Rijksinstituut voor Volksgezondheid
en Milieu
*Ministerie van Volksgezondheid,
Welzijn en Sport*

Bilthoven, 12-07-2011

Aan: [redacted]

Betreft: Addendum bij "Complications with pelvic floor repair systems – a literature review" dd june 2011.

Beste [redacted]

Zoals telefonisch afgesproken op 6 juli 2011, hebben we de literatuur die je ons hebt gestuurd bekeken:

- Zeven van de publicaties zijn retrospectieve studies (Alperin et al, 2008; Deffieux et al, 2007; Gagnon et al, 2010; Wetta et al,2009; Aungst et al, 2009; van Raalte et al, 2008; Margulies et al, 2008), en vallen daarmee buiten onze inclusiecriteria.
- Twee publicaties zijn op indirecte wijze opgenomen in onze literatuur review:
    - van Raalte et al, 2008 opgenomen in de publicatie van Feiner et al, 2008
    - Milani et al, 2005 opgenomen in de publicatie van Le et al, 2007.
- De overige vijf publicaties zijn prospectieve studies (Withagen et al, 2010; Altman et al, 2008; Ignjatovic et al, 2010; Milani et al, 2009; Lowman et al, 2008; Hinoul et al, 2008). Deze voldoen wel aan onze inclusiecriteria.

We hebben onderzocht wat de oorzaak is dat we bovengenoemde vijf prospectieve studies hebben gemist in onze eerdere searches. Uiteindelijk bleek dat we bij het zoeken op productnaam alleen hebben gezocht op de zoekterm 'Gynecare Prolift', de productnaam gespecificeerd door de fabrikant. We hebben niet gezocht op de separate term 'Prolift'. Alleen in dat laatste geval kwamen de publicaties die jij ons stuurde naar voren. We hebben hierop een aanvullende search gedaan met deze zoekterm.

De zoekterm Prolift (geen begin datum tot 31 mei 2011, Engels) leverde in Pubmed 42 publicaties op, waarvan:

- Elf retrospectieve studies[1-11].
- Zes case reports [12-17]
- Zes publicaties specifiek over de operatietechniek[18-23]
- Drie publicaties al opgenomen zijn in het RIVM literatuur review [24-26]
- Zestien prospectieve studies die niet eerder waren geïdentificeerd [27-42]

In tabel 1b is een overzicht opgenomen van de 16 extra prospectieve studies. Van een aantal studies kon niet meer op tijd het volledige artikel worden verkregen. Hiervan zijn gegevens op basis van het abstract opgenomen. Table 1b kan dus beschouwd worden als een aanvulling op tabel 1 in het eerder opgeleverde literatuur review.
De bevindingen van de zestien extra prospectieve studies hebben we naast de resultaten van het eerder opgeleverde literatuur review gelegd. De resultaten van de extra studies komen overeen met de bevindingen zoals beschreven in het eerder opgeleverde literatuur review.
Vermeldenswaardig zijn de volgende bevindingen:

- Additioneel zijn er drie prospectieve studies gevonden waarin het Prolift systeem is vergeleken met andere producten [29, 31, 32]. Uit deze studies blijkt er geen duidelijk verschil te zijn tussen de verschillende producten.
- Er zijn geen prospectieve studies gevonden van voor 2002.

Onze excuses voor de gang van zaken. Dank dat we via jouw opmerkzaamheid alsnog de aanvullende search hebben kunnen uitvoeren. Als je vragen hebt naar aanleiding van dit addendum, dan kun je vanzelfsprekend contact opnemen met één van ondergetekenden.

Met vriendelijke groet,

[redacted]
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Table 1b Overview post-operative complications in prospective studies

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Su et al, 2011[27]	None	71	Prolift, Ethicon	SUI	41%	12 months	Prevalence of SUI was not significant different before and after surgery (54% vs 41%)
				Recurrent prolapse	2.8%	?	
				Prolonged bladder drainage	5.6%	?	
				Transient urinary tract infection	1%	?	
				Mesh exposure	1%	?	
				Hematoma	1%	?	
				Pelvic infection	1%	?	
Long et al, 2011[29]	None	108	Perigee/ Apogee® (AMS, Inc., Minnetonka, MN, USA) (n= 60) or Prolift® (Ethicon, Inc., Piscataway, NJ, USA) (n = 48)	Urinary tract infection	11.7% (Perigee/Apogee®) 16.7% (Prolift®)	?	Chi-square and Fisher's exact test showed no significant differences between both devices in other intraoperative and postoperative comparison.
				Voiding dysfunction	3.3% (Perigee/Apogee®) 2.1% (Prolift®)	?	
				Perineal hematoma	0% (Perigee/Apogee®) 2.1% (Prolift®)	?	

