be affected by concomitant surgery, which was performed

Table 3
- Comparison of Pre and Post Surgery POPQ.

	Pre POPQ C	Post POPQ C
$n=$	132	100
Range	-6 to $+10$	-12 to $+8$
Median	-3	-7
Stdev	4	2.5
	Pre POPQ Aa	Post POPQ Aa
$n=$	128	100
Range	-1 to $+3$	-3 to $+3$
Median	0	-2
Stdev	1.9	1.6
	Pre POPQ Ba	Post POPQ Ba
$n=$	128	100
Range	-3 to $+10$	-3 to $+4$
Median	$+1$	-2
Stdev	3	1.7
	Pre POPQ Ap	Post POPQ Ap
$n=$	127	100
Range	-3 to $+3$	-3 to $+3$
Median	-1	-2
Stdev	2.1	1.6
	Pre POPQ Bp	Post POPQ Bp
$n=$	127	100
Range	-3 to $+10$	-3 to $+3$
Median	0	-1
Stdev	3	1.4
	Pre POPQ GH	Post POPQ GH
$n=$	73	100
Range	2–8	2–7
Median	5	4
Stdev	1.1	0.8
	Pre POPQ PB	Post POPQ PB
$n=$	73	100
Range	2–7	3–6
Median	4	4
Stdev	0.9	0.6
	Pre POPQ TVL	Post POPQ TVL
$n=$	86	100
Range	5–11	6–13
Median	8	8
Stdev	1.3	1.2

for 4.6% ($n=8$) of participants. The most frequent concomitant surgery was rectopexy in 5 women (3%), followed by TVT in 2 women (1%) and laparoscopic colposuspension for 1 women (0.6%).

Data from EPAQ was analysed to assess functional outcome post. EPAQ provides scores from 0 to 100 with higher scores representing more severe symptoms. Therefore a patient reporting an improvement in symptoms would have a lower symptom score post-operatively. Persistent bowel and bladder symptoms following LSCP were reported as detailed in Table 4. Bowel symptoms were both the most prevalent and bothersome symptoms at follow-up. Despite experiencing on-going symptoms, the prevalence and bothersomeness of both bowel and bladder symptoms had significantly improved following surgery.

Responses to EPAQ questions within the vaginal domain demonstrated a significant improvement in prolapse symptoms reported post-operatively as detailed in Table 4. 76 (76%) of participants reported no awareness of vaginal bulge at study follow up. Women's perception of sexual function improved from a mean of 42 pre-operatively to 25 post-operatively. However the percentage of women reporting that they were sexually active did not change pre (53% $n=31$) and post-operatively (52% $n=60$).

Mesh extrusion

No mesh complications were identified during the course of the study. However, one patient required a posterior vaginal repair 12 months post LSCP which was performed without mesh. When this patient was seen as part of the research study, 28 months following LSCP, there was no evidence of mesh extrusion. However, 12 months later the patient was diagnosed with upper posterior vaginal wall extrusion of mesh requiring surgical management. The mesh extrusion was noted along the path of the posterior repair wound.

Mesh palpability

It had been noted that mesh was palpable in many of the women examined vaginally after LSCP with standard weight mesh. In this study mesh palpability was assessed using a non-validated palpability assessment (Appendix A). Mesh was palpable during examination in only 3 women (3%). The palpable mesh was identified in the three cases during study participation at 19, 21 and 34 months post-operatively. Since the examination was only performed on one occasion in each case, it is not known whether this is a progressive phenomenon. All three women reported dyspareunia when completing study questionnaires but had no other symptoms. When their medical records were reviewed it was noted that all three women reported dyspareunia pre-operatively, with one woman's dyspareunia worsening since her surgery. No further treatment was requested for any of the women with palpable mesh. Dyspareunia was also an issue for women who did not have palpable mesh. 54% ($n=47$) reported this as a symptom post-operatively. When comparing dyspareunia pre and post operatively, 6.5% ($n=2$) of participants experienced de novo dyspareunia, mesh was not palpable upon examination for either patient.

Anatomical and functional outcome and mesh extrusion over time

All patients were invited to participate regardless of the period of time since surgery. The outcomes have been divided between short-term (less than 12 months since surgery), medium-term (12 months to 5 years since surgery) and long-term (more than 5 years since surgery) Table 5.

