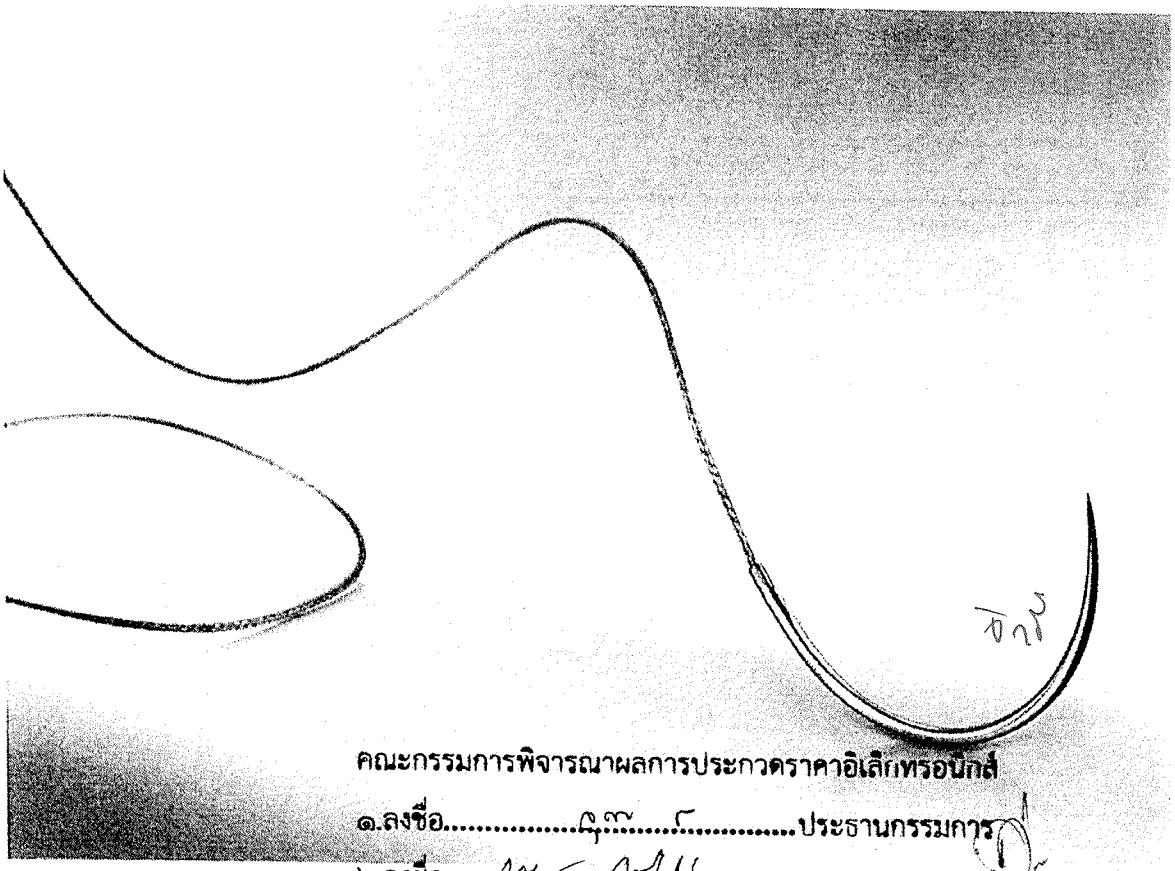
B BRAUN

NOVOSYN®

TECHNICAL FILE



คณะกรรมการพิจารณาผลการประกวดราคาอิเล็กทรอนิกส์

๑.ลงชื่อ.....ประธานกรรมการ

๒.ลงชื่อ.....กรรมการ

๓.ลงชื่อ.....กรรมการ

1 DESCRIPTION

Novosyn® is a sterile, absorbable surgical suture material produced from a copolymer composed of 90% glycolide and 10% L-lactide. Novosyn® is coloured violet with the colouring D&C Violet No. 2 (C. I. 60725) to make it recognizable, but is also available undyed in the natural beige colour. The braided threads are treated with an absorbable synthetic coating consisting of a mixture of equal parts of a copolymer consisting of glycolide and L-lactide and calcium stearate so that they slide easily without causing a sawing effect.

2 INDICATIONS

Novosyn® is indicated for soft tissue approximation and/or ligation in general surgery, when surgical practice requires the use of synthetic, absorbable, braided suture material.

Novosyn® sutures are also for use particularly in gynaecology and urology. Novosyn® is also indicated for ophthalmology and for microsurgery if an absorbable suture material is preferred.

3 CONTRA INDICATIONS

Novosyn® suture materials are contra-indicated for applications where prolonged support of the wound closure by the suture material is required.

The use of this suture is contraindicated on patients with known sensitivities or allergies to its components

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SHARING EXPERTISE

4 MATERIAL SPECIFICATIONS

Material: copolymer composed of 90% glycolide and 10% L-lactide (PGLA 90/10) . ← คุณลักษณะเฉพาะข้อ ๓.๑

Coating: Polyglactin 370 + calcium stearate. ← คุณลักษณะเฉพาะข้อ ๓.๒

Colour: Novosyn® is coloured violet with the colouring D&C Violet No. 2 (C. I. 60725) and also available undyed in the natural beige colour.

USP sizes: USP 8/0 (0,4 metric) to USP 2 (5 metric). ← คุณลักษณะเฉพาะข้อ ๓.๔

Tensile strength retention: 50% at 21 days, 75% at 14 days and 25% at 28 days. ← คุณลักษณะเฉพาะข้อ ๓.๕

Mass absorption: Hydrolysis, complete mass absorption in 56 till 70 days. ← คุณลักษณะเฉพาะข้อ ๓.๕

Sterilization: Ethylene oxide. ← คุณลักษณะเฉพาะข้อ ๓.๗

5 STORAGE / HANDLING / SHELF LIFE

Storage: Novosyn® does not require special storage conditions.

Shelf-Life: 5 years. ← ข้อกำหนดอื่นๆข้อ ๕.๑

Packaging: DDP (Direct Dispense Packaging), TD for Take-off combinations and RCP (RacePack®) ← คุณลักษณะเฉพาะข้อ ๓.๑๐

6 CERTIFICATIONS ← ข้อกำหนดอื่นๆข้อ ๕.๓

Novosyn® suture is CE marked according to Directive 93/42/EEC on Medical Devices (MDD) and it is classified as a class III product.

