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Modelling and experimental investigation of mechanical performances of braided polyamide sutures

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This work aims at predicting the braiding parameters which can lead to sutures having optimal mechanical performances for specific surgical intervention. The braiding parameters include yarn count and machine settings. Effects of yarns characteristics and machine parameters on a polyamide braid mechanical properties have also been studied. Yarn count and sheet yarn number are proven to be the most significant factors. Predictive models of the suture mechanical responses based on yarn characteristics and machine parameters have been developed and it shows very significant level. Using simultaneous contours plots, manufacturing conditions permitting to obtain optimal mechanical properties meeting the requirements of the US Pharmacopeia for the diameter and tensile strength are determined for sutures having USP number from 3-0 to 2.

Keywords: Linear regression, Mechanical properties, Polyamide braided suture, Prediction model

1 Introduction

Braided structures are commonly used in surgery as ligaments, stents, nerves and sutures [1, 2]. Braided multifilament sutures are commonly used in surgery because of their excellent flexibility, knot security and handling proprieties compared to monofilaments [3, 4]. Braided suture manufacturing process is described in literature but the available data describes only some steps of this process[5-7]. There are reel lacks of information about manufacturing conditions of braided suture and especially about effect of manufacturing conditions on suture tensile proprieties. Braided sutures are generally obtained by using a circular braiding machine.

Today's tubular braiding machines still employ the principles of earlier machines. Each sheet yarn is individually controlled by carriers of bobbin that moves along a predetermined path causing yarns interlacement and form the braid structure[5, 8]. The different interlacing patterns are accomplished by varying the motion of the carriers. There are three of typical tubular braided patterns, viz diamond, regular and Hercules[9]. Regular tubular braid is usually chosen in order to obtain suture with very small diameters and smooth surface.

The geometry of a braided structure is linked to many variables, including braid angle, diameter and pick count. Braid angle is defined as half of the angle between the interlacing yarns in the vertical direction. It is the most important parameter that determines the cover factor of braided structure. A low carrier speed with a high take-up speed generates loose braided structures with low braiding angles and, consequently, low cover factor. But high carrier speed and low take-up speed give closely packed braided structures having higher braiding angles and better cover factors [10, 11].

Although braiding is old used technique for producing suture, many attempts have been made to improve the properties of braided suture. Indeed, many sutures exhibit failure after implantation. Chesterfield *et al.* [8] developed helical braided sutures. These sutures are formed by yarns which intersect inside the braid and are parallel to longitudinal axis of braid. They observed that these sutures reveal minimal friction when they penetrate through wound tissue. Suture knot security is also improved in the case of these structures. However, sutures today available in the market are still made by classical tubular braiding machine. In fact, because of technological limit of helical braiding machine, it was not possible to manufacture suture with all required diameters.

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Other initiatives [8, 12, 13] have focused on producing sutures using tubular braids by varying braiding conditions, such as sheet yarns number, yarn count of sheet yarns and cabled core, number and diameter of filaments in sheath yarns and in cabled core. They have established intervals of these various parameters which permit to obtain braids having acceptable strength and surface roughness. They observed that the smoother surface is obtained by using maximum possible number of filaments and sheet yarns. In fact, they used filaments with very small diameters that allow the use of a high number of sheet yarns and to obtain compact suture surface. Kaplan *et al.*[12] investigated the influence of braiding parameters on some suture performances, such as tensile strength and knot pull strength. Available data is limited to few analyses on effect of manufacturing conditions. However, there is no available research showing how to establish relation between manufacturing parameters and sutures properties.

In a work, Rawal *et al.*[14] developed tensile analytical model of braided sutures in order to predict stress–strain behaviour of braided sutures based on braid geometry, braid kinematics, and constituent monofilament properties. The model has accounted for the changes in the braid geometry, including braid angle, diameter, and Poisson’s ratio. However, proposed model is limited to tensile strength property and did not consider effect of manufacturing conditions.

The purpose of this paper is therefore to develop braided sutures by varying the manufacturing parameters, such as yarn count, take-up speed and type of braiding machine and to study the effect of these parameters on suture mechanical properties. Prediction models for the mechanical properties are also developed using linear regression method. Finally, an optimization of these properties is performed by referring to preferred properties reported in literature and meeting the requirements of the US Pharmacopeia for diameter and tensile strength.