Table 1b (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Long et al, 2011[29]	None	108	Perigee/ Apogee® (AMS, Inc., Minnetonka, MN, USA) (n= 60) or Prolift® (Ethicon, Inc., Piscataway, NJ, USA) (n = 48)	De novo worsened dyspareunia	16.7% (Perigee/Apogee®) 25% (Prolift®)	?	
				Mesh exposure	10.0% (Perigee/Apogee®) 16.7% (Prolift®)	Between 6 and 24 weeks	
Lowman et al, 2008[38]	None/unknown	129	Prolift	Dyspareunia	17%	12 months	Purpose of this study was to determine the de novo dyspareunia rate with the Prolift procedure
Ignjatovic et al, 2010 [32]	None	76	TVT/TOT* with colporrhaphy (n= 39) and Prolift (n =37)	De novo pelvic organ prolapse	20.6% (n = 6/29) (TVT/TOT) 7.4% (n= 2/27) (Prolift)	12 months	This work was supported by the grant from the Ministry of Science of Serbia
				Pelvic pressure	16.6% (n= 3/18) (TVT/TOT) 19% (n = 4/21) (Prolift)	12 months	
				Mesh exposure	10.8% (n = 4/37) (Prolift)	12 months	

*TVT= tension free vaginal tape, TOT = transobturator tape

Table 1b (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Ignjatovic et al, 2010 [32]	None	76	TVT/TOT* with colporrhaphy (n= 39) and Prolift (n =37)	Bladder emptying	27.2% (n = 3/11)(TVT/TOT) 21.4% (n = 3/14) (Prolift)	12 months	
				Rectal emptying	40% (n= 2/5) (TVT/TOT) 86% (n = 6/7) (Prolift)	12 months	
				Urgency	28.6% (n= 4/14) (TVT/TOT) 41.7% (n = 5/12) (Prolift)	12 months	
Altman et al, 2008 [42]	Yes	123	Prolift	Mesh exposure	1.6%	2 months	Advisor for Gynecare Scandinavia.
Milani et al, 2009 [35]	Yes	46	Prolift	Mesh exposure	15%	12 months	Sponsored educational activities for Gynecare Benelux
Abou-Elela et al, 2009 [37]	None/Unknown	20	Prolift and concomitant Tension-Free vaginal Tape-Obturator	Persistent asymptomatic Prolapse	10%	Mean 8 months	

Table 1b (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Withagen et al, 2010 [33]	Yes	150	Prolift	Postoperative hematoma	3%		Sponsored educational activities for Gynecare Benelux
				Temporary postoperative urinary retention	7%		Resolved within 11 days
				Mesh exposure	10%	4% after 6 months and 6% after 12- months	
				Novo dyspareunia	0.6%		
				Pain	0.6%		
Milani et al, 2011 [28]	Yes	127	Partially absorbable mesh	Mesh exposure	10.2%	12 months	Sponsored educational activities for Gynecare Benelux. Information collected from abstract of the publication.
				De novo dyspareunia	2%	12 months	
Lo et al, 2010 [30]	None/unknown	43	Gynecare Prolift Pelvic repair System, Ethicon	Mesh extrusion	2.3%	12 months	Information collected from abstract of the publication
				Asymptomatic recurrent prolapse rectocele	4.7%	12 months	

Table 1b (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Cornu et al, 2010 [31]	None/unknown	45	Prolift and TVT*-Secure (n= 4), TVT-Secure (n = 41	De novo overactive bladder	11%	Mean follow-up was 30.9 =/- 9.8 months	Information collected from abstract of the publication. In the abstract no distinguishes were made between complications in the two groups.
				Urinary tract infection	6.7%	Mean follow-up was 30.9 =/- 9.8 months	
Su et al, 2009 [34]	None/unknown	33	Prolift	Worsening sexual functioning	73%	After 6- months	Information collected from abstract of the publication
Rechberger et al, 2008 [36]	None/unknown	21	Total Prolift system	Recurrence of cystocoele	14.2%	12 months	Information collected from abstract of the publication
				SUI	9.5%	12 months	
				Overactive bladder	14.3%	12 months	
				Dyspareunia	30.8% (4/13)	12 months	
				Occasional but severe pelvic pain causing difficulty with walking and moving	14.3%	12 months	

*TVT= tension free vaginal tape

Table 1b (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Hinoul et al, 2008 [39]	None/unknown	48	Prolift	Mesh exposure	10.4%	?	Information collected from abstract of the publication
				Urgency symptoms persisted	14% (3/21)	?	
				De novo urgency	2.1%	?	
				De novo stress incontinence	13% (4/30)	?	
				De novo dyspareunia	15% (3/20)	?	
Pacque et al, 2008 [40]	None/unknown	30	Prolift	Mesh exposure	20%	?	Information collected from abstract of the publication
				Re-appearance prolapse	6.7%	At 6 months	Concomitant procedures were not significantly related to risk of erosion, but the erosion group was younger.
Ignjatovic et al, 2008 [41]	None/unknown	23	Prolift	none			Information collected from abstract of the publication. Correction of pelvic organ prolapse was achieved in 21 out of 23 (91.3%). Complete continence after the surgery in 20 out of 23 (86.9%). Significant improvement in voiding symptoms without deterioration of voiding function.

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