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Investigation of the Basic Dimensional Properties and Biomechanical Performance of Artificial ACL Grafts Produced by 3-D Braiding Method

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Article

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ABSTRACT

In the current study, an investigation of basic dimensional properties and biomechanical performance of artificial ACL grafts produced by the 3-D braiding method was carried out. Artificial ACL grafts were produced using the 3-D braiding process. All 3-D braiding grafts were produced using various technical yarns for raw and bio-finishing grafts. Ethylene oxide (EtO) sterilization was applied to all grafts. The effects of yarn types, yarn counts, and 3-D braiding constructions on EtO sterilized raw and bio-finished artificial ACL grafts were examined. In conclusion; the tensile strength and thickness values of all 3-D braiding structured ACL grafts were suitable for artificial ligament grafts. Additionally, its grammage values were extremely light. The yarn type, yarn count, and 3-D braiding construction were the most effective process parameters on thickness, grammage, and tensile strength values. They can be improved by using x2-layered 3-D braiding structures, thicker yarn counts, and more than 1 core yarn in similar studies to be conducted in the future.

KEYWORDS

ACL graft, dimensional properties, biomechanical performance, 3-D braiding, bio-finishing

INTRODUCTION

Artificial ACL grafts have been used with synthetic-based technical yarns and 3-D braiding structures since the early 1970s. This study was the first study on 3-D braiding structures using technical yarns applied to the chitosan bio-finishing process in the world. ACL ligament tape has 2 functions, to prevent the tibia from rotating forward on the femur and to protect normal bio-mechanical knee motion to prevent meniscus damage. The length of the ACL ligament band, which consists of numerous and usually collagen filaments, varies between 31 mm and 38 mm. Its diameter varies between 10 and 12 mm [1]. Its structure consists of extracellular matrix (ECM) and fibroblast cells that can migrate there. In ligaments, there are 28 types in total, with I and III-type collagen fibres being common [2]. Ligaments have a length varying between 25 mm and 35 mm and a diameter of cylindrical geometry between 4 mm and 10 mm. Ligaments have cross-sections that taper from the ends to the middle. The

position of the native ACL ligament in the knee from the femoral space to the tibia is anterior (front), medial (middle), and distal (distant), respectively [3-6].

When the biomechanics of the natural ACL graft is examined, it consists of 3 behaviours. It consists of the finger (toe) as the first region, linear (linear) as the second region, and yield as the third region [7]. The characteristic viscoelastic behaviour of the ligament depends on the persistent creep, tension relaxation, and hysteresis behaviours in a time-dependent strain rate [8]. The maximum breaking force of 6 young people between the ages of 16 and 26 is 1730 N and the modulus of elasticity is 182 N/mm² [5,9]. They have between 600 N and 2400 N for their maximum breaking force, they have also between 9 mm and 11 mm for their lumen diameter, have low hysteresis, have tissue-core growth in the lumen, have dense structure, have inelasticity of the structure and have some per cent elongation at breaking in another resource. Their design criteria are such as biocompatible, biodegradable, biostable, high tensile strength of the yarns, high abrasion resistance, high radial strength, and tension-strain behaviour similar to the natural ACL ligaments. Moreover, they should be non-toxic, easy to use, high performance/low cost, and high tissue-inducing capacity [6,10,11]. It can be coated with chemicals such as CHI, HAp, and BG to accelerate graft healing by cross-linking with the GA chemical [5,12]. Knee stability, graft ruptures, risk of infection, pain, suffering, and loss of mobility are important situations for the graft healing process. Moreover, various other bio-mechanical tests such as fatigue strength and creep tests should be applied results with short, medium, and long-term in-vitro test results [12]. Teflon, Carbon, Goretex, Styker-Dacron, Leeds-Keio, Kenned-LAD, LARS, ABC surgicraft, and Mathys in ligamys as artificial ACL grafts lad were introduced in the early 1970s, but the majority of those made from synthetic-based raw materials were discontinued in the early 1990s. [6,12,13]. Artificial ACL grafts in biomaterials can be produced in tube form using natural or synthetic-based raw materials such as Col, Si, Ni, PE, PP, PA, PET, UHMWPE, PPD-T, PAA, PAc, PVDF, PTFE, PVA, PCL, PGA, PLA, PLLA, PLCL, PLGA, PMHB, PTFE, C and SS by using braiding, weaving, and knitting production methods, which are various textile production methods [5,6,11,12,14-26]. Production parameters of textile-based production methods used in biomaterial production are such as yarn types, yarn counts, filament numbers, inter-fibre friction forces, and biological, chemical, and mechanical properties of yarns, their construction and density values are important production parameters and are extremely effective on the bio-mechanical performance values of biomaterials. Physical properties such as thickness, grammage, tensile strength, shear strength, elasticity, modulus of elasticity, maximum breaking force, the maximum per cent elongation at break, energy absorption, packing degree of the yarns, shapeability, and dimensional stability vary [11,19-22]. A summary of the status of various commercial artificial ACL grafts can be seen in Table 1 [12,27-51].

Table 1. Summary of the status of various commercial artificial ACL grafts [12,27-51]

Graft name	Material	Textile Structure	Limitations	Maximum braking force (N)	Maximum modulus of elasticity (N/mm ²)	Maximum per cent elongation at break (%)
Natural ACL in the human body	Collagen autograft	Collagen tapes	Donor site morbidity, Low disease transmission, Low knee stability, Low motion function	2160	242	11.6
Gore-Tex	PTFE	Braiding structure in tube form with 24 braid yarns consisting of 3 twisted yarns	Inward wear	5300	322	9
Stryker Dacron	PET or PP	Woven structure in tube form with between 4 and 6 wrapped woven strips	Biased (anterior- posterior)	3631	39	18.7
Leeds-Keio	PET or PP	Woven structure in tube form	Degenerative changes	2200	200	35
Kennedy- LAD	PET or PP	Narrow woven strip with braiding structure	ACL cannot be used alone	1730	56	22
LARS	PET	High-twist woven construction	Bone tunnel expansion	4700	200	None
ABC surgicraft	PET or PET/C	Narrow woven construction with 24 braid yarns	Early breakouts	3130	None	None
Mathys in ligaments	PE or UHMWPE	1.8mm diameter for braiding structure	Early breakouts, Complications, Low knee stability	Belirtilmemiş	None	None

Braid yarns can be produced by the yarn carriers by moving half clockwise and the other half counterclockwise on the yarn path and performing all these movements on a minimum of 1 centre yarn in the axial direction, 3-D braiding structures can be produced [6,21,24,25,52,53]. Braiding constructions can be produced in 3-D tube and 2-D flat types.