2 Materials and Methods

2.1 Suture Materials

Different multifilament PA 6-6 (Polyamide 6-6) yarns having yarn counts of 44, 88 and 110 dtex were used for suture manufacturing. These yarns were selected because of their high biocompatibility and medium tenacity to develop suture for dermatological intervention. Indeed, PA 6-6 material with medium tenacity is often used to obtain suture characteristics, required to the generated constraints during healing, and also it does not cut the skin during tying[15].

2.2 Suture Manufacturing

The 8, 12 and 16 HERZOG circular braiding machines (HERZOG machine, Type 80, Germany) were used. Braided sutures with 8, 12 and 16 non-texturized polyamide 6-6 sheet yarns having different counts were prepared by using a 1/2 interlacing braid geometry obtained through 1/2 sequential carrier motion. The geometry of a braided structure is linked to many variables, including braid angle, diameter and pick count. Braid angle is defined as half of the angle between the interlacing yarns in the vertical direction. The ratio of angular speed of the bobbins to the take-up speed determines the braid angle. So, braid angle can be changed by varying the take-up speed [16]. Jedda *et al.* [17] reported that mechanical properties of the braided structures are influenced by braid take-up speed, which is related to machine cogwheel ratio (CR). Indeed, at the output of the braiding machine, the movement of the braided structure is transmitted via a gear train composed by consecutive cogwheels. These cogwheels adjust the take-up speed of the machine by varying CR. The CR, also known as speed ratio, is the ratio of the angular velocity of the input gear (cogwheel) to the angular velocity of the output gear. It can be calculated directly from the numbers of teeth on the gears in the gear train. CR is varied during this study in order to have suture with a pick count between 50/cm and 100/cm as reported by Chiestfield *et al.*[8] and Kaplan *et al.*[12] .

A full factorial design of experiments was considered for sutures manufacturing (Table 1), in which three factors were taken into account. Factors, such as yarn count and sheet yarn number have three levels, while CR have five levels. According to this plan, we produced $3^{k_1} \times 5^{k_2}$ samples of braided sutures where k_1 is the number of factors having 3 levels and k_2 is the number of factors having 5 levels. Consequently, 45 samples were produced.

Table 1—Full factorial design of experiments PA 6-6

Factors	Levels				
	-2	-1	0	1	2
Yarn count, dtex	-	44	88	110	-
Sheet yarn number	-	8	12	16	-
Cogwheel ratio (CR)	0.059	0.064	0.069	0.075	0.080

2.3 Testing of Mechanical Properties

Suture needs to respond to a number of physiological and biomechanical requirements. Manufactured sutures have to meet the requirements of the US Pharmacopeia and present at least mechanical performances of marketed sutures. Consequently, diameter, tensile strength, extension at break, ultimate tensile strength (UTS) and Young's modulus were determined and analyzed in this study. Mechanical properties of manufactured suture were determined from load–strain curves obtained by straight pull until break test. Mean friction coefficient difference (FCD-mean) that expresses slipperiness of suture surface was also determined. Indeed, the slipperiness of suture is an essential organoleptic property of suture because a rough suture cannot be used under any conditions. Experimental measurement conditions of these properties will be described in the following section. All tests were carried out under a controlled environment of 21± 1°C temperature and 65% ± 2% relative humidity according to ASTM D1776-04.

2.3.1 Determination of Diameter

Suture diameter was determined according to the USP32-NF27 S2 <861> method described in USP32-NF27 S2 monograph for non-absorbable sutures. A dead weight mechanical thickness gauge (SODEMAT-Troyes-France), equipped with a direct digital reading and graduated in 0.02 mm divisions was used. Then, USP number corresponding to each measured diameter was determined according to USP32-NF27 S2 monograph.

2.3.2 Determination of Mechanical Properties

For this test, we used a traction machine (dynamometer LLOYD, England) and a constant rate of extension. All tensile tests were performed according to ASTM D76-99 standard. Load cell was chosen such that the tensile force of tested sutures was between 10% and 90% of the load cell's capacity [18].

We used a straight pull tests procedure adopted from Instron test method, as explained in previous works [19, 20]. The braided suture specimen undergo a longitudinal traction until rupture at a strain rate of 300 mm/min [19] with a 100 N load cell and 150 mm initial gauge length. We determined average value and standard deviation of tensile strength (N), ultimate tensile strength (UTS) (MPa), Young's modulus (GPa) and extension at break (%).