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B|BRAUN

7 LABELS / SYMBOLS

(1) NEEDLE CODE

(2) DESCRIPTION OF THE SUTURE

(3) PRODUCT NAME

(4) USP AND EP SIZE ← คุณลักษณะเฉพาะข้อ ๓.๙

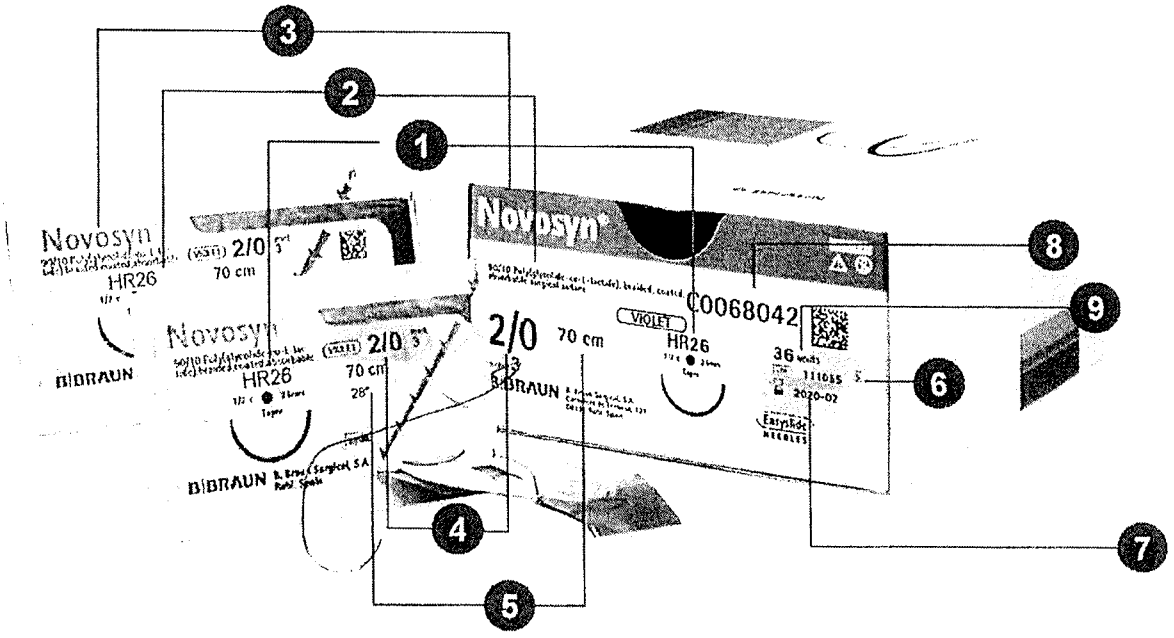
(5) LENGTH OF THE SUTURE

(6) BATCH CODE ← คุณลักษณะเฉพาะข้อ ๓.๘

(7) EXPIRY DATE (YEAR-MONTH-DAY) ← คุณลักษณะเฉพาะข้อ ๓.๘

(8) ARTICLE NUMBER

(9) NUMBER OF UNITS



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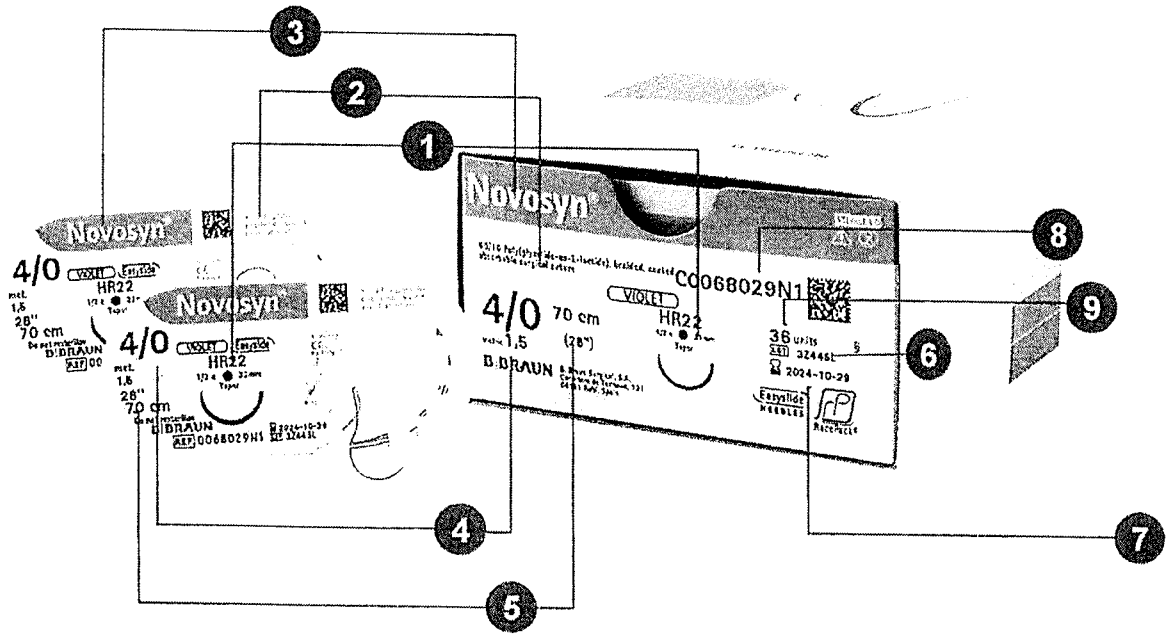

LOT / REF / STERILE EO

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Resorption (Absorption)

Resorption is still called «loss of mass».[11]
Once implanted, the suture material may either remain in the body or be broken down.
This difference in behaviour leads to sutures being classed under two categories: non-absorbable sutures and absorbable sutures.

- Non-absorbable sutures remain in the body permanently and offer long-term support; in the event of their being used superficially (on the skin or mucosa = e.g. episiotomy), they will have to be removed.
- Absorbable sutures disappear in the more or less long term; the degradation profile depends on the chemical composition of the threads.

  There are absorbable sutures for use short-term (approx. 50 days), medium-term (60 to 90 days), long-term (180 to 210 days) and extra-long-term (390 days).
- The mechanism of degradation varies according to the origin (see term) of the material from which the suture is made. Absorbable synthetic sutures are broken down by hydrolysis (see term), which guarantees homogeneous, regular, predictable degradation and creates physiological metabolites (products of degradation).B. Braun offers an extensive range of non-absorbable and absorbable sutures.

Steel

Steel is used for making surgical needles but also for making a certain type of sutures.
The needle (see term) is one of the main elements of a suture and must have certain properties in order to ensure optimum results both functionally and aesthetically.
B. Braun Medical focuses special attention on the design and manufacture of its needles, for the purpose of providing users with very high quality products.
All our «Easyslide» needles are made from a 300 stainless steel alloy, a unique material that gives them excellent torsional and breaking strength.
This way, their initial quality is maintained throughout the operation.
Moreover, our «Easyslide» needles are silicone-coated for greater precision and smoother tissue penetration.
Stainless steel is also the material used as the basis for certain sutures, such as our non-absorbable monofilament and multifilament steel suture. This robust, resistant suture is used specifically in orthopaedic and thoracic surgery for bone approximation (e.g. Steelex), or tendon repair (e.g Tendofil®)

คุณสมบัติเฉพาะข้อที่ ๓.๖

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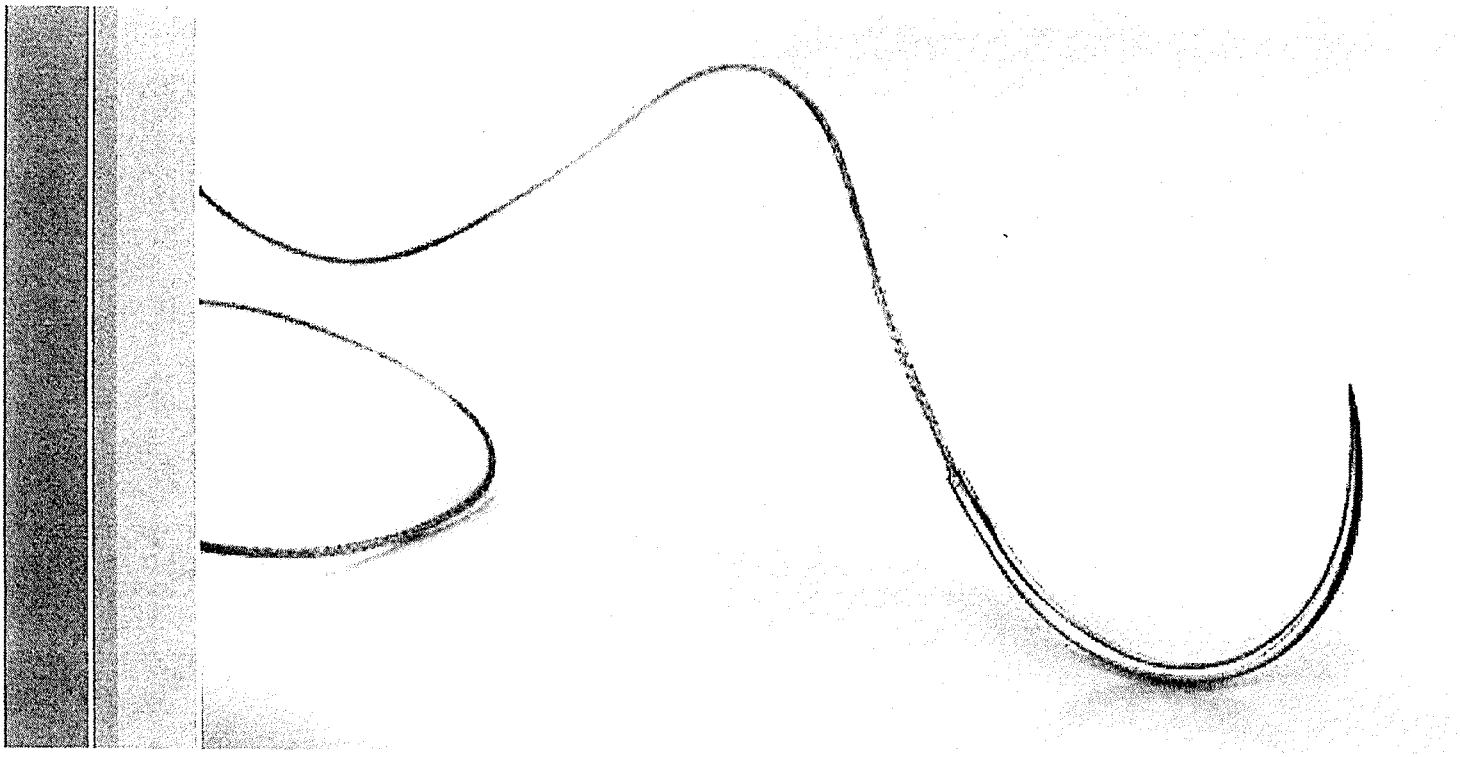
Novosyn®

Your alternative choice in PGLA suture

Mid-term synthetic absorbable braided and coated suture made of Polyglactin 910*



Sutures

* Novosyn® is a suture material produced from a copolymer composed of 90% glycolide and 10% L-lactide

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SHARING EXPERTISE

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Novosyn®

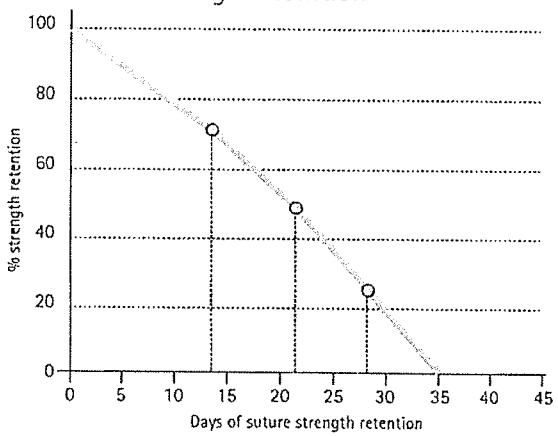
Your alternative choice in PGLA suture

Mid-term degradation profile

Novosyn*, your alternative choice that consists of braided Polyglactin 910 fibers.

The high initial tensile strength of the Polyglactin 910 sutures provides the needed critical wound support for an improved tissue healing.

In vivo strength retention*

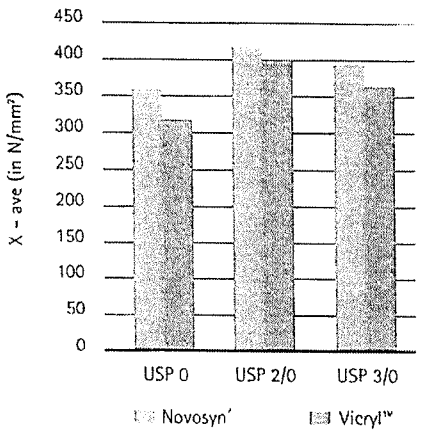


Novosyn* is a mid-term absorbable suture:

75% initial tensile strength	14 days
50% initial tensile strength	21 days
25% initial tensile strength	28 days
Complete mass absorption	56 – 70 days

** GLP Report_071024*

Knot pull tensile strength[a)]



a) Three sample T-test for Novosyn vs. Vicryl size 2/0 and 3/0 suggests P value=0,000; and for Novosyn vs. Vicryl size 0 suggests P value=0,003. If the P value is equal to or smaller than .05, signify that the result is statistically significant.