In addition, it has production process parameters such as braid angle, volume ratio, unit cell, crossover region, undulation region, and matrix region. Braiding structures are produced generally in diamond, regular, and hercules braiding constructions [6,21,24,25,53-55]. The usage areas of braiding structures are biomedical and industrial, especially artificial vessels and surgical yarns [6,21,24,25,53,56]. The mechanical properties of braiding structures are determined by the number of braid yarn, yarn type, yarn count, filament number, braiding angle, braid yarn path length, and drafting speed. [6,24-26,53,55]. Especially, braiding structures in biomaterials are generally produced with 12, 16, 18, and 32 braiding yarn numbers, diamond or double-layer braiding structures, and various synthetic-based yarns with PET-dominated, which have thin yarn counts, and single-layer or double-layer structures. [23,25,55]. The advantages of the braiding production method are the high yarn ratio on the mandrel, the production of shapes with complex geometries, the installation with low capacity, and the minimum labour costs. The disadvantages of braiding structures are that they have a low braiding angle° and can be produced as preforms with complex geometry [21,23,25,26,53-56]. The thermal process is applied as a post-process after production to ensure dimensional stability in braiding structures [55]. There is a risk of infection or non-repairing, but they are more effective for the recovery function in the stability of the knee in braiding structures [6,55,56].

Temperature, time, pH, and the types and concentrations of auxiliary chemicals used are effective process parameters that vary depending on the raw material to be applied in the impregnation process [5,57,58]. Tensile strength values generally increase as the concentrations of auxiliary chemicals used and process times increase. Thus, the change in the types and amounts of atoms in the raw material and especially the increase in the number of C atoms [59].

Ideal biomaterials should be selected according to a specific area of use and subjected to a sterilization process. The sterilization stage is the final stage responsible for removing microorganisms from the surfaces of biomaterials. Ethylene oxide (EtO) sterilization is an extremely important process for the future uses of the human body. Therefore, the possible effects of EtO sterilization on the surfaces of biomaterials should be carefully studied [60]. It is the most widely used sterilization method in biomaterials due to its high penetration capacity and high efficiency at low temperatures. The relative humidity of EtO can vary between 40% and 80%, its gas concentration is between 450 and 1200 mg/L, its temperature is between 40 °C and 65 °C, and its exposure time can vary from a few hours to a few days [61,62].

The importance, innovation, and purpose of this study, it was based on the knowledge that 3-D braiding structures for artificial ACL grafts can be produced using various conventional or technical yarns and that they have basic dimensional tests and high bio-mechanical values at the required values.

The originality part, unlike other previous experimental studies, was carried out to determine the application of the bio-finishing process and what changes the bio-finishing processes cause in basic dimensional tests and bio-mechanical tests compared to the raw process.

EXPERIMENTAL

Materials and Methods

Materials

Ultra-high molecular weight polyethylene (UHMWPE), which is composed of long chains of ethylene monomers with high molecular weight, the aliphatic and semi-crystalline structure is a thermoplastic polymer. It has also high chemical and mechanical properties. Moreover, it is a biocompatible polymer [5,63]. Para-aramid (PPD-T), which is composed of at least 85% bonding of amide groups to 2 aromatic-structured benzene rings with a very long polymer chain, lyotropic liquid crystalline structure. It has also high thermal, chemical, and mechanical properties. Moreover, it is a biocompatible polymer [5,64].

Polyester (PET), which is composed of methylene, carbonyl, and ester groups with a very long polymer chain is a semi-crystalline structure. It has also high thermal, chemical, and mechanical properties. Moreover, it is a biocompatible polymer. HT PET has 0.8 times less amorphous region orientation than normal PET. Therefore, its mechanical properties are higher than normal PET. Glutaraldehyde (GA) is a biocompatible biological chemical that contains abundant aldehyde groups in its structure and is used as a biological crosslinker with chitosan for film forming in various experimental studies [5,65].

Chitosan (CHI), which is a fibrous biopolymer can be produced by the N-deacetylation process of chitin, which is abundant in shellfish such as crabs, crayfish, and shrimp. It has linear-chain N-acetyl-2-amino-2-deoxy-D-glucopyranose biopolymer with β -(1-4) bonding. It can be used as films, membranes, beads, and composite structures forms. It is an effective adsorbent with outstanding chelation behaviour to bind tightly with many organic and inorganic substances, including pollutants. However, pure chitosan has some obvious disadvantages such as low mechanical properties, chemical stability, and difficulty in recovering adsorbents from water after adsorption. The bonding of magnetic materials on chitosan together with other binding agents will prevent oxidation, improve stability, and facilitate the separation of the adsorbent from the reaction mixture [5,66].

As a result of theoretical investigations of UHMWPE, PPD-T, and HT PET have been widely used as raw materials thanks to their high tensile strength and use in biomedical applications. 3-D braiding structures are used as a common based on textile production method in biomedical applications.

Because they provide high tensile strength values in various axes and induce the growth of collagen fibres arising from their porous structure on the artificial graft.

CHI has been used in biomedical applications. Because, it is biocompatible, to increase biocompatibility, can be easily used in various forms, and supports the attachment and growth of collagen fibres. N-acetyl-d-glucosamine (2%) has been used in this experimental study thanks to its high dispersion and homogeneous distribution of CHI. Moreover, GA has been used as a biological biocompatible cross-linker thanks to its improved binding mechanism of CHI to inert raw grafts. Ethylene oxide (ETO) sterilization has been used thanks to its high penetration power at low temperatures and its widespread use in the biomedical field. Considering the tests applied by DIN EN ISO 13934-1 standard is available for tensile strength test [10].