2.3.3 Determination of the Mean of Friction Coefficients Difference

We have used the friction twist method to study friction properties of fabricated braided sutures. We have developed the friction coefficient difference (FCD) test in our previous works [21]. Two sutures were warped together and tension revealed by the displacement of one each other was recorded (F). Sutures are compared in term of average of friction coefficient differences (FCD-mean = $\overline{\mu s - \mu k}$) between successive maximum friction (μ_k) and minimum friction (μ_s) coefficients corresponding to generated forces in stick (F_k) and slip (F_s) points of suture materials. This difference reflects the ease or difficulty of suture strand displacement between each other during tying. The friction coefficients (μ_s and μ_k) were determined[22] using the following equation:

$$\mu = \frac{\log(F/T_0)}{n\pi\beta} \qquad \ldots (1)$$

where μ is the friction coefficient; *F,* the recorded tension; T_0, the initial tension; n, the warp number; and β, the angle between warped sutures

2.4 Statistical Analysis and Linear Regression Model

Ten specimens were tested in each case. Generated effect diagram in the following section presents mechanical properties mean values. We identified the most influential factors on suture performances by analyzing main effects plot. Thus, main effects plot represents the mean value of the output responses for each level of controlling factors[23]. This plot is basically used to compare the significance of controlling factors effects and to determine the most important factor influencing the studied response.

We also studied relationship between suture performances and braiding parameters (yarn count, sheet yarn number, and CR) by using multiple linear regression method. Following Eq. (2) presents general regression model. Using this equation, we established relationships between sutures mechanical performances (Y) and their manufacturing parameters (X_i): where X_i (i=1-3) are, respectively sheet yarn number, count yarn & CR, while a_i, b_i and c_i are the regression constants and n (n=3) is the variables number. Equation (2) is shown below:

$$Y = a_0 + \sum_{i=1}^{n}\left(a_i X_i + b_i X_i^2\right) + \sum_{i=1}^{n}\left(\sum_{j>i}^{n} c_{ij} X_i X_j\right) \qquad \ldots (2)$$

The MINITAB 17 software (Minitab Statistical Software, MINITAB Ltd., Coventry, UK) was used to develop mechanical properties models. To test the significance of each model we analyzed the coefficient of determination (R^2) and Fisher's test of the model (p-value). High values of R^2 show good correlation. Qadir *et al.*[24] reported that model with R^2 higher than 50 % is significant. In this study, we considered models with p-values smaller than 0.05 and R^2 higher than 75 % as significant models. Contour plots method was then used to identify main factors conditions that optimize each response.

3 Results and Discussion

In this study, the full factorial experiment plan has been used as adopted previously (Table 1) to establish a predictive model for each studied property. This involves two steps of investigation to be done: (i) the relevance of the effect of each parameter on each braiding conditions of the suture and establish and (ii) development of mathematical model permitting prediction of each property based on its most influential parameters (most significant). This allows, in addition, to reduce the number of parameters to be considered when solving the optimization problem without harming the quality of the optimum.

3.1 Effect of Manufacturing Parameters on Braided Sutures Mechanical Properties

In order to identify the impact of each braiding conditions on mechanical properties of PA suture. MINITAB 17 tool has been used to plot the main effects diagrams.

3.1.1 Effects of Braiding Parameters on FCD-mean

To evaluate the topology of manufactured sutures surfaces, the effect of braiding parameters on FCD-mean has been studied. Results show that the three factors (CR, sheet yarn number, yarn count) have significant effects on the FCD-mean (Fig. 1). Increasing the sheet yarns number and the yarn count leads to an increase of FCD-mean. This phenomenon is likely caused by structure undulations which are accentuated at suture surface as a result of the increase of braiding angle. This proves the advantage of using low yarn count in the case of suture produced by high sheet yarn number (12 and 16 spindles). This is in accordance with the recommendations of Chesterfield *et al.*[8] and Kaplan *et al.*[12] who recommended the use of low yarn count with a maximum sheet yarn number in order to obtain suture with low friction coefficient.

The drop of FCD-mean as consequence of the increase of the CR is justified by the reduction in braiding angle. Indeed, yarns are inclined from the axis of the braid, as the motion of yarns between each other is difficult, revealing a high friction coefficient.

3.1.2 Effects of Braiding Parameters on Tensile strength and Ultimate Tensile Strength

Figure 2 shows the effect of the variation of each braiding parameter on tensile strength. It can be sees that CR has no significant effect on tensile strength.