Novosyn shows a similar KPTS performance than the market reference[1]*

Novosyn* is indicated for applications where surgical practice requires the use of synthetic, absorbable, braided suture materials, particularly in the region of the gastro-intestinal tract, in gynaecology, urology and ligatures.
Novosyn* is also indicated for ophthalmology (e.g. strabismus operation) and for microsurgery (e.g. peripheral nerve anastomosis and still growing tissues) if an absorbable suture material is preferred.

Tissue Layer / Surgical Speciality	Frequently used needle
Muscular Layers	HR30 – HR76 / HRC37 – HRC80
Visceral surgery (Gastro Intestinal, Biliary & Urology)	HR10 / FR26
Subcutaneous	HR13 – HR26
Tendons, Ligaments & Fascia closure in Traumatology & Orthopedic surgery	HS15 – HS48 / 2xGS13
General Skin Closure	DS9 – DS35 / DSMP19 – DSMP24 / GS60
Minimal Invasive Surgery (MIS)	DR / SKR / PRC / SR / DRC
Ophthalmic Surgery & Sizes	DRm / HLm / DLm / HLM / VLM / 6 mm / 8 mm / 10 mm

Excellent knotting performance

Easy and smooth knot run-down

Novosyn® provides a very easy and smooth knot run-down.

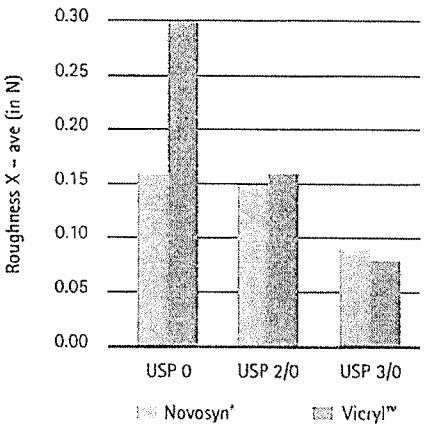
Gentle knot repositioning

Enables the surgeon to run down the knot to the precise position required.

High knot holding capacity

Novosyn® conveniently holds aligned wound edges together supporting closure during the complete healing process.

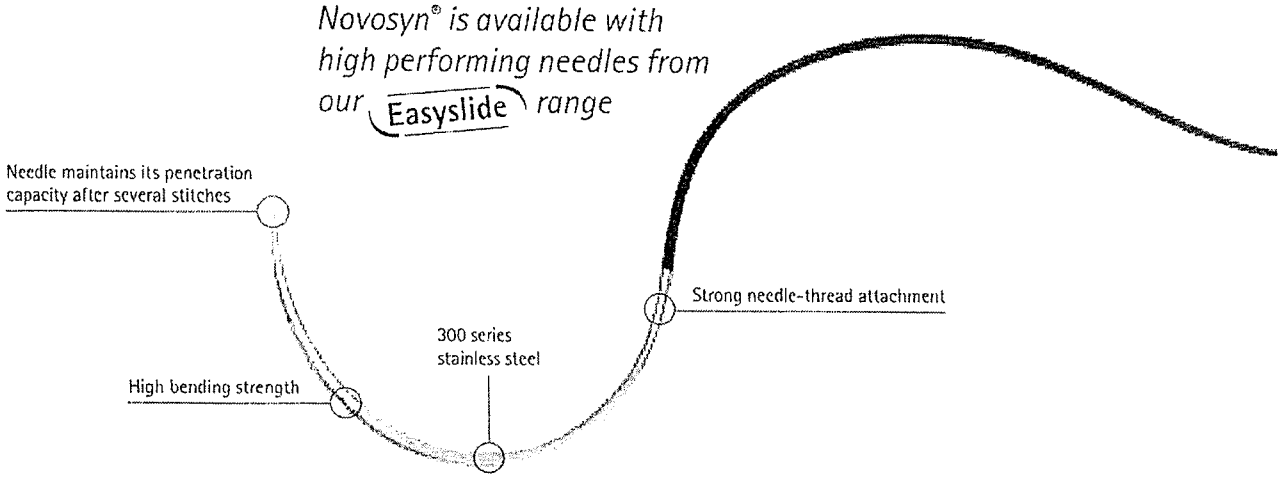
Knot run-down strength[b)]



b) Three sample T-test for Novosyn vs. Vicryl size 0 suggests P value=0,011; for Novosyn vs. Vicryl size 2/0 suggests P value=0,000, and for size 3/0 suggests P value=0,076.

Novosyn® shows a better knot run-down than the market reference[1]

Novosyn® is available with high performing needles from our Easyslide range



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1 B. Braun R&D Testing Service Report - SDS/02/NVN/03, PTR/02/FF/0228/JLT-B, PTR/02/FF/0227/JLT-B, PTR/02/FF/1057/JLT-B.

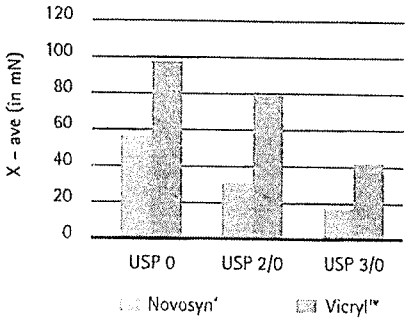
Novosyn®

Your alternative choice in PGLA suture

Enhanced pliability

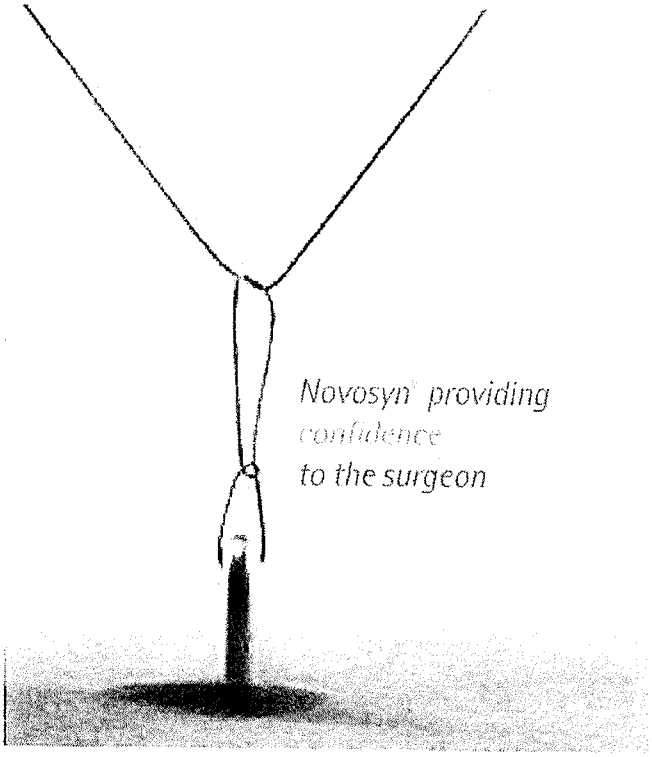
The enhanced pliability of Novosyn® provides the surgeon with a good handling of the suture.

Flexibility[c]



c) Three sample T-test for Novosyn vs. Vicryl size 0, 2/0 and 3/0 suggests P value=0,000, in all three cases. If the P value is equal to or smaller than .05, signify that the result is statistically significant.

Novosyn® shows a better flexibility performance than the market reference[2]



Novosyn® providing confidence to the surgeon

Little inflammatory reaction

Internal comparison studies have shown that Novosyn® reduces the tissue reaction that can be caused by sutures.
PGLA suture from B. Braun was compared to the market standard in a 3 months *in vivo* study. The following sutures were compared in the study: Novosyn® USP 1, USP 2-0 and USP 4-0, and Vicryl™ USP 1, USP 2-0 and USP 4-0. 6 different lots, per USP size, were used for the study for Novosyn® and 6 different lots number for Vicryl™.

The study sample size was N=82 rats. One rat died 1 day postoperatively. Therefore in total 81 animals were analysed. The surgical procedure was to implant the suture material in the paravertebral muscles by subcutaneous continuous suturing. Novosyn® suture was placed on the left side of the body and Vicryl™ on the right side.
The suture removal was performed at 5 different time points (4, 6, 8, 10 and 12 weeks post-operation) for the tissue and suture analysis: macroscopically and histologically.