Methods

In experimental this study, raw artificial ACL ligaments biomaterials were produced with 3-D braiding technology, and their sample codes include like these respectively that UHMWPE yarns, 3-D solid yarn form, 45 braid angles, a diamond of braiding construction, 1 piece of core yarn with 445 dtex and 16 pieces braid yarns with 445 dtex for braiding structures of T1 sample. UHMWPE yarns, 3-D solid yarn form, 45 braid angle, double braided of braiding construction, 1 piece of core yarn with 445 dtex, and 16 pieces braid yarns with 445 dtex for braiding structures of T2 sample. PPD-T yarns, 3-D solid yarn form, 45 braid angle, the diamond of braiding construction, 1 piece of core yarn with 1670 dtex, and 16 pieces braid yarns with 1670 dtex for braiding structures of T3 sample. PPD-T yarns, 3-D solid yarn form, 45 braid angles, double braided of braiding construction, 1 piece of core yarn with 1670 dtex, and 16 pieces braid yarns with 1670 dtex for braiding structures of T4 sample. HT PET yarns, 3-D solid yarn form, 45 braid angle, diamond of braiding construction, 1 piece of core yarn with 1670 dtex, and 16 pieces braid yarns with 1670 dtex for braiding structures of T5 sample. HT PET yarns, 3-D solid yarn form, 45 braid angle, double braided of braiding construction, 1 piece of core yarn with 1670 dtex, and 16 pieces braid yarns with 1670 dtex for braiding structures of T6 sample. All grafts were coded R for raw material form and B for bio-chemical finishing material form. Moreover, the purpose of T coding in this study was the aim was to observe the effects of the yarn types used, yarn counts (dtex) used, and braiding constructions used on their basic dimensional tests and biomechanical tests. The chemical recipe of bio-chemical finishing had some technical information like this liquid (Flotte) ratio: 1:10, Chitosan (85% in purity) with powder form 2%, N-Acetyl-D-Glucosamine (2% in purity) 7% with liquid form, Glutaraldehyde (99% in purity) with liquid form 25% and Acetic acid (80% in purity) with liquid form 1%.

Braiding production process

In the braiding production preparation, some technical yarn bobbins in the creel were transferred to the braid bobbins bypassing the control of the yarn tension meter. UHMWPE, PPD-T, and HT PET technical yarns were also used as core and braid yarns with different yarn counts (dtex) in their manufacturing process. The braiding production preparation process and braiding production process were carried out in Bursa Bağcı Elyaf and Apparel Materials Construction Industry Trade Limited Company in Bursa. The braiding production process can be seen in Figure 1, respectively.

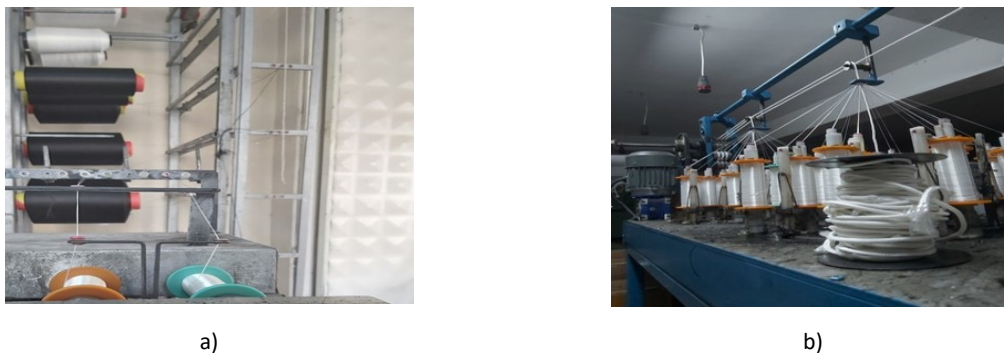


Figure 1. (a) Preparation process for 3-D braiding process; (b) 3-D braiding production process

Bio-chemical finishing process

pH values of the solution were measured by the P-510 portable pH meter of Peak Instruments INC. Solution ambient temperature was also measured with the help of a mercury thermometer (Maximum operating temperature was 115 °C). An all-in-one method was applied for the preparation of a bio-chemical solution. All biological chemicals, which have chemicals as liquid forms were prepared by the bath (flotte) recipe with the help of beakers. Grammage measurements were taken with the help of a grammage device for chemicals in powder forms and then added to the solution with the help of beakers were a liquor volume of 1 L. All chemicals were prepared by the bio-chemical finishing process recipe. Time (t) for 3 hours, the temperature of (T_{ort}) 70 °C, and between 5 and 5.5 for pH were determined in process parameters of the bio-chemical finishing of the chemical recipe. The bio-chemical finishing process was carried out at Bursa Technical University in Bursa. The colour change state of the bio-chemical solution was observed in the solution. Impregnation of the braiding grafts with a continuous method in a foulard made of glass material, which was a chemically inert and light polymeric material was applied as a process. It was applied to the impregnation process in 10 passages for 30 minutes for bio-chemical bonding of the braiding textile structures and the biological chemical solution. Bio-chemical finishing processes can be seen in Figure 2.

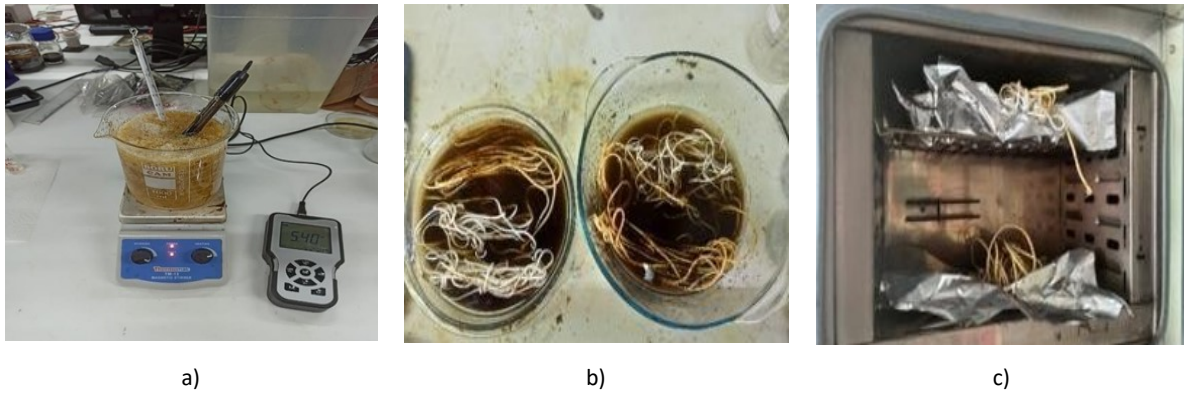


Figure 2. (a) Bio-solution preparation process; (b) bio-padding process; (c) bio-thermosetting process