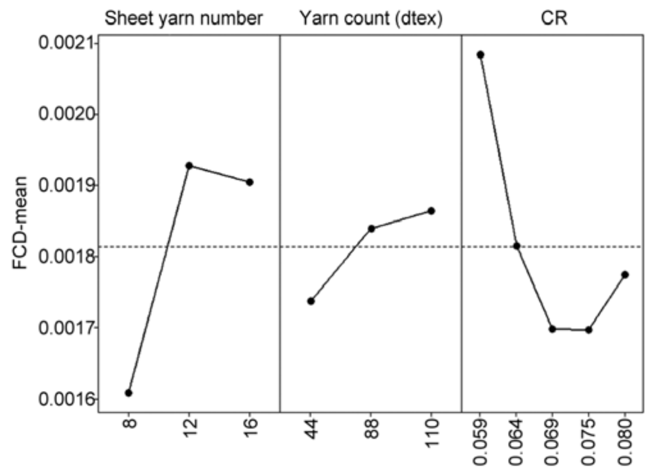

Fig. 1—Main effect plot of braiding parameters on FCD-mean

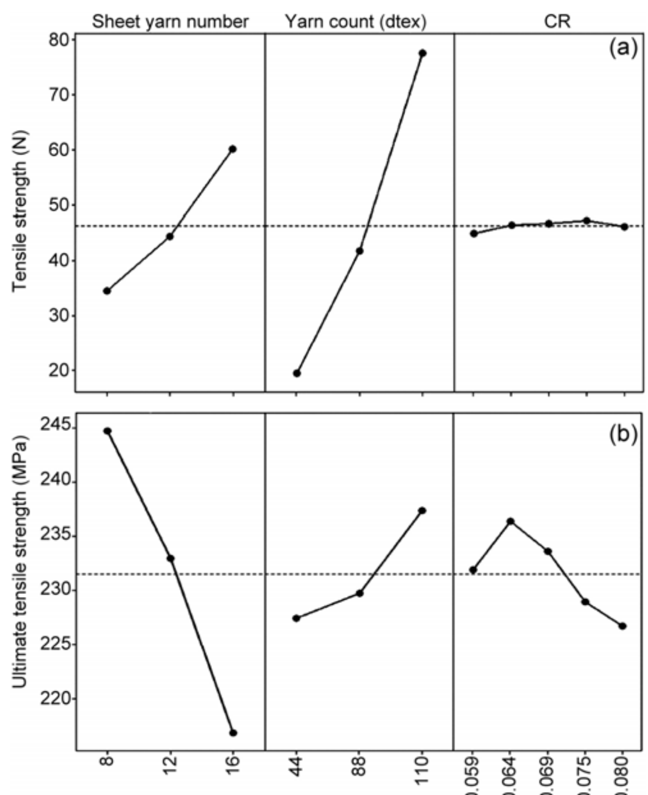

Fig. 2—Main effects plot of braiding parameters on (a) tensile strength, (b) UTS

However, this parameter has a small effect on UTS. This can be explained by the fact that UTS is affected by suture diameter which has nonlinear behaviour as function of CR. Increasing CR to 0.064 leads to reduce of suture diameter, while suture diameter increases at CR levels higher than 0.064 due to yarn relaxation in braid in the output of braiding machine. Consequently UTS drops by increasing CR.

Tensile strength is proportional to sheet yarn number and yarn count. The PA 6-6 count is the most influencing parameter on the tensile strength. These findings are similar to those mentioned byJedda *et al*. [17]. From Fig. 2, it can be observed that UTS is inversely proportional to sheet yarns number, whereas UTS is proportional to yarn count. This can be explained by the fact that UTS is inversely proportional to diameter. UTS decreases with increasing diameter, caused by the increase in sheet yarns number

3.1.3 Effects of Braiding Parameters on the Young's modulus

Figure 3 shows plots of main effects of braiding parameters on Young's modulus of the PA 6-6 suture. The value of the Young's modulus drops rapidly when the yarn count passes from 44 to 88 dtex and when sheet yarn number increases from 8 to 16, and finally it continues to decline slowly. This phenomenon is explained by the increase in the inclination of filaments relatively towards the braid axis caused by an increase in cover factor of the braid under the effect of increasing yarn count and sheet yarn number. Indeed, as the filaments are inclined relatively towards braid axis, the braid deformation becomes easy at low tensile forces, generating consequently, a decrease in Young's modulus.