Table 4

-Comparison of Pre and Post Surgery Functional Outcome.

	Pre Urinary Quality of Life	Post Urinary Quality of Life	Significance
<i>n</i> =	77	72	
Symptomatic patients <i>n</i> =	66	35	
Percentage of symptomatic patients	86%	49%	<i>p</i> = .01
Mean	37.7	16.5	
Stdev	28.1	25.6	
	Pre Bowel Quality of Life	Post Bowel Quality of Life	Significance
<i>n</i> =	72	71	
Symptomatic patients <i>n</i> =	38	35	
Percentage of symptomatic patients	53%	49%	<i>p</i> = .01
Mean	18.5	13.1	
Stdev	24.1	21.3	
	Pre Vaginal Quality of Life	Post Vaginal Quality of Life	Significance
<i>n</i> =	73	132	
Symptomatic patients <i>n</i> =	72	29	
Percentage of symptomatic patients	99%	22%	<i>p</i> = .01
Mean	50.3	10.2	
Stdev	32.9	19.6	

Table 5

-Study outcomes for short, medium and long-term follow-up participants.

	PFDI20 <1 year	PFDI20 1 year-5 year	PFDI20 >5years
<i>n</i> =	16	102	25
Mean	16.5	22	24.1
Stdev	19.7	5.5	20.2
	PGI <1 year	PGI 1 year-5 year	PGI >5years
<i>n</i> =	16	101	25
Mean	1.8	2	1.7
Stdev	1.3	1.6	0.7
	POPQ C <1 year	POPQ C 1 year-5 year	POPQ C >5years
<i>n</i> =	11	69	16
Median	-8	-7	-7
IQR	-8.5 to -7	-8 to -6	-7.5 to -6.5
	Mesh palpability <1 year	Mesh palpability 1 year-5 year	Mesh palpability >5years
<i>n</i> =	11	70	16
Palpable mesh	0	3	0
%	0	4%	0%

Patients in the long term follow-up group had higher PFDI scores than those in the shortest follow-up group. The global impression of improvement did not differ between groups of different follow-up length.

The median position of the POPQ measurement 'C' was similar at all time periods demonstrating the durability of anatomical outcome. The likelihood of mesh palpability does not appear to increase over time with all 3 cases being reported in the medium-term follow-up group.

Comment

This is the first study to report a cohort of patients undergoing LSCP using an ultra-light weight polypropylene mesh 19 g/m². The study has demonstrated good, durable anatomical and patient reported outcomes.

The reason for using a lighter weight mesh is the theoretical reduction in mesh extrusion and dyspareunia. Brown et al and

Liang et al demonstrated that this ultra-lightweight mesh (19 g/m²) generated a reduced inflammatory response and better tissue remodelling when compared to other meshes [5,6]. The outcomes in this current study can be compared to a previous published cohort from the same institution [2], using a heavier polypropylene mesh (Ethicon, Johnson & Johnson Medical Limited, USA) with a density of 82.5 g/m². Whilst it is acknowledged that there are limitations when making comparisons between two cohorts, at different times, the surgical technique of LSCP has not changed significantly over the time period and the study population is a comparable group of patients; the only significant change at our institution has been the use of the new ultra-lightweight mesh. A comparison of the two cohorts, in Table 6, suggests that use of an ultra-lightweight mesh does not appear to have any negative effect on the vaginal support. There appears to be a lower incidence of mesh extrusion with the ultra-lightweight mesh, although the 2005 study had a longer follow-up interval. The median follow-up in the 2005 cohort was 66 months compared to 28 months for the

Table 6

Comparison of study outcome data with 2005 study [2].

After surgery	2005 [2]	Current study
Failure of apical support	8%	2%
Awareness of a lump/bulge	38%	24%
Urinary symptoms improved	28%	63%
Urinary symptoms no change	49%	26%
Urinary symptoms worsened	23%	11%
Bowel symptoms improved	44%	34%
Bowel symptoms no change	48%	47%
Bowel symptoms worsened	8%	18%

current cohort. The only mesh extrusion within the ultra-lightweight mesh cohort was in a woman who had a posterior repair 12 months following LSCP; it is possible that opening the posterior vaginal wall during this procedure may have increased the potential for mesh extrusion particularly since the extrusion occurred along the posterior repair wound. It is reported in the literature that when hysterectomy is performed concomitantly with LSCP the risk of mesh extrusion increases significantly [7]. Possible explanations for this include devascularisation of the vaginal cuff and bacterial infection [7]. In the department's previous experience, mesh extrusion has developed up to 8 years after surgery. It is not known whether this is related to the mesh type. The current cohort only contained 25 women who had undergone surgery more than 5 years earlier. Future research exploring the long-term outcome of LSCP performed with Restorelle mesh in a large cohort of women who are more than 5 years post-surgery is required to answer this question.