After operations are PBS bio-chemical (in-vitro condition) process, fixing, and ethylene oxide (EtO) sterilization process

PBS biochemical was used to provide the in-vitro value of pH 7.2. 20 tablets were used for a total of 2 L, with 1 tablet equivalent to 100 mL of water. A total of 12 grafts are available. This post-treatment process was applied to all grafts twice. In total, 6 raw grafts 6 bio-chemical finishing processes, and separately EtO sterilization treated grafts were used. It was also subjected to thermal drying and fixation processes in an oven at 115 °C for 10 minutes at Bursa Technical University in Bursa. As the last operation, EtO sterilization was applied at the Çekirge State Hospital in Bursa with 1 atm pressure at 50 °C, and for 16 hours ambient conditions. Post-treatment processes can be seen in Figure 3, respectively.

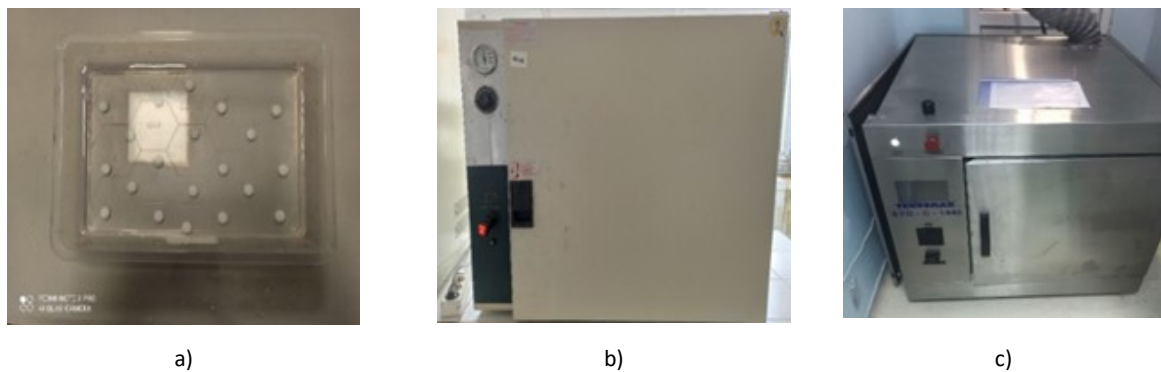


Figure 3. (a) Applied PBS chemical; (b) drying and fixing processes; (c) ethylene oxide (EtO) sterilization process

RESULTS AND DISCUSSION

Optical microscope images

Optical microscope images were taken with an Olympos brand instrument (x30) at Bursa Uludağ University. It is shown in Figure 4. Optical microscope images of raw and bio-finished with EtO sterilization for all grafts can be seen in Figure 5 and Figure 6, respectively.



Figure 4. Olympos brand optical microscope instrument (x30)

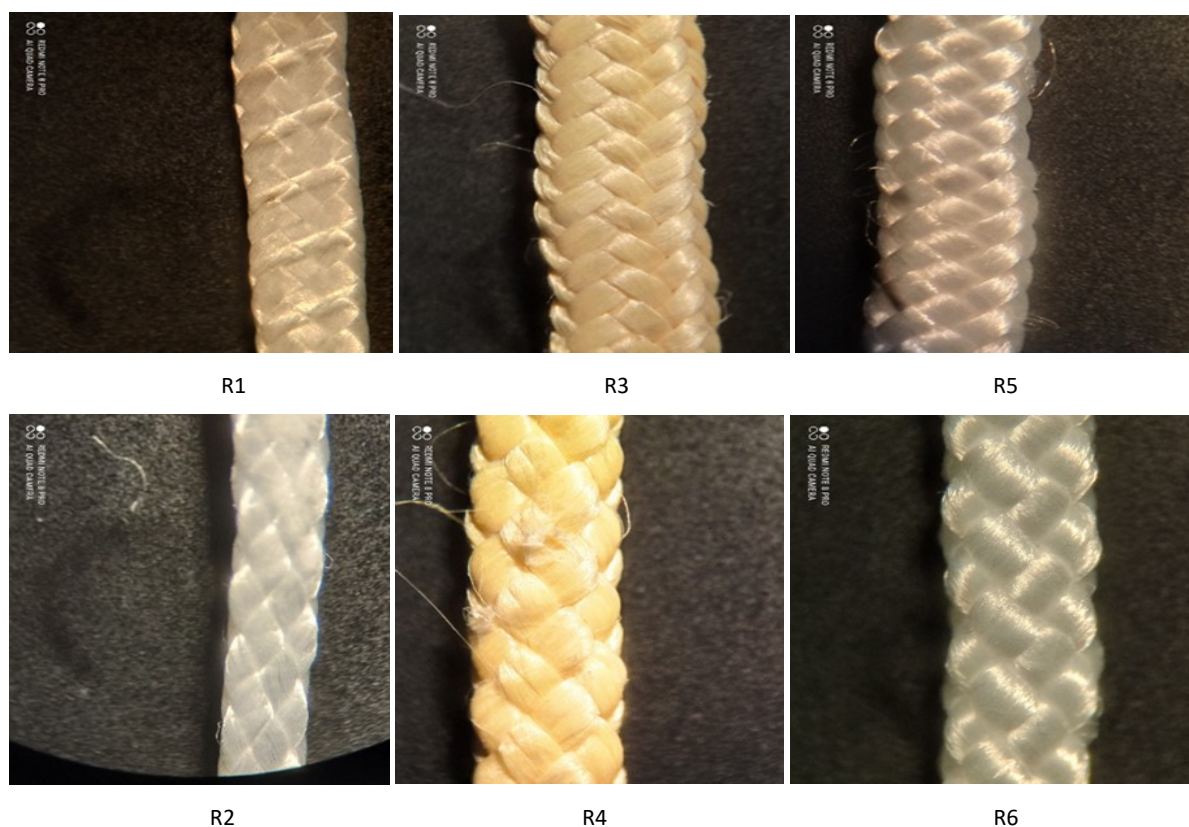


Figure 5. All raw (R) grafts (x6)