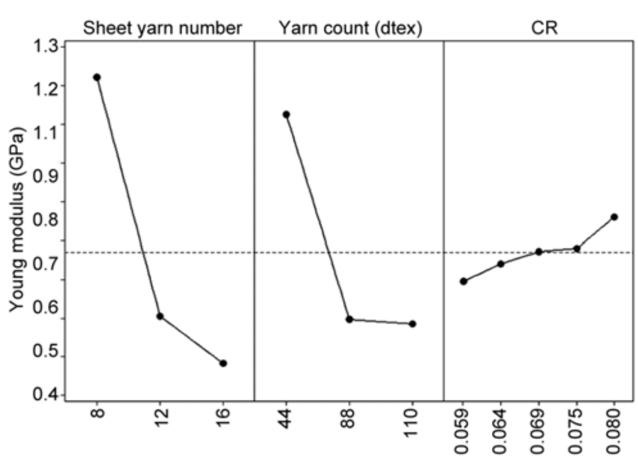

Fig. 3—Main effects plot of braiding parameters on Young's modulus

Regarding the effect of CR, Young's modulus increases by increasing CR. It has been demonstrated by Jedda *et al*. [17] that a decrease in braid angle leads to an increase in stiffness. This is due to the fact that, when the braiding angle decreases, yarns become more parallel to the braid axis and less undulated in the braid. So, the deformation of the braid under low forces becomes difficult and the Young's modulus increases accordingly. Rawal *et al*.[14] proves the same findings related to the impact of filaments orientation during the tensile test on Young's modulus. This has also been reported by Alpyildiz[25], who studied the geometry of tubular braids.

3.1.4 Effects of Braiding Parameters on Extension-at-break

The yarn count and sheet yarn number are the most influential parameters for affecting extension at break (Fig. 4). The increase of extension-at-break generated by the increase in sheet yarn number and yarn count is explained by the increase of the cover factor which is linked to the increase of braiding angle. Indeed, the increase of yarn count or sheet yarn number in the same unit length creates denser structure (high cover factor). This has been theoretically demonstrated in the work of Rawal *et al*.[14], who showed that the elongation of the braid is proportional to the cover factor. This factor is directly influenced by the diameter and number of filaments composing the braid. Furthermore, the decrease in extension at break with increasing CR is related to the decrease of the braid angle. This has been also report in a previous work [26, 27].

In the light of above findings, a mathematical model has been developed with multiple linear

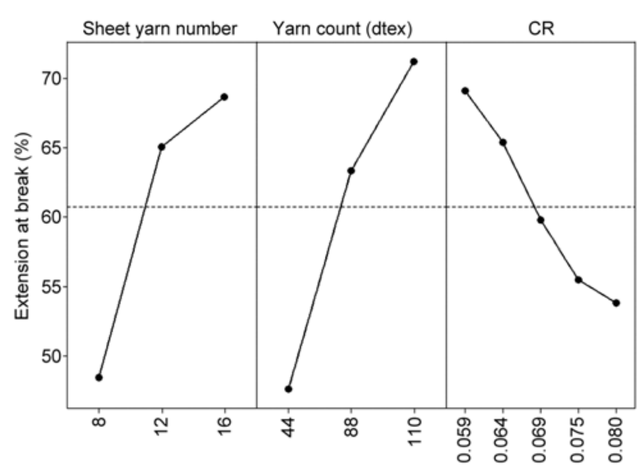

Fig. 4—Main effects plot of braiding parameters on Extension at break

regression method connecting braiding parameters to the studied mechanical properties of suture.

3.2 Prediction of Mechanical Properties of Suture Using Multiple Linear Regression Method

The aim of this prediction is to preview manufacturing parameters values permitting to obtain a suture having optimal mechanical properties which satisfy surgeon needs. Prior to the development of mathematical models, we have to check if the mechanical properties studied for different samples follow a normal distribution. Thus, Ryan-Joiner (RJ) normality tests have been performed for each property and proved their normal distribution. Indeed, linear regression coefficient RJ close to 1 confirms the existence of a significant difference between measured properties of suture samples produced by different braiding parameters.