Novosyn® shows less inflammatory reaction after suture implantation than the market reference[3]

Histological outcome with respect to infammatory reaction after subcutaneous implantation of the suture materials in the rabbit

Infiltration of inflammation cells		4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
Average Score	Novosyn®	1,13	1,27	1,20	1,06	0,83
	Vicryl™	1,60	1,53	1,80	1,33	1,22

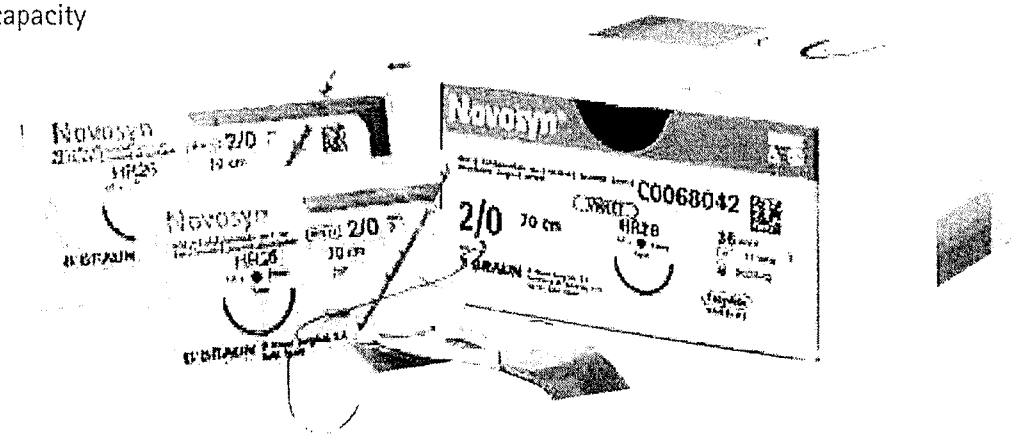
Infiltration of inflammation cells

Score	No. cell layers
0	None
1	2-3 cell layers
2	4-6 cell layers

2 B. Braun REtD Testing Services Report - SDS/02/NVN/03, PTR/02/FF/0228/JLT-B, PTR/02/FF/1057/JLT-B.
3 C. Freytag, M. Weber. Nahtmaterialresorption in der Ratte Implantation i.m. Ermittlung des in-vivo Masseabbaus von PGLA-Nahtmaterial Michi-GLP. Frey-Tox Germany; Lab-Nr 02913, 2007.

The new PGLA suture generation

- Smooth knot run-down
- Gentle knot repositioning
- High knot holding capacity
- Low inflammatory reaction
- High quality Easyslide needles
- Open surgery and M.I.S. needle / thread combinations



B. Braun is one of the world's leading healthcare supplier with different production facilities all over Europe. Novosyn® is produced at our Centre of Excellence for Closure Technologies in Spain where B. Braun aims to satisfy extraordinary quality demands, accompanied by a finely tuned integral quality and environment management system.

Novosyn®

Product Features	
Structure	Multifilament
Chemical composition	Polyglactin 910
Colour	Violet and undyed
Coating	Polyglactin 370 + calcium stearate
Size	USP 2 (metric 5) - USP 8/0 (metric 0.4)
Tensile strength retention	50% tensile strength retention at 21 days 0% tensile strength retention at approx. 35 days
Mass absorption	Hydrolysis, complete mass absorption in 56 till 70 days
Indication	General soft tissue approximation and / or ligation in all surgical specialities
Sterilization	Ethylene oxide (EO)

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Novosyn®

Needle-thread combination

Needle	Thread	USP (metric)							
		5/0 (1.0)	4/0 (1.5)	3/0 (2.0)	2/0 (3.5)	0 (4.0)	1 (5.0)	2 (6.0)	3 (7.0)
1/2 circle round bodied needle									
HR 13	45			C0068449	C0068450	C0068451			
	70			C0068006	C0068007	C0068008	C0068009		
	90					C0068452			
	violet								
Easyslide	45			C0069405	C0069407	C0069408			
	70				C0069007	C0069008			
	undyed								
HR 13	4 x 45				C0088718	C0088719			
Easyslide	8 x 45				M0088190	M0088191			
	take off violet								
2xHR 13	70					C0068910			
Easyslide	violet								
HR 13ss	45						C0088320	C0088321	C0088322
	70						C0068120	C0068110	C0068111
	violet								
Easyslide	70							C0069758	
	undyed								
HR 17f	70					C0068888			
Easyslide	violet								
HR 17	45					C0088340			
	4 x 45						C0088717	B0088712	
	8 x 45						M0088186	M0088188	
	70			C0068011	C0068012	C0068013	C0068014	C0068015	C0068016
	90					C0068853	C0068854	C0068855	
	violet								
	4 x 45						B0069712		
	8 x 45						M0069021		
Easyslide	70			C0069011	C0069012	C0069013	C0069014	C0069015	
	undyed								
HR 17b	70				C0068144	C0068147	C0068152		
Easyslide	violet								
HR 17	4 x 45					C0088713	C0088714		
	8 x 45					M0088185	M0088187		
	4 x 70					C0088613	C0088614		
	8 x 70					M0088255	M0088256		
	violet								
	4 x 45					C0089713			
	8 x 45					M0089020			
	4 x 70					C0089613	C0089612		
	8 x 70					M0089190	M0089191		
Easyslide	take off undyed								

C Box of 36 units | B Box of 24 units | G Box of 12 units | M Box of 6 units

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Needle		Thread								
		Gauge size	5/0	4/0	3/0	2/0	0	1	2	3
			(1)	(1.5)	(2)	(3)	(3.5)	(4)	(5)	(6)
1/2 circle round bodied needle										
	HR 17b		8 x 45				M0068153			
Easyglide		take off	violet							
	HR 17		30	C0068469						
Easyslide		loop	violet							
	2xHR 17		70			C0068904				
Easyslide			90	C0068869	C0068870					
			violet							
	2xHR 17b		70	C0068163	C0068176					
Easyglide			violet							
	HR 17s		45			C0088335				
			70		C0068113	C0068114	C0068115	C0068116	C0068118	
Easyslide			violet							
			45		C0068795					
	HR 20		70		C0068765	C0068766	C0068767			
			90			C0068763				
Easyslide			violet							
	HR 20		4 x 45			C0088783				
Easyslide		take off	violet							
			20			C0068069	C0068004			
			45		C0068001	C0088325	C0068005			
			4 x 45	C0088621	C0088622		C0088624			
			8 x 45	M0088175	M0088176		M0088179			
			70	C0068028	C0068029	C0068030	C0068031	C0068032		
			90		C0068438	C0068877	C0068881	C0068876		
	HR 22		120			C0068078	C0068880			
			140		C0068521					
			violet							
			4 x 45	B0069728						
			8 x 45	M0069110						
			70		C0069029	C0069030	C0069031	C0069032	C0069033	
			90			C0069720				
Easyslide			undyed							

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Novosyn®

Needle-thread combination

Needle	Thread	USP (metric)							
		5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)	3 (6)
HR 26s	45				C0068019				
	70			C0068089	C0068090	C0068091	C0068092	C0068093	
	4 x 70					B0068135			
	8 x 70					M0068295	M0068305		
	90			C0068589	C0068590	C0068591	C0068592	C0068613	
	violet								
Easyslide	70			C0069089	C0069090	C0069091	C0069092		
	undyed								
HR 26s	4 x 45			C0088789	C0088790	B0088791	B0088792	B0088793	
	8 x 45			M0088163	M0088164	M0088165	M0088166	M0088167	
	4 x 70					B0088691	B0088692	B0088693	
	8 x 70					M0088232	M0088233	M0088234	
Easyslide take off	violet								
2xHR 26s									
	90						C0068915		
Easyslide	violet								
HR 26ss	45					C0068890			
	70				C0068790	C0068791	C0068100	C0068793	
	90						C0068580	C0068642	
Easyslide	violet								
HR 26ss	4 x 45				C0088810				
	8 x 45				M0088160				
	4 x 70						B0088015		
Easyslide take off	violet								
HR 30	70	C0068035	C0068046		C0068047	C0068048	C0068049	C0068045	
	90	C0068445	C0068446		C0068447	C0068448	C0068645		
	violet								
	70		C0069046		C0069047	C0069048	C0069049		
	90					C0069448	C0069449		
Easyslide	undyed								
HR 30	4 x 45				C0088761	B0088762	B0088763		
	8 x 45				M0088155	M0088156	M0088157		
	4 x 70		C0088660		B0088661	B0088662			
	8 x 70		M0088228		M0088229	M0088230			
Easyslide take off	violet								
2xHR 30									
	70				C0068747				
	90					C0068174			
Easyslide	violet								

C Box of 36 units | B Box of 24 units | G Box of 12 units | M Box of 6 units

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๑.ลงชื่อ.....ประธานกรรมการ

๒.ลงชื่อ.....กรรมการ

๓.ลงชื่อ.....กรรมการ

Needle Length mm	Filament Needle size color	USP (metric) 7/0 (0.2)	6/0 (0.7)	5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)
3/8 circle, reverse cutting needle										
2xHS 48 Easyslide	90 violet								B0068683	
HS 55 Easyslide	70 violet								C0068227	
3/8 circle, reverse cutting needle										
DS 9 Easyslide	45 violet	C0068202								
	45 undyed	C0069205								
DS 12 Easyslide	45	C0068206	C0068207	C0068208						
	70 violet	C0068506	C0068507	C0068508						
	45	C0069206	C0069207	C0069208						
	70 undyed	C0069330	C0069331							
2xDS 12 Easyslide	45 violet	C0068706	C0068769							
	30		C0069707							
	45 undyed	C0069706								
DS 16 Easyslide	45		C0068212	C0068213	C0068214	C0068215				
	70		C0068512	C0068513	C0068514					
	90 violet		C0068511							
	45		C0069212	C0069213	C0069214					
	70 undyed				C0069302					
DS 19f Easyslide	45 undyed			C0069217						