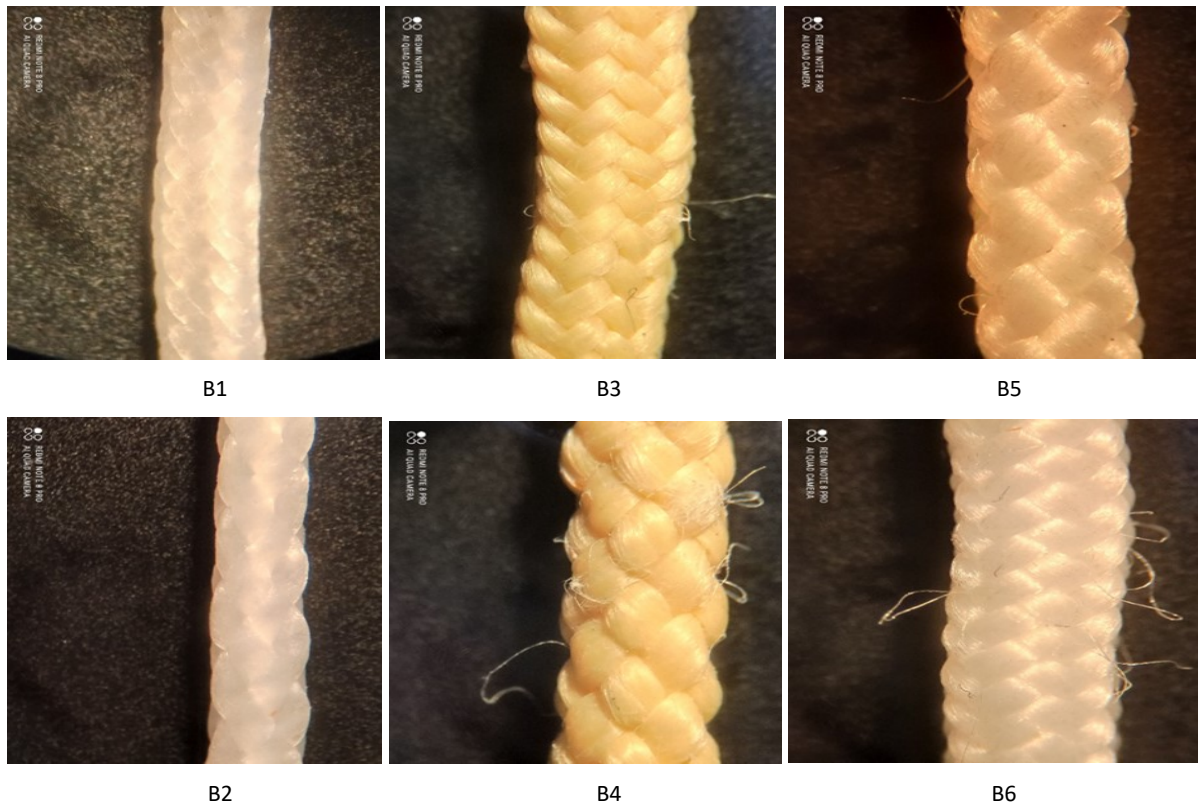


Figure 6. All bio-finished (B) grafts (x6)

Thickness (mm) and grammage (g/m) measurements

Thickness (mm) measurements were taken using the R&B Cloth Thickness Tester and grammage (g/m) measurements were also taken using a Mettler PJ 300 instrument at Bursa Uludağ University. They can be seen in Figure 7, respectively.



a)



b)

Figure 7. (a) R&B cloth thickness tester; (b) Mettler PJ 300 instrument

They had been carried out after 24 hours of conditioning under 1 atm atmospheric pressure. In addition, applied test conditions were 20 ± 2 °C as temperature and 65% as rH. Arithmetic averages of 5 replicates for 6 different grafts in 2 different conditions for raw and bio-chemical finished grafts were

taken so that the total grafts were 12 grafts. Thickness values (mm) and grammage values (g/m) of raw and bio-finished grafts are presented in Table 2.

Table 2. Thickness values (mm) and grammage values (g/m) of raw and bio-finished grafts

Sample code	Thickness values (mm) of raw (R) grafts	Thickness values (mm) of bio-finished (B) grafts	Grammage (g/m) values of raw (R) grafts	Grammage (g/m) values of bio-finished (B) grafts
T1	0.530	0.974	0.928	1.380
T2	0.610	0.936	0.896	1.233
T3	2.128	2.586	3.788	5.720
T4	1.888	2.652	4.336	5.560
T5	2.072	2.294	3.984	5.773
T6	2.100	2.316	3.968	5.120

Thickness values (mm) of raw grafts were T3 > T6 > T5 > T4 > T2 > T1 respectively and bio-finished grafts were also T4 > T3 > T6 > T5 > T1 > T2, respectively. Grammage values (g/m) of raw grafts were T4 > T5 > T6 > T3 > T1 > T2 respectively and bio-finished grafts were also T5 > T3 > T4 > T6 > T1 > T2, respectively. According to thickness (mm) changing ratios (%) results from highest to lowest like these were T1 > T2 > T4 > T3 > T5 > T6 respectively. According to grammage (g/m), changing ratios (%) results from highest to lowest like these were T3 > T1 > T5 > T2 > T6 > T4 respectively. Thickness and grammage changing ratios (%) of raw and bio-finished grafts were presented in Table 3.