Linear regression models are used to predict each suture mechanical properties. The identification of significant parameters is performed through Student test. Thus, parameters which have p values lower than significance level ($p < 0.05$) are considered in the model. We note that the remaining effects have p values inferior than 0.05. Table 2 shows models obtained by linear regression for diameter (*Y*1), tensile strength (*Y*2), extension at break (*Y*3), Young's modulus (*Y*4) and FCD-mean (*Y*5). Based on R^2 and p values, the statistical significance of the models has been proved.

Results presented in Table 2 show that extension at break, Young’s modulus and FCD-mean are related to the three manufacturing factors, while diameter and tensile strength are only related to yarn count and sheet yarn number. Except the case of FCD-mean, the R^2 values are higher than 90 % which is very significant. R^2 of FCD-mean is 75.26 % which can also be considered significant.

3.3 Simultaneous Optimization of Suture Mechanical Properties

Response surface designs are frequently used with linear models to perform predictions. This method is used to predict manufacturing values allowing to obtain a suture having optimal mechanical properties respecting the US pharmacopoeia requirements and also satisfying preferences listed in literature[15, 28]. Two dimensional contour plots of response surfaces present plotted curves of established model in terms of two factors (xi, xj). These plots permit to display two design factors (xi, xj) on the plot. All remaining factors are held constant. In our case, three models are presented by three factors, whereas two models contain two factors. So, yarn count and sheet yarn number are the two used factors to draw surface contours plot, while the CR is kept constant equal to 0.08, 0.069 and 0.059.

Figure 5 shows an example of the obtained contour plots and the response surfaces in the case of suture having USP number 2-0.In order to determine the combination of predictor manufacturing parameters for which the responses are optimized, we used the hypotheses presented in Table 3 which permits to meet the requirements of the US Pharmacopeia for diameter and tensile strength. The limits intervals of Young's modulus and extension at break are selected more rigorously than for marketed sutures cited in the literature [28]. Because of the lack of information on accepted limits of the friction coefficient for sutures, FCD-mean limit is purposely chosen as low as possible.

Table 2—Linear regression models relating braiding conditions and sutures mechanical properties of PA 6-6 suture

Parameters	Y1		Y2		Y3		Y4		Y5	
	a_i	p	a_i	p	a_i	p	a_i	p	a_i	p
Constant	0.368	0.001	28.06	0.000	63.67	0.000	0.50	0.000	$1.80\ 10^{-3}$	0.000
Sheet yarn number	0.079	0.000	12.20	0.000	10.04	0.000	-0.37	0.000	$0.11\ 10^{-3}$	0.048
Yarn count	0.100	0.002	29.01	0.000	11.77	0.000	-0.27	0.000	$0.06\ 10^{-3}$	0.006
Cogwheel Ratio (CR)	-	-	-	-	-8.00	0.000	0.07	0.004	$0.14\ 10^{-3}$	0.040
Sheet yarn number*Sheet yarn number	-	-	2.94	0.001	-6.51	0.000	0.25	0.000	-	-
Yarn count * Yarn count	-	-	18.54	0.000	-	-	0.19	0.000	-	-
CR*CR	-	-	-	-	-	-	-	-	-	-
Yarn count * Sheet yarn number	0.018	0.000	5.61	0.000	-	-	0.06	0.019	$0.325\ 10^{-3}$	0.000
Sheet yarn number *CR	-	-	-	-	-4.36	0.000	-	-	-	-
Yarn count *CR	-	-	-	-	-	-	-	-	-	-
R^2	94.73%		98.83%		90.46%		91.45%		75 .26%	

a—Coefficient and p—The p-value for each term tests the null hypothesis that the coefficient is equal to zero (no effect).