จ.๒๕

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๓.ลงชื่อ.....กรรมการ

Novosyn®

Needle-thread combination

		Thread (quantity/length) colour	USP (Metric) 6/0 (0.7)	5/0 (1)	4/0 (1.5)	3/0 (2)	2/0 (3)	0 (3.5)	1 (4)	2 (5)
[illegible]										
3 threads of 45 cm	(#664)	3 x 45 violet	C0058622	C0058623	C0058624	C0058625	C0058626	C0058627	C0058629	C0058630
6 threads of 45 cm	(#665)	6 x 45 violet		C0058643	C0058644	C0058645	C0058646	B0058647	B0058649	B0058650
12 threads of 45 cm	(#666)	12 x 45 violet			C0058664	C0058665	C0058666	B0058667	B0058669	B0058670
10 threads of 60 cm	(#667)	10 x 60 violet		C0058180	C0058181	C0058182	C0058183	B0058567	B0058568	
2 threads of 70 cm	(#668)	2 x 70 violet			C0058404	C0058405	C0058406	C0058407	C0058409	C0058410
5 threads of 70 cm	(#669)	5 x 70 violet			C0058444	C0058445	C0058446	C0058447	B0058449	B0058450
4 threads of 90 cm	(#670)	4 x 90 violet					C0058064	C0058065		
5 threads of 90 cm	(#671)	5 x 90 violet				C0058455	C0058456	C0058457		
1 thread of 140 cm	(#672)	1 x 140 violet		C0058203	C0058204	C0058205	C0058207	C0058208	C0058209	C0058210
1 thread of 150 cm	(#673)	1 x 150 violet			B0058704	B0058705	B0058706	B0058707	B0058709	B0058708
3 threads of 45 cm	(#674)	3 x 45 undyed		C0059623	C0059624	C0059625	C0059626	C0059627	C0059629	C0059630
6 threads of 45 cm	(#675)	6 x 45 undyed		C0059643	C0059644	C0059645	C0059646	B0059647	B0059649	B0059650
12 threads of 45 cm	(#676)	12 x 45 undyed			C0059664	C0059665	C0059666	B0059667	B0059669	B0059670
2 threads of 70 cm	(#677)	2 x 70 undyed			C0059404	C0059405	C0059406	C0059407	C0059409	C0059410
5 threads of 70 cm	(#678)	5 x 70 undyed			C0059444	C0059445	C0059446	C0059447	B0059449	B0059450
1 thread of 140 cm	(#679)	1 x 140 undyed		C0059616	C0059204	C0059205	C0059207	C0059208	C0059209	C0059210
[illegible]										
1 thread of 250 cm	(#680)	1 x 250 violet				G0058715	G0058716	G0058717	G0058719	G0058720
1 thread of 250 cm	(#681)	1 x 250 undyed				G0059715	G0059716	G0059717		

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C Box of 36 units	B Box of 24 units	G Box of 12 units	M Box of 6 units

In Vivo Knot Scoring Model for a Multifilament Suture

Rainer M. Bargon, PhD, Erich K. Odermatt, PhD,* and Dieter Menne, PhD†*

Background: A surgical knot is the key feature to assure appropriate wound support while combining tissue edges. Little evidence is available on the in vivo behavior of knots and the evaluation of knots in the living tissue. This study introduces a knot score model, which is defined by microscopic evaluation and the loop-holding capacity.

Materials: In a double-blinded and comparative study, 3 surgeons placed 10 intramuscular single-loop sutures in the longissimus muscle group of the dorsolumbar region at each side parallel to the vertrebral column. For accomplishing the study, 72 rabbits and 3 calibers of a test and control suture were used. On the fourth day, the knot safety was assessed by microscopical and mechanical analyses for scoring and classifying the knots of the different suture materials into the defined categories for loop-holding capacity. The statistical evaluation was performed using Hodges-Lehmann rank score. A Wilcoxon test was used to estabilish a significant difference between the suture types.

Results: When comparing Novosyn (Aesculap AG) with Vicryl (Johnson & Johnson Medical GmbH) a comparable knot safety was assessed based on a 95% confidence interval.

Conclusions: The new method compares the knot safety between 2 braided multifilament sutures in the living tissue. Results were discussed and examined for statistical significance.

Key Words: loop holding, knot score, Vicryl, Novosyn, in vivo study, suture comparison

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The proper use of knots represents a critical step for the approximation of divided tissues, or during the ligation of organs and vessels. In open surgery characterized by an easy accessable site, flat or symmetric knots, being facile to tie, may be used. However, with the increasing demand for laparoscopic interventions, knotting techniques become more sophisticated. The surgeon is faced with several problems while knotting in a limited range of motion: The visualization of the knotting process is far more difficult due to the projection of the knots on a flat screen and due to the absence of a direct mechanical feedback from the tissue. Therefore, the surgeon prefers to knot outside the site by using asymmetric knots, also called sliding knots. The loops are prepared extracorporally and positioned in a second step on the tissue surface through a trocar sleeve. Further loops are applied through the trocar to tighten the first loop and for fixing the knot. In general, the surgeon has the possibility to control the fixation of the knot by adjusting the tension of the loop forming thread. However, in practice, the surgeon often lacks this possibility because of insufficient mechanical feedback from the tissue when fixing the first throw and because of the danger of tissue traumatization after further manipulation of the knot. Moreover, the perfect knotting technique is still being discussed and surgical training programs are still being developed.[1–3]

Therefore, a method is urgently needed which could determine objectively the knot safety of certain knot types in a surgical operation field.

In general, the loop-holding capacity (LHC)[4] is often used as a possible parameter for the evaluation of the knot security. The LHC represents the force required for breaking the knot or causing it to slip within a loop. It is influenced by intrinsic (suture-dependent) determining factors such as surface morphology,[5] surface friction,[6] chemical composition,[7–9] suture gauge,[10] and extrinsic (technique-related) factors such as surgical knot configuration and the tension applied during knotting,[7,11] or knot volume.[12–14] The measurement of the LHC has also drawbacks, especially when smaller suture calibers should be evaluated as the latter tend to tear out of the tissue or may break due to lower initial tensile strengths. Thus, more knots for statistical evaluation would be needed. This study overcomes such practical problems because a microscopic nonhaptic evaluation is presented. Using a new knot scoring system, we evaluated the knot safety in vivo microscopically.

Knots have been studied by numerous methods for assessing the knot safety by in vitro tests,[15–17] especially for arthroscopic knots[18–20] but only scarcely literature exists on the evaluation of knots directly on the tissue under physiological conditions.[17,21,22] The purpose of this study is to provide a method to evaluate the knot safety of new sutures on a routine basis.

This study has been conducted to compare the knot safety of a test suture with a control suture. An in vivo study was conducted to simulate the knot-tying process on a living tissue rather than on artificial materials, which hardly represent a valid model for the mechanical tissue response, the presence of enzymes or body fluids such as blood and fat.

MATERIALS AND METHODS

Animals and Study Management

The study was conducted on 72 female and male specific pathogen free-albino rabbits of the breed New Zealand white having an average body weight of 2.5 kg. The individually housed rabbits were kept under controlled climatic conditions at 20 ± 3°C with a 10-fold air change

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The investigation was conducted at FREY-TOX GmbH, 04916 Herzberg, Germany.
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every hour and a relative humidity between 30% and 70%. The animals were maintained on a 12-hour light/dark cycle, provided with commercially available rabbit feed (Altromin, Germany) and tap water ad libitum, both being controlled and analyzed on a regular basis.

Selection of the Animal Model

Routinely, tensile strength degradation is monitored in rabbits in vivo by combining known animal models.[23,24] The intramuscular implanation according to ISO 10993-6 is routinely carried out in rats to verify the in vivo suture absorption.[23] The subdermal tissue implantation in rabbits has been used to evaluate the tensile strength degradation of absorbable and nonabsorbable surgical sutures.[24] We used an intramuscular suture implantation into rabbits to accommodate 20 defined suture loops per animal.

The animal trials have been approved by an official ethics committee (Gesch.Z.: 32-44456+4#3032/2007 and Gesch.Z.: 32−44456+4).

Suture Materials

The suture material used in the study are presented in Table 1. Novosyn was used as the test suture and Vicryl as the control suture.

Surgery

All rabbits were randomized using the envelope system. The rabbits were anesthetized using ketamine 10% (40 mg/kg body weight) and xylazine 2% [6 mg/kg body weight] intramuscularly. The region of the paravertebral muscles was broadly clipped free of fur, cleaned, and disinfected. In the median section of the vertebral column, an incision was placed and the subcutaneous tissue was mobilized to free the musculus longissimus maximus. In each rabbit, small incisions on each side of the vertebral column were made and 10 intramuscular single-loop sutures were placed in the longissimus muscle group of the dorsolumbar region parallel to the vertebral column. In the study, 3 USP sizes have been tested: USP 2/0, USP 3/0, and USP 4/0. For each size, 8 animals were killed. All 3 sizes were evaluated by 3 different surgeons resulting in 72 animals for the whole study. The 3 surgeons were blinded in the study for the suture material and during the sections in which the surgeons were not present all animals were evaluated and classified by the staff of Frey-Tox, who did not take part in the knotting procedure.

All 3 surgeons have been trained in the knotting technique for a defined knot to ensure the comparability of the results obtained by the different users. The above-described method allows the measurement of the knotting behavior and security of different materials by excluding the individuality of the surgeon's hand. On the left-hand side of the figure the knot is adjacent to the tissue and on the right-hand side at the surgeon's side (Fig. 1).

The ears of the knot have been cut short to 5 mm with a deviation of ± 1 mm.

After the surgery, the animals received intravenous injections of physiological sodium chloride solution (10 mL/kg body weight).

Four days after the surgery, the animals were killed and the implants were examined.

Microscopic Examination and Evaluation of the Data Obtained

All implants have been evaluated using a surgical microscope (Zeiss, Germany) and a digital camera.

In the beginning, all knots were evaluated for being open or closed. Furthermore, the latter was examined regarding the number of loops loosened or opened.

Summarizing the data obtained, the knots were divided into 4 categories as given in Table 2.

Examples of theses knots may be found in Figures 1B–E. Knots showing a knot score (KS) of 0 are tight (Fig. 1B). Knots with a KS of 1 show a loose last loop (Fig. 1C) starting from the surgeon's side to loose. Knots with an open last loop fall into the KS of 2 (Fig. 1D).

Open knots showing 3 open loops or knots with 1 open loop and 1 loose loop are categorized into the KS of 3 (Fig. 1E). A nonparametric rank score is computed analogous to the Hodges-Lehman estimator used in rank tests.[25] Each of the 10 knot pairs of the control and test suture per animal were compared against each other.