Table 3. Thickness and grammage changing ratios (%) of raw and bio-finished grafts

Sample code	Thickness changing ratio (%)	Grammage changing ratio (%)
T1	+83.77	+48.70
T2	+53.44	+37.61
T3	+21.52	+51.00
T4	+40.47	+28.23
T5	+10.71	+44.90
T6	+10.28	+29.03

According to other experimental studies, the diameter of natural and artificial ACL grafts was between 10 and 12 mm. They had also between 4 and 10 mm. The length of artificial ACL grafts was between 31 and 38 mm. They had also between 25 and 35 mm. [3,4].

The thickness for all artificial ACL graft grafts was thinner than natural or artificial values in the human body due to some parameters in 3-D braiding structures such as their chemical structures, diameters, and filament numbers of fibres and yarns. The thickness values of all bio-finished grafts were higher

compared to all raw grafts. It was determined that diamond and double-layer structures did not affect thickness values and grammage-changing ratios. Lower thickness values were observed for UHMWPE structured artificial ACL grafts (T1 and T2), which had less filament count and finer yarn count. They had also the most sensitive and the highest thickness-changing ratios. It was determined that diamond and double-layer structures did not affect thickness values and thickness-changing ratios. Higher thickness-changing ratio values were observed for PPD-T structured artificial ACL grafts (T3 and T4) than HT PET structured artificial ACL grafts (T5 and T6), which had the same filament count and thicker yarn count. Because their yarn types and chemical structures were different. Yarn count was effective on the results of thickness and thickness-changing ratios. Moreover, the low thickness of all grafts will provide convenience in surgery no matter what reconstruction technique is applied in ACL reconstruction.

Their grammage values were not found in the literature. The grammage for all of the artificial ACL grafts was extremely low so they were light. The grammage values of all bio-finished grafts were higher compared to all raw grafts. It was determined that diamond structures had an effect on grammage values and grammage-changing ratios than double-layer structures. Lower grammage values were observed for UHMWPE structured artificial ACL grafts (T1 and T2), which had less filament count and finer yarn count (dtex). It was determined that diamond structures had an effect on grammage values and grammage-changing ratios than double-layer structures. Yarn count was effective on the results of thickness-changing ratios and grammage-changing ratios. Moreover, the low grammage of all grafts will provide convenience in surgery no matter what reconstruction technique is applied in ACL reconstruction. Yarn count was effective on results of thickness, thickness-changing ratios, grammage values, and grammage-changing ratios. Moreover, the low thickness and grammage of all grafts will provide convenience in surgery no matter what reconstruction technique is applied in ACL reconstruction.

Tensile strength results of bio-mechanical tests

It was aimed to determine the tensile strength bio-mechanical test results and the changes in the bio-mechanical structure of the produced biocomposite grafts before and after finishing EtO sterilization. They had been carried out after 24 hours of conditioning under 1 atm atmospheric pressure. In addition, the conditions of application of the tests were 20 ± 2 °C and pH: 6.5. The tensile strength tests were carried out on all grafts. After, arithmetic averages of 5 replicates for 6 different grafts in 2 different conditions like raw and bio-chemical finished grafts were taken and presented in Table 2. Thus, the total grafts were 12 grafts in a 5 kN capacity Shimadzu AGS-X Plus branded device in Fiber and Polymer Engineering - 2 laboratories at Bursa Technical University. Tensile strength test results were evaluated by DIN EN ISO 13934-1 standards. It can be seen in Figure 8.



Figure 8. Shimadzu AGS-X Plus universal test device

Tensile strength data results are presented in Table 4.

Table 4. Tensile strength results of raw and bio-finished grafts

Sample code	Maximum braking force for raw (R) grafts (N)	Maximum per cent elongation for raw (R) grafts (%)	Maximum braking force for bio-finished (B) grafts (N)	Maximum per cent elongation for bio-finished (B) grafts (%)
T1	909.399	46.932	643.550	39.763
T2	1191.330	35.858	577.924	29.469
T3	995.030	31.047	464.923	34.309
T4	1277.060	22.239	760.220	24.056
T5	1000.900	58.639	606.299	33.293
T6	1008.680	51.951	594.122	28.195

Maximum braking force (N) and maximum per cent elongation (%) changing ratios (%) of raw and bio-finished grafts (%) were also presented in Table 5.

Table 5. Maximum braking force (N) and maximum elongation (%) changing ratios of raw and bio-finished grafts (%)

Sample code	Maximum braking force (N) changing ratio (%)	Maximum per cent elongation changing ratio (%)
T1	-41.309	-18.029
T2	-106.139	-21.680
T3	-114.078	+9.507
T4	-67.985	+7.553
T5	-65.083	-76.590
T6	-69.776	-84.256

The single-layered production was used to produce artificial ACL graft grafts with 3-D braiding structure thanks to minimum raw material consumption, minimum energy consumption, minimum labour, and maximum bio-mechanical performance values in this experimental study.

In an experimental study, PTFE and PET yarns were used in yarn counts of 440, 113, 181, and 158 d tex. Narrow woven fabric grafts were produced. They were produced in warp density varying between 96 and 120 and weft density varying between 9 and 34. Then, it was processed with PBS chemicals to provide an in-vitro environment. In conclusion, all grafts had maximum breaking strength between 1200 and 1700 N and per cent elongation at the break between 8.3 and 26.6%.

Moreover, it was determined that yarn type, yarn count, and warp and weft density values affect the biomechanical properties of the artificial ACL graft [10]. When the tensile strength test results, maximum breaking force, and maximum breaking percentage elongation values for the ACL graft in humans in this experimental study were not suitable and lower values than the mechanical properties of commercialized artificial ACL grafts (between 1730 N and 5300 N and between 9% and 35%) [12,27-51]. Maximum breaking force values of raw grafts were $T4 > T2 > T6 > T5 > T3 > T1$ respectively and maximum per cent elongation at breaking values of raw grafts were $T5 > T6 > T1 > T2 > T3 > T4$ respectively. Maximum breaking force values of bio-chemical finished grafts were $T4 > T1 > T5 > T6 > T2 > T3$ respectively and maximum per cent elongation at break values of bio-chemical finished grafts was $T1 > T3 > T5 > T2 > T6 > T4$ respectively.