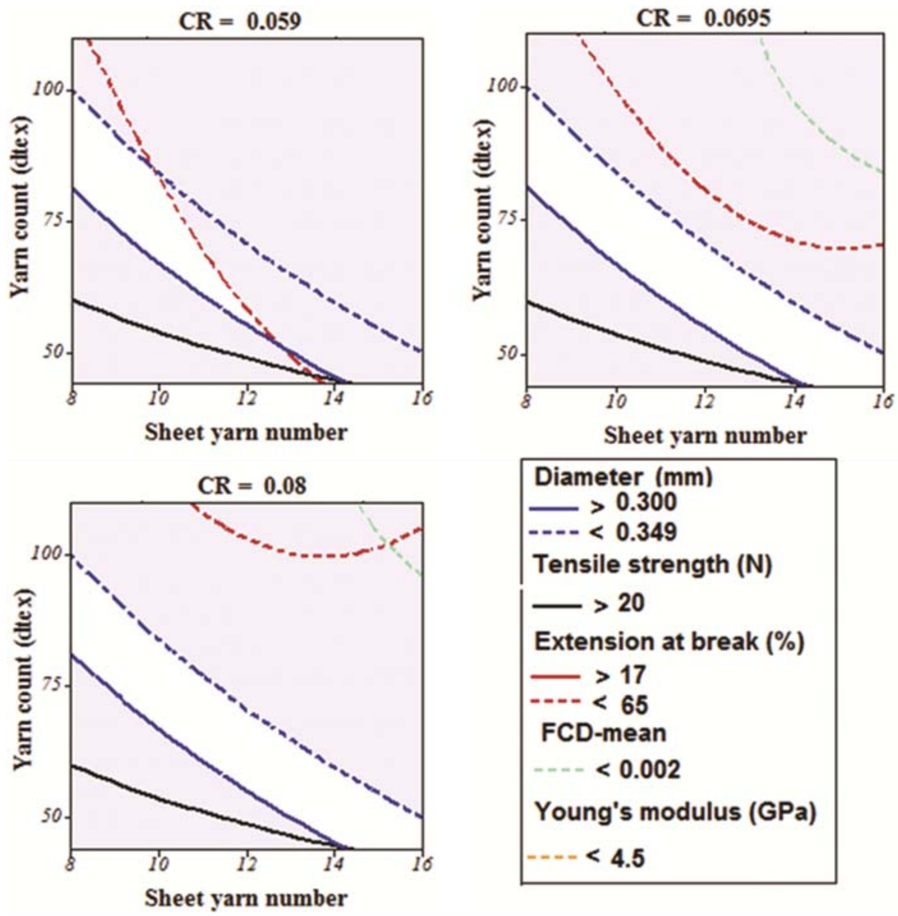

Fig. 5—Simultaneous contours plots of mechanical properties of braided sutures having USP 2-0

Table 3—Desired mechanical properties intervals as a function of USP number

USP number	Diameter, mm	Tensile strength, N	Extension-at-break, %	Young's modulus, GPa	FCD-mean
3-0	> 0,20 et < 0,299	>13	> 17 et < 65	< 4,5	< 0,002
2-0	> 0,30 et < 0,349	>20	> 17 et < 65	< 4,5	< 0,002
1-0	> 0,35 et < 0,399	>28,4	> 17 et < 65	< 4,5	< 0,002
1	> 0,40 et < 0,499	>35,6	> 17 et < 65	< 4,5	< 0,002
2	>0,50 et < 0,599	>50	> 17 et < 65	< 4,5	< 0,002

Table 4—Braiding conditions for obtaining optimal properties

USP number	Sheet yarn number	Yarn count, dtex	CR
3-0	8	44-56	≥ 0.0695
		56 - 80	0.059-0.08
	12	44-54	0.059 – 0.08
2-0	8	82-100	0.059 – 0.08
	12	56-70	≥ 0.0695
	16	44-50	≥ 0.0695
1-0	8	100-110	0.059 - 0.080
	12	72-86	≥ 0.0695
	16	50-62	≥ 0.0695
1	12	87-102	= 0.080
	16	64-89	= 0.080
2	16	92-97	= 0.080

Optimal zones are shown non colored in contours plots. Braiding conditions determined from the areas of compromise are summarized in Table 4 for each USP number. Thus, for each USP number, the optimal manufacturing conditions, sheet yarn number, the yarn count and CR can be determined. This is of big practical interest for suture manufacturers who can determine easily manufacturing conditions that allow to obtain precise suture performances.

4 Conclusion

The main objective of this study is the investigation of the effect of yarn characteristics (yarn count) and machine parameter (CR, sheet yarn number) on the braid mechanical properties (tensile strength, ultimate tensile strength, extension at break, Young's modulus and FCD-mean). Several braids have been manufactured from different yarns in order to be used as PA 6-6 suture. It is found that the yarn count and sheet yarn number are most significant parameters.

Linear regression model is used in order to predict mechanical properties as function of manufacturing conditions. Simultaneous surface plots are then generated in order to optimize mechanical properties of suture. Finally we identified conditions permitting to produce optimal sutures having properties which meet USP requirements related to tensile strength and diameters and better performances than those of marketed sutures.

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