Microscopic inspection was used for classifying the knots into certain categories. Each of the 10 knots of the control and test suture per animal were compared against each other, giving 100 comparisons for each preparation when no data were missing. For each animal, a nonparametric score is computed analogous to the Hodges-Lehman estimator used in rank tests. The knot of the suture type with the smaller KS number obtained 1 point. If both the knots showed the same KS, the LHC expressed in Newton (see the section on knot-holding capacity) was used to resolve the tie. If the LHC and the KS number for both the competitors were identical no point was given. The Novosyn Rank Score (NRS) indicates how often Novosyn was superior to Vicryl when compared. As an example, if, for instance, Novosyn obtained 52 points and Vicryl obtained 48 points, the individual animal-related rank score for Novosyn would be 52/(52+48)=0.52. Rank scores were approximately normal and analyzed by a linear mixed model using the statistical software R.[26,27] The Sweave function[28] was used to automatically generate reports based on the R code in TeX format. To determine the NRS from the individual animal-related rank scores the nonparametrical Hodges-Lehmann estimate was calculated for each suture size. In addition, the Wilcoxon test was used to calculate whether the deviation of the estimate would be

TABLE 1. Characterization of the Suture Materials

Art.-No.	Name	Color	Size	Needle	Thread	Lot
C0088640	Novosyn	Violet	2-0	HR26	4 × 70 cm	014206
C0088641	Novosyn	Violet	3-0	HR26	4 × 70 cm	014206
C0088642	Novosyn	Violet	4-0	HR26	4 × 70 cm	014206
V775E	Vicryl	Violet	2-0	SH_{plus}	8 × 45 cm	UP8GQRM0
V774E	Vicryl	Violet	3-0	SH_{plus}	8 × 45 cm	UP8DBMQ0
V773E	Vicryl	Violet	4-0	SH_{plus}	8 × 45 cm	UL8HWBM0

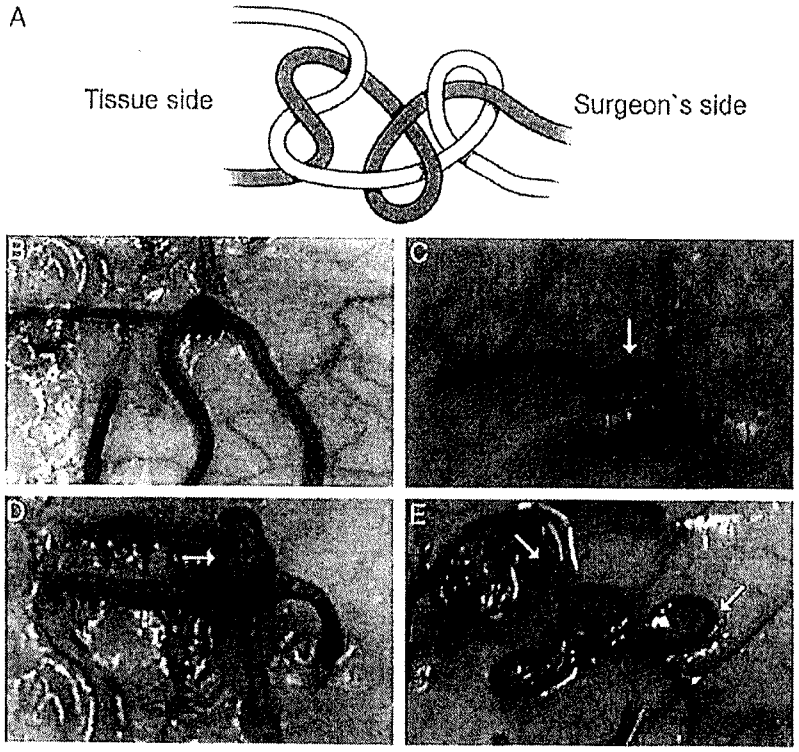

FIGURE 1. A, Represents the scheme of the knot configuration 1-S//S used in the study. The knot score 0 being a tight knot (B), knot score 1 being a knot with the last loop (arrow) loosened (C), knot score 2 being a knot with the last loop (arrows) opened (D), and knot score 3 a knot being opened (arrows) completely (E) are shown as the knots were found in situ.

significantly different (estimate >0.5) on the basis of a confidence interval level of 95%.

Measurement of the LHC

The LHC was measured in Newton on the implant directly using a calibrated spring balance (Chatillon). For each size (except Novosyn USP 2/0), 240 knots have been evaluated. The hook of the self-fixating spring balance was positioned beneath the knot and pulled perpendicular to the tissue surface. In certain cases, when the suture cut through the tissue no value could be obtained. Those knots were excluded from the evaluation of the LHC.

RESULTS

Intraoperative Results

During surgery, no opening or loosening of any knot was observed. Both sutures were placed easily in the tissue and possessed a smooth surface. No difference was observed in handling between the test and control sutures. In general, the suture material was well tolerated by all animals and no unusual clinical findings were observed.

Microscopic Evaluation

The estimate and the 95% confidence intervals (lower/upper) of the medians of the NRS are given in Table 3.

The NRS for the 3 different sizes is based on the median of the estimate from the individual rank scores from all animals. The deviations of the median are similar for Vicryl and Novosyn and both sutures show a very similar knot security. The line at 0.5 would reflect an equal ranking of Novosyn and Vicryl as only 2 competitors were compared (Fig. 2).

The Knot Scores based on microscopical findings are summarized in Table 4.

From Table 4 it is clear that most of the knots in all 3 sizes were tight in both suture types. A few knots with the last loop loose were obtained for Novosyn USP 2/0, Novosyn USP 3/0, and Vicryl USP 2/0. One open knot (score of 3) was obtained for Vicryl USP 3/0. No knots were found with a score of 2.

TABLE 2. Knot Score as a Parameter of Knot Safety

Open Knot	Open Loop	Loose Loop	Knot Score	Description	Figure
0	0	0	0	All loops are tight (3 throws)	1B
0	0	1	1	Last loop is loose (3 throws)	1C
0	1	0	2	Last loop is open (2 throws)	1D
1	1	1	3	Last loop is open and before last is not tight (2 throws)	—
1	3	0	3	Open knot (0 throws)	1E

TABLE 3. Estimates and 95% Confidence Intervals of the Medians of the Novosyn Rank Score

		Estimate	Confidence	
USP	*P*	Median	Lower	Upper
2/0	0.20	0.61	0.46	0.77
3/0	0.01	0.62	0.54	0.69
4/0	0.12	0.60	0.46	0.73

Some sutures tore out the tissue and needed to be excluded from the evaluation of LHC. Approximately one-third of the knots tore out in the sizes USP 4/0. As anticipated, the number of sutures that could not be evaluated decreased with the suture diameter (Table 5).

Measurement of LHC

Seven groups of LHC were formed and the results are given in Figure 3.

For the majority of knots, the LHC could be determined as shown in the column, named LHC in Table 5. The remaining few knots were torn out of the tissue. As anticipated, smaller suture calibers showed a higher tendency to saw through the tissue when the knot was pulled. The majority of knots in the suture size USP 2/0 fell into the group 20 N $< x \leq 22$ N, whereas for USP 3/0 and USP 4/0 most of the knots were classified into 1 common group 18 N $< x \leq 20$ N. The difference may be explained by the varying ratios of cross-sectional areas of the different calibers. The ratio of USP 2/0 versus USP 3/0 (compared with USP 3/0 vs. USP 4/0) is 9/4 (and 16/9), which means that the ratio between the former 2 sizes is much larger compared with the latter.

Remarkably, 9 knots of Novosyn USP 2/0 showed a low knot-holding capacity. However, no open loops were detected among these knots as can be seen from Table 4. These small LHC values were compensated by 30 knots with a very high LHC of more than 26 N of which 10 knots were present in the Vicryl suture.

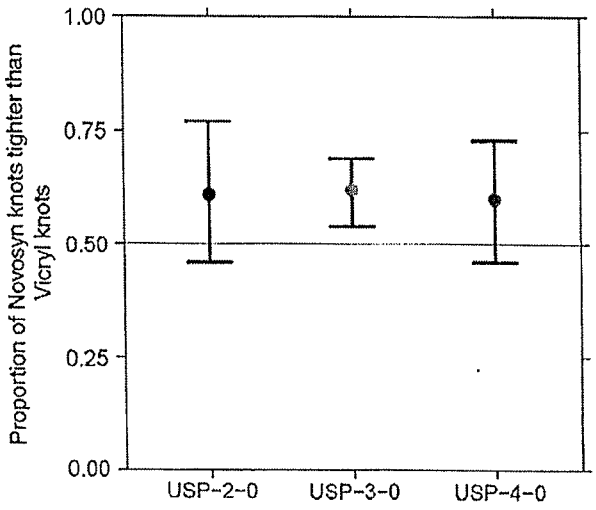

FIGURE 2. Novosyn Rank Scores and 95% confidence interval.

TABLE 4. Knot Scores of Novosyn and Vicryl

			Knot Score			
Material	USP	Total	0	1	2	3
Novosyn	2/0	239*	232	7	0	0
	3/0	240	236	4	0	0
	4/0	240	240	0	0	0
Vicryl	2/0	240	238	2	0	0
	3/0	240	239	0	0	1
	4/0	240	240	0	0	0

*One knot could not be found during section.

DISCUSSION

The use of rank scores has the advantage to use a relative scale of evaluation rather than absolute numbers, which could be rather arbitrarily assigned to different knot types. In addition, it is a common understanding that knots with more loose or open throws would be less secure. Therefore, the NRS was introduced taking into account a relative knot evaluation. By these means, different surgeons participating in the study could not distort the results obtained, because only knots within 1 animal were compared to ensure the surgeon-based individuality of the data obtained. In contrast, the impact of an open knot and of a less trained surgeon would not distort results so easily as it would be using a weighted rank score as any weighting factor would be arbitrarily chosen and would have a major impact on the results.