Ten women (7%) perceived that their condition had worsened post-operatively despite only one of these women having anatomical prolapse and an overall improvement in all EPAQ scores. Due to the long-term nature of the study, this may reflect participant reporting of new symptoms which have occurred since surgery but are not related to the LSCP. However, data from both studies (Table 6) demonstrates that many women experience persistent bowel and bladder symptoms following LSCP regardless of the mesh used and the support gained. Hence patients should be advised that although surgery may correct anatomical defects it is difficult to predict the functional outcome.

The use of different outcome measures between this and our earlier study prevents direct comparison of study findings. In 2005 participants were simply asked whether they had experienced an improvement, no change or a worsening of their bladder and bowel symptoms. Therefore although the findings facilitate some comparison between the studies, limitations with this comparison is acknowledged.

The percentage of women who were sexually active before and after surgery did not change which suggests that prolapse surgery and a subsequent improvement in prolapse symptoms, does not increase the likelihood that a woman will be sexually active. For many women there may be reasons other than prolapse which impact upon their sexual activity. The study evaluated sexual function using EPAQ. Within EPAQ dyspareunia is a collection of symptoms of discomfort and pain, such as vaginal dryness, lack of sensation, tightness and obstruction. Some women reported an improvement in dyspareunia but for over half of the sexually active women the problem persisted. Therefore although LSCP may improve sexual function for women whose cause of dyspareunia is obstruction due to prolapse, dyspareunia related to other issues may remain unchanged.

We hypothesised that mesh palpability would be associated with dyspareunia. However mesh was only palpable in three women, all of whom reported pre-operative dyspareunia with one lady's symptoms worsening following surgery. Dyspareunia was also an issue for over half of women who did not have palpable mesh, therefore the relationship between mesh palpability and dyspareunia is not clear.

It is possible that post-operative infections were under reported in this study as the incidence of these events was collected from hospital records. Reduced length of hospital stay means that minor post-operative complications are more likely to be reported after discharge from hospital.

It is possible that women who were least satisfied with their surgical outcome were less motivated to participate in the study. Conversely, those who were least satisfied with their surgical outcome may also have been increasingly motivated to participate in the study to access further treatment and assessment. The influence of selection bias amongst the sample is unknown.

It is acknowledged that the generalisability of the findings may be restricted as the sample is limited to women who had surgery performed by one group of surgeons.

This study demonstrates that LSCP performed with an ultra-lightweight polypropylene mesh improves patient's functional and anatomical outcome. The diagnosis of a single mesh extrusion within this patient cohort suggests that ultra-lightweight mesh is associated with a lower risk of a mesh extrusion than LSCP performed with heavier mesh. The use of the lighter mesh does not appear to reduce the strength of the support provided.

Conflict of interest

The authors declare that they have no conflict of interest.

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Ethical approval

This research study has been reviewed by the National Research Ethics Service Committee North West - Greater Manchester Central. Reference: 12/NW/0277.

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Contribution to authorship

All authors made substantial contributions to this study and article. LD, WK, KW, FR and ARBS participated in the design and/or execution of the study, the interpretation of the data, and the drafting and/or revision of the article. All authors approve this version to be published.

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Appendix A. Palpability Assessment

Palpability Rating (Not a Validated Rating Scale)	
Anterior Compartment	
4.1 Inside hymenal ring	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
4.1.1 Pain Assessment:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
4.2 4 cm from the introitus at midline	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
4.2.1 Pain Assessment:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
4.3 Apex	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
4.3.1 Pain Assessment:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
Posterior compartment	
4.4 Inside hymenal ring	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
4.4.1 Pain Assessment:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
4.5 4 cm from the introitus at midline	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
4.5.1 Pain Assessment:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10
4.6 Apex	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
4.6.1 Pain Assessment:	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10

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