All raw grafts had higher maximum breaking force and lower maximum breakage percentage values compared to all bio-finished grafts (except for T3 and T4 grafts). Double-layer structures were found to have higher maximum breaking force and lower maximum breaking percentage compared to diamond structures in all raw grafts. It was determined that the double-layered structures had a higher maximum breaking force and low per cent elongation at break values compared to diamond structures for all raw grafts. Because double-layered constructions had longer pitch lengths and fewer pitch numbers than diamond structures in the 3-D braiding constructions.

Yarn type, yarn count, filament number, and 3-D braiding construction did not affect the maximum breaking force observed in all bio-finished grafts. The diamond structure was found to have a higher maximum breaking percentage compared to the double-layer structures in all raw and bio-finished grafts. Maximum breaking force changing ratios grafts results from the highest to lowest for differences of all grafts were $T3 > T2 > T6 > T4 > T5 > T1$ respectively.

The decrease in maximum breaking force was the most observed in the PPD-T sample (T3), which had diamond braiding construction. The decrease in maximum breaking force was the least observed in the UHMWPE sample (T1), which had diamond braiding construction. Moreover, a reduction in maximum breaking force above 100% was grafted in only 2 grafts.

These were the UHMWPE sample (T2), which had double-layer braiding construction, and the PPD-T sample, which had diamond braiding construction (T3). Thus, the effect of yarn type, yarn count, and braiding construction on the maximum breaking force change ratios was not observed, but they generally caused a decrease in the maximum breaking force change ratios.

Maximum per cent elongation changing ratios results from the highest to lowest for differences of all grafts were variable due to yarn type. While an increase was observed in PPD-T grafts (T3 and T4), which had diamond and double-layer braiding constructions, a decrease was observed in UHMWPE (T1 and T2) and HT PET (T5 and T6) grafts, which had diamond and double-layer braiding constructions. The decrease values in per cent elongation at breaking (%) were determined as $T6 > T5 > T2 > T1$ from the highest to the lowest, respectively. The increase values in per cent elongation at breaking (%) were determined as $T3 > T4$, from the highest to the lowest, respectively.

It was observed that the double-layer braiding construction was more effective on the decreased values in per cent elongation at breaking compared to the diamond braiding construction. Moreover, HT PET grafts (T5 and T6) were more effective in breaking compared to UHMWPE grafts (T1 and T2). Thus, the yarn type and braiding construction were effective on the decrease values in per cent elongation at breaking. HT PET sample (T6), which had double-layer braiding construction was the most affected by the decreased values in percent elongation at breaking. UHMWPE sample (T1), which had diamond-layer braiding construction was the least affected by the decreased values in percent elongation at breaking.

It was observed that the diamond braiding construction was more effective in increasing values in per cent elongation at breaking compared to the double-layer braiding construction. The increased values in per cent elongation at breaking were observed only for PPD-T grafts (T3 and T4). Thus, the yarn type and braiding construction were effective on the increased values in per cent elongation at breaking. PPD-T sample (T3), which had diamond braiding construction was the most affected by the increased values in percent elongation at breaking. PPD-T sample (T4), which had double-layer braiding construction was the least affected by the increased values in percent elongation at breaking.

In conclusion, it was determined that yarn type, yarn count, and braiding construction were generally effective on the tensile strength values of artificial ACL grafts. No sample suitable for the maximum breaking force ranging from 1730 to 5300, which was the tensile strength value stated in the literature, could be identified. [14,30-54]. Only PPD-T grafts (T3 and T4) in raw grafts were suitable for maximum per cent elongation at breaking.

When placing this artificial ACL graft in the femoral space between the femur and tibia bones, the graft material must be light, have high bio-mechanical values, be non-toxic, carcinogenic or allergic, support tissue adhesion and development at the tissue-graft interface, not slip, and are easy to use in artificial ACL graft reconstruction. It must be workable, and dimensionally stable but have some elasticity [8]. Moreover, all raw and bio-finished grafts produced were found to have suitable bio-mechanical values as artificial ligament grafts. (Maximum breaking force values ranging from 600 to 2400 N and diameter values varying from 9 mm to 11 mm) [10].

It is thought that the possible artificial ACL grafts that can meet these conditions can be PPD-T grafts (T3 and T4). To ensure this situation, all single-layer raw and bio-finished grafts must be produced as at least x2 layers. Thus, it will be observed that knee stability will increase and graft ruptures, risk of infection, pain, suffering, and loss of mobility will decrease, too. Moreover, various other bio-mechanical tests such as fatigue strength and creep tests will reveal more advanced results with short, medium, and long-term in-vitro test results. In addition, the types, concentrations, pH, temperatures, and duration of chemicals used are important and effective parameters.

The type of yarn used, yarn count, braiding construction, bio-finishing recipe chemical type, concentration, pH, temperature, and time can be changed for the next artificial ACL ligament studies.

Statistical analysis results of bio-mechanical tests

The analyses of variance were executed to predict the significance of the process variables (x2). Their interaction form was presented on both raw and bio-finished artificial ACL graft groups with a 99% confidence level. Process variables were yarn type, yarn count, or braiding construction. Non-repetitive two-factor ANOVA analysis was calculated in the Excel 2013 program.

Non-repetitive two-factor ANOVA analysis for thickness values

Statistical results for non-repetitive two-factor ANOVA analysis for thickness values were calculated in Table 6.

Table 6. Statistical results for non-repetitive two-factor ANOVA analysis for thickness values

Anova: Two Factors Without Replication						
Conclusion	Say	Total	Average	Variance		
Line 1	2	1,504	0,752	0,098568		
Line 2	2	1,546	0,773	0,053138		
Line 3	2	4,714	2,357	0,104882		
Line 4	2	4,54	2,27	0,291848		
Line 5	2	4,366	2,183	0,024642		
Line 6	2	4,416	2,208	0,023328		
Column 1	6	9,328	1,554667	0,589436		
Column 2	6	11,758	1,959667	0,625961		
ANOVA						
Variance Source	SS	df	MS	F	P-value	F criterion
Lines	5,972654	5	1,194531	57,24716	0,000206	10,96702
Columns	0,492075	1	0,492075	23,5824	0,004649	16,25818
Error	0,104331	5	0,020866			
Total	6,56906	11				

The process parameters of yarn type, yarn count, or braiding construction (x2 factors) were significant, and effective on the thickness values for both raw and bio-finished artificial ACL grafts groups. Because the P-value was <0.01.