Although, it was clear that such knot configuration would not reflect a suitable and safe knot for the laparoscopic surgery, in total only 3 single throws were applied. Usually, surgeons would use more than 3 throws to fix a surgical knot or at least commonly change the direction of the loop and the thread end under tension to secure the knot.[1]

Obviously, 1 knot configuration does not provide a general rule for knot safety of all other knots but at least describes the knot safety of 2 suture materials regarding 1 selected knot configuration under comparable conditions. The knot has been selected based on the research results indicating that some knots would slip whereas others may rather break.[18,19] Among the breaking knots, a knot being able to slip as well was sought and established in the knot configuration 1-S//S//S[19] minus the last throw, 1-S//S. The specific modified knot configuration was shown to be

TABLE 5. Novosyn and Vicryl Knots That Were Torn out the Tissue

Material	USP	Total	LHC†	Δ‡
Novosyn	2/0	239*	222	17
	3/0	240	218	22
	4/0	240	173	67
Vicryl	2/0	240	204	36
	3/0	240	193	47
	4/0	240	160	80

*One knot could not be found and number represents the total number of knots that were evaluated.

†Number of knots with a positive LHC.

‡Number of knots of which no LHC could be determined, since the latter were torn out of the tissue.

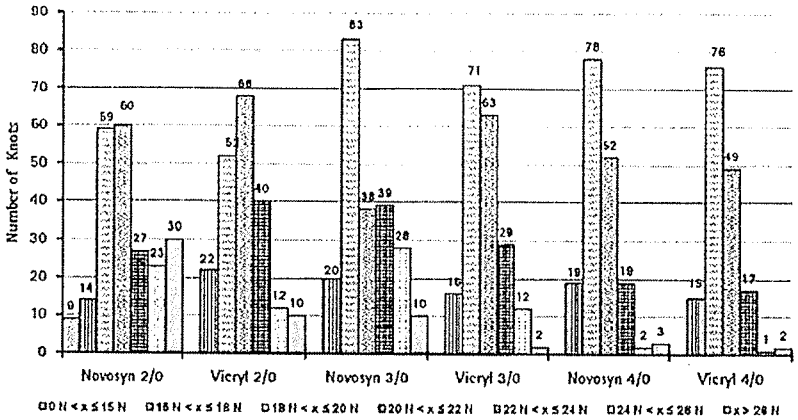

FIGURE 3. Presentation of the loop-holding capacity for sutures used during this study at defined force levels (in Newton) as measured with a spring balance.

beneficial for accomplishing the double-blinded study for the evaluation of knot safety. Furthermore, the chosen knot allows a comparison between slipping and breaking of the knot in contrast to the general surgical routine, in which breaking knots must be used. In surgery, a slipping knot would not be used or tolerated due to high risks of slack knots. Regarding the NRS, no significant differences were found between the sizes USP 2/0 and USP 4/0.

However, the size USP 3/0 showed a higher knot-holding capacity for Novosyn. This higher NRS in USP 3/0 is less attributed to the number of tight knots but rather to the loop-holding capacities between both the suture types.

When comparing the histograms of Novosyn USP 3/0 and Vicryl USP 3/0, a right-skewed distribution of the knots on the Newton axis for Novosyn was observed resulting in a slightly superior LHC. However, if Novosyn USP 2/0 was compared with Vicryl then some slightly weaker knots which did not occur in Vicryl were accompanied with stronger knots in Novosyn. The number of strong knots (> 26 N LHC) for Novosyn USP 2/0 was sufficient to compensate for the abundance of 5 knots among the 239 knots compared with Vicryl showing a knot with the last loop loosened resulting in a comparable NRS for this suture size. Only for the size USP 3/0 the distribution of loop-holding capacities between Vicryl and Novosyn was very similar although a slight preference for strong knots exists for Novosyn, which finally resulted in a difference between Novosyn and Vicryl for size USP 3/0. Therefore, no significant difference between Novosyn and Vicryl was found between USP 2/0 and USP 4/0 regarding Novosyn Rank Score.

CONCLUSIONS

We presented a knot scoring model, which was used to evaluate knot safety mainly based on the visual appearance of the knot. Combined with mechanical tests the method presented should be a useful tool to describe and evaluate knot properties of different kinds of sutures.

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ORIGINAL ARTICLE

Strength of sliding knots in multifilament resorbable suture materials

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Abstract Experimental laboratory study was made to test the knot integrity of identical, non-identical and parallel sliding knots, with three and five throws, made with synthetic resorbable multifilament suture materials. The knots were made with Novosyn (polyglactin 612), Safil (polyglycolic acid), Vicryl (polyglactin 612) and Vicryl plus (polyglactin 910 + triclosan), all with suture size: 3-0 USP. Per material 10 knots for every kind of knot were tested in a tensiometer, resulting in a total of 240 tests. Sliding knots with three throws were compared with the five throw sliding knots, and a comparison of the loop-holding capacities (LHC) of the different suture materials was made. Differences in suture material, knot type, and number of throws in the knot had a remarkable effect on knot performance. Adding two extra throws to a three throw non-identical or parallel sliding knot resulted in significantly more reliable knots ($P<0.05$). In identical sliding knots, this effect was not seen, but these knots showed low LHCs, indicating poor knot reliability. Compared to the other suture materials, Safil showed significantly lower LHCs. Most of the mean LHCs of the various knots with Vicryl, Vicryl Plus or Novosyn were not statistically different from each other. Identical sliding knots appeared to be very unreliable, especially when made with three throws. Non-identical and parallel slipknots with five throws demonstrated superior knot integrity compared with the same knot types with three throws. Safil had inferior knot properties as compared to the other materials, but Vicryl, Vicryl Plus and Novosyn behaved virtually the same. The type of knot and the use of different suture materials have important influence on the integrity of the knot. A high knot reliability is nowadays all the more important because of the frequent use of resorbable suture materials. The suture gradually loses strength during the resorption process, so that an extra margin of safety neutralizes the effect of this process.

Keywords Knots · Sliding knots · Knot reliability · Sutures · Resorbable multifilament sutures

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Introduction

The choice for a particular suture material and knot type is frequently a matter of personal preference of the surgeon or hospital tradition [1], but using a specific material or knot can have great consequences for the patient. Breakage or slippage of a suture can lead to serious complications. Wound dehiscence, incisional hernia or internal haemorrhage may derive from knot failure in the abdominal wound [2]. Therefore, the holding power of a knot should, next to knot bulk, tissue reaction and handling properties, be considered an important factor in electing a particular suture material [3]. Nevertheless, to date, only few studies investigating the properties of suture materials and knots have been published. The studies that have been published often deal with older or even out-of-date suture materials.

Although the flat square knots are considered very secure with low failure rates across a variety of suture materials [4], sliding knots are the most frequently used in surgery. Gynaecologic surgeons also prefer sliding knots, because of the advantage that one suture end

can be kept under constant tension while tying in the narrow deep spaces of the vagina and the pelvis. Therefore this study examined the performance of different types of sliding knots made with modern, resorbable suture materials.

Materials and methods

Sterile suture material, intended for operating room use, was obtained from the hospital's stock. The tested synthetic resorbable multifilament suture materials were: Novosyn (polyglactin 612), Safil (polyglycolic acid), Vicryl (polyglactin 612) and Vicryl Plus (polyglactin 910 + triclosan). In all cases suture size 3-0 United States Pharmocopeia (USP) was tested. The analysed knots were: identical, non-identical and parallel sliding knots, all with three and five throws. To describe the different knots, a code system was used that was described previously [5]. Figure 1 shows the codes of the tested knots and the corresponding configuration. Identical sliding knots were made by repeating the same tying action with the same hand, e.g. backhand or forehand. Non-identical sliding knots were made by alternating backhand and forehand tying with the same hand. Parallel sliding knots were made by changing the suture thread that was kept under tension and alternately tying the suture with the left and right hand.

Per material 10 knots for every kind of knot were tested, resulting in a total of 240 tests. After soaking for 15 min in saline, the suture materials were tied around two elliptical rods attached to a board. The knots were carefully tied by one of the authors (JBT), and the type was verified before the knot was tied tight. Then the tension on the loop was removed by rotating one of the rods, so that the suture loop could be removed. Blinded to the tested suture material and knot type, the other author (NvL) placed the loop over two polished metal axles in a tensiometer. The axles moved apart at a constant rate of 25 mm/min and caused increasing tension on the loop. The strength by which failure of the loop occurred was registered to define the "loop-holding capacity" (LHC): the force required to break the suture or provoke slippage in the knot [6]. This measure was registered in newtons and used in the further analysis of the experiments. The way of knot failure was noted to determine whether certain knot types failed more frequently due to slippage or breakage.

Results

In 186 of the 240 tests, knot failure was due to slippage of the knot: 73.3 % (N=44) in the Novosyn group, 85.0 % (N=51) in the Safil group, 71.1 % (N=43) in the regular Vicryl group and 80.0 % (N=48) in the Vicryl Plus group. In the remaining 54 tests, the suture broke in the knot or in the immediate vicinity of the knot.

Table 1 shows the mean LHCs with standard deviation for each type of knot. A comparison of the LHCs of the

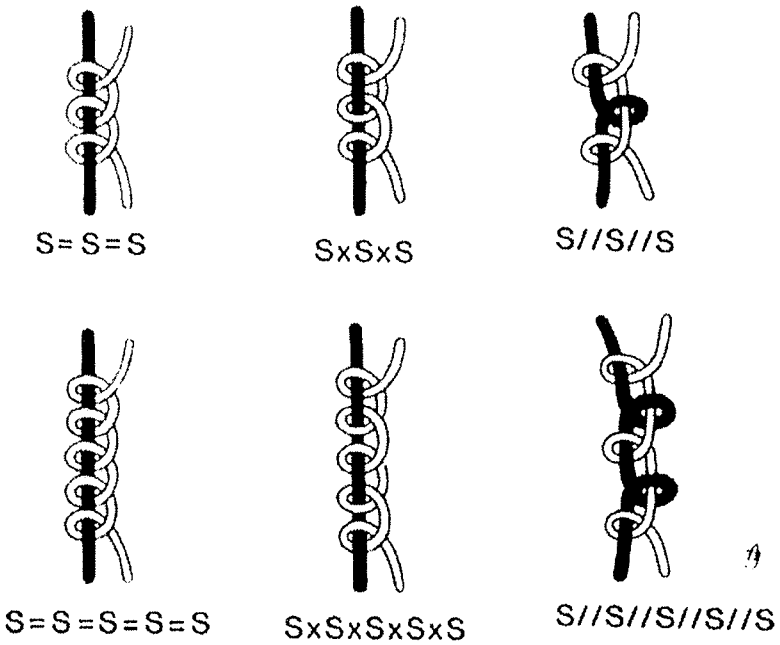

Fig. 1 Configuration and code of the six different knots studied. Sliding throws (*S*), identical throws around the same suture (*equals sign*), nonidentical or crossed sliding throws around the same suture (*multiplication sign*), sliding throws alternately tied around different sutures (*double solidus*)

Table 1 Mean loop-holding capacity with standard deviation as determined in six different kinds of slipknots, for each type of suture material

Knot type	Suture material			
	Vicryl plus	Vicryl	Safil	Novosyn
S=S=S	5.3±0.95	7±5.73	3.1±2.08	4.8±1.75
S×S×S	21.5±11.79	18.8±9.77	9.5±4.06	22.9±14.56
S//S//S	29.8±9.87	35.8±15.38	21.0±6.02	43.4±17.33
S=S=S=S=S	11.4±4.90	10.8±1.93	3.2±1.93	4.2±4.13
S×S×S×S×S	28.7±5.25	34.0±15.52	18.6±6.52	37.6±11.05
S//S//S//S//S	57.6±3.81	58.4±2.32	50.4±7.35	59.3±2.87

different suture materials is shown in Table 2. In the comparison of regular Vicryl and Safil, Vicryl showed superior knot profiles. The only exception was in the three throw identical sliding knot. Besides for the identical slipknot with five throws (S=S=S=S=S) the comparison of Vicryl and Novosyn showed no significant differences in all the knot types. Novosyn sutures were more reliable than Safil in four of the six knots tested. Vicryl Plus showed the same knot performance as compared to regular Vicryl.

Sliding knots with three identical throws around the same suture (S=S=S) appeared to be very unreliable (Table 1). The adding of two extra throws resulted in a significantly more secure knot only in the Vicryl Plus group (Table 3). All the non-identical slipknots with five throws (S×S×S×S×S), irrespective of the suture material, showed significantly higher LHCs compared with the same knot types with three throws (S×S×S; Table 3). The comparison of parallel slipknots with three (S//S//S) vs. five throws (S//S//S//S//S) displayed the same, except for the Safil group (Table 3).

Discussion

This study shows remarkable differences in knot strength between different sutures, knot types and numbers of throws in the knot (Fig. 2). The identical sliding knots with three throws (S=S=S) appeared to be very unreliable. When two identical throws were added (S=S=S=S=S), the difference was only significant in the Vicryl Plus group. All the non-identical slipknots with five throws (S×S×S×S×S) showed significantly higher LHCs compared with the same knot types with three throws (S×S×S). The parallel sliding knots displayed the same, except for the Safil group. This discrepancy between sutures of the effect of adding two extra throws to the knot might be explained by the finding that even five throw identical sliding knots show poor knot reliability. In other words, a change from very poor to poor is still not good enough. The consequence of this is that the application of identical sliding knots should be discouraged in clinical practice and this confirms earlier findings of this kind [6].

On the evidence of these experiments, there is no significant difference between regular Vicryl and Vicryl Plus. Apparently, the adding of an aseptic compound to the suture to prevent wound infection has no demonstrable effect on the friction coefficient of the suture and its knot reliability. The comparison of Vicryl and Safil showed superior results for Vicryl in all knot types tested, except for the identical sliding knot with three throws (S=S=S). The comparison of Vicryl and Novosyn showed no differences, except for the identical slipknot with five throws (S=S=S=S=S) in which Vicryl did better. All the knot

Table 2 Statistical analyses of differences in loop-holding capacities between the different suture materials

Values in upright represent a statistical significant difference, determined by a Mann–Whitney test over the two samples. Values in italics represent statistically nonsignificant differences

Knot type	Compared suture materials			
	Vicryl plus vs. Vicryl regular (*P* value)	Vicryl vs. Safil (*P* value)	Vicryl vs. Novosyn (*P* value)	Novosyn vs. Safil (*P* value)
S=S=S	*0.939*	*0.146*	*0.675*	*0.059*
S×S×S	*0.820*	0.001	*0.161*	0.006
S//S//S	*0.256*	0.011	*0.384*	0.002
S=S=S=S=S	*0.702*	<0.001	0.003	*0.908*
S×S×S×S×S	*0.704*	0.014	*0.449*	<0.001
S//S//S//S//S	*0.675*	0.013	*0.401*	0.003

Table 3 Statistical analyses of differences in loop-holding capacity between three and five throw slipknots, per suture material

Suture material	Compared knot types		
	S=S=S=S=S vs. S=S=S (*P* value)	S×S×S×S×S vs. S×S×S (*P* value)	S//S//S//S//S vs. S//S//S (*P* value)
Vicryl plus	<0.001	0.034	<0.001
Vicryl (regular)	*0.111*	0.008	<0.001
Safil	*0.908*	0.004	*0.053*
Novosyn	*0.234*	0.005	<0.001

Values in upright represent a statistical significant difference, determined by a Mann–Whitney test over the two samples. Values in italics represent statistically nonsignificant differences

types showed higher LHCs with Novosyn in comparison with Safil, besides the identical slipknots with three and five throws (S=S=S and S=S=S=S=S). These findings indicate that Safil has inferior knot performance as compared to Vicryl and Novosyn. Novosyn and Vicryl showed similar knot profiles.

Our results comply with former investigations [7]. In a more recent study, Ivy et al. compared the knot integrity of non-identical sliding knots with three and six throws, made with polydioxanone and polyglactin 910 sizes 0 and 2 USP. This study also showed that an increasing number of throws resulted in significantly more reliable knots and decreasing knot failure due to slippage, irrespective of the suture type or gauge [8].

There is still little knowledge about the exact forces that a knotted suture in the human body must be able to tolerate. These forces probably differ among individuals, they differ among the type of tissue they are in and they are liable to many local factors. Until further knowledge is acquired, it seems advisable to ensure that a knotted surgical suture is at least as strong as the tissue it surrounds [1]. The surgeon can improve the strength of a knotted suture loop in different ways. Changing the suture gauge is one way [9], and choosing a suture material with better knot profiles is another. As shown in this study, the surgeon can also add more throws to the knot. And last but not least, the surgeon can change to another type of knot that is more reliable. This has been an important vision for years, but nowadays, it is all the more important because of the frequent use of resorbable suture materials. During the resorption process, the suture gradually loses strength. A high knot reliability is therefore even more important, in that an extra margin of safety neutralizes the effect of this process. Every surgeon should have knowledge of the differences in knot security between the variable suture materials and knot types, and should strive to make the most secure knot, with the ideal suture material for the task and a minimal amount of foreign body suture material.

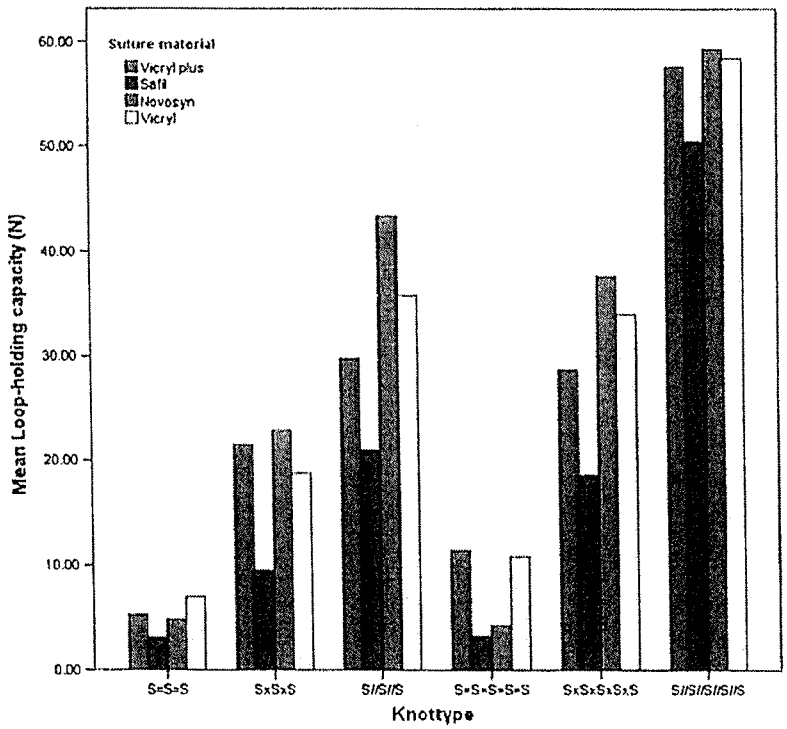

Fig. 2 Mean loop-holding capacities per material clustered by knot type

Declaration of interest The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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