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Mini Review

Development of a Textile Suture with Improved Properties

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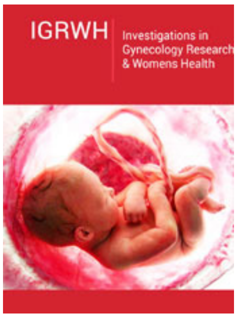

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Abstract

In any surgical procedure, a suture is considered crucial. In the case of post-operative are the wound closure related to surgical procedure continues to pose a problem. Presently, Oxidized Regenerated Cellulose (ORC) is being commonly used in the absorption of hemostatic materials. But ORC medical suture product is not commercially available. It has been aimed to produce innovative braided suture by TEMPO-mediated Oxidation Regenerated Cellulose (TORC) so as to obtain a suture material having and perfect in mechanical properties. A circular braiding machine has been used to produce sutures from regenerated cellulose strands. The braiding is followed by TEMPO-mediated oxidation treatment as an option. Various investigation techniques that include ATR-FTIR, electrical conductivity, XRD analysis, physical properties and *in vitro* degradation properties have been used to characterize the sutures under various oxidation time. It has been further shown that the RC sutures have been oxidized and formed the carboxylic (-COOH) functional group. There has been a gradual increase in the carboxyl content in the case of TORC sutures due to extension of oxidation time. This has been accompanied by a gradual reduction in the strength, weight, and diameter of TORC sutures. Also, it is established that the knot pull strength of the TORC declined after 4 weeks. It has been shown that TEMPO oxidation reaction significantly promoted the degradation of TORC sutures. Overall, TORC sutures were successfully produced with favorable biodegradability, revealing potential prospects of clinical applications.

Keywords: Biodegradability; Characterization; Surgical sutures; Oxidized regenerated cellulose; *In vitro* degradation; Tensile strength

Introduction

Suture materials have a wide range of applications in the surgical field. The demand for suture is growing by millions of dollars annually [1]. The purpose of a suture is to stabilize the wound and promote natural healing [2]. Therefore, optimal biocompatibility and mechanical properties are necessary for ideal suture materials. Based on their degradation properties, sutures can be divided into absorbable and non-absorbable sutures [2,3]. Non-absorbable sutures need to be removed from the human body after the wound has healed. Removing sutures from deep tissue involves a second injury, making the procedure more painful for patients. Moreover, removing sutures in pediatric patients or difficult-to-access anatomical areas is clinically challenging. In this context, absorbable