Non-repetitive two-factor ANOVA analysis for grammage values

Statistical results for non-repetitive two-factor ANOVA analysis for grammage values were calculated in Table 7.

Table 7. Statistical results for non-repetitive two-factor ANOVA analysis for grammage values

Anova: Two Factors Without Replication						
Conclusion	Say	Total	Average	Variance		
Line 1	2	2,308	1,154	0,102152		
Line 2	2	2,129	1,0645	0,056785		
Line 3	2	9,508	4,754	1,866312		
Line 4	2	9,896	4,948	0,749088		
Line 5	2	9,757	4,8785	1,600261		
Line 6	2	9,088	4,544	0,663552		
Column 1	6	17,9	2,983333	2,605891		
Column 2	6	24,786	4,131	4,84153		
ANOVA						
Variance Source	SS	df	MS	F	P-value	F criterion
Lines	36,15037	5	7,230075	33,26519	0,000766	10,96702
Columns	3,951416	1	3,951416	18,18026	0,007986	16,25818
Error	1,086733	5	0,217347			
Total	41,18852	11				

The process parameters of yarn type, yarn count, or braiding construction (x2 factors) were significant, and effective on the grammage values for both raw and bio-finished artificial ACL grafts groups. Because the P-value was <0.01.

Non-repetitive two-factor ANOVA analysis for maximum breaking force values

Statistical results for non-repetitive two-factor ANOVA analysis for maximum breaking force values were calculated in Table 8.

Table 8. Statistical results for non-repetitive two-factor ANOVA analysis for maximum breaking force values

Anova: Two Factors Without Replication						
Conclusion	Say	Total	Average	Variance		
Line 1	2	1552,949	776,4745	35337,85		
Line 2	2	1769,254	884,627	188133,5		
Line 3	2	1459,953	729,9765	140506,7		
Line 4	2	2037,28	1018,64	133561,8		
Line 5	2	1607,199	803,5995	77854,97		
Line 6	2	1602,802	801,401	85929,17		
Column 1	6	6382,399	1063,733	19461,46		
Column 2	6	3647,038	607,8397	9201,133		
ANOVA						
Variance Source	SS	df	MS	F	P-value	F criterion
Lines	105505,7	5	21101,13	2,790616	0,142227	10,96702
Columns	623516,7	1	623516,7	82,45981	0,000271	16,25818
Error	37807,31	5	7561,461			
Total	766829,6	11				

The process parameters of yarn type, yarn count, or braiding construction (2 factors) were significant, and effective on the maximum breaking force values for both raw and bio-finished artificial ACL grafts groups. Because the P-value was <0.01.

Non-repetitive two-factor ANOVA analysis for percent of maximum elongation at breaking values

Statistical results for non-repetitive two-factor ANOVA analysis for the per cent of maximum elongation at breaking values were calculated in Table 9.

Table 9. Statistical results for non-repetitive two-factor ANOVA analysis for per cent of maximum elongation at breaking values

Anova: Two Factors Without Replication						
Conclusion	Say	Total	Average	Variance		
Line 1	2	86,695	43,3475	25,69728		
Line 2	2	65,327	32,6635	20,40966		
Line 3	2	65,356	32,678	5,320322		
Line 4	2	46,295	23,1475	1,650745		
Line 5	2	91,932	45,966	321,2099		
Line 6	2	80,146	40,073	282,1738		
Column 1	6	246,666	41,111	188,7302		
Column 2	6	189,085	31,51417	29,96848		
ANOVA						
Variance Source	SS	df	MS	F	P-value	F criterion
Lines	713,3293	5	142,6659	1,876373	0,253215	10,96702
Columns	276,2976	1	276,2976	3,633927	0,114933	16,25818

Error	380,164	5	76,0328
Total	1369,791	11	

The process parameters of yarn type, yarn count, and braiding construction were not significant, and effective on the per cent of maximum elongation at breaking values for both raw and bio-finished artificial ACL grafts groups. Because the P-value was > 0.01 .

Thus, process parameters such as yarn type, yarn count, or braiding construction were significant, and effective factors in the thickness, grammage, and maximum breaking force values for both raw and bio-finished artificial ACL grafts groups. However, they were meaningless and did not affect the per cent maximum breaking elongation values for both raw and bio-finished artificial ACL grafts groups.

CONCLUSION

As a result of statistical ANOVA analysis, the significance and effect of some process parameters on the results of thickness, grammage, and tensile strength tests applied to all artificial ACL graft groups were examined. Thus, the yarn type, yarn count, or braiding construction were generally significant and effective on the thickness, grammage, and tensile strength values of artificial ACL graft groups except for per cent maximum breaking elongation values for both raw and bio-finished artificial ACL grafts groups. No sample was suitable for use as an artificial ACL graft, but it was suitable for use as an artificial ligament graft. Moreover, grafts of the PPD-T as yarn type can be considered more suitable for use as an artificial ligament graft. All grafts must be produced in x2 layers to have appropriate bio-mechanical values. Thus, it will be observed that knee stability will increase and graft ruptures, risk of infection, pain, suffering, and loss of mobility will decrease, too. Moreover, various other bio-mechanical tests such as fatigue strength and creep tests will reveal more advanced results with short, medium, and long-term in-vitro test results. In addition, the types, concentrations, pH, temperatures, and duration of chemicals used are important and effective parameters. Finally, The type of yarn used, yarn count, braiding construction, bio-finishing recipe chemical type, concentration, pH, temperature, and time can be changed for the next artificial ACL ligament studies.

Conflicts of Interest

The author declares no conflict of interest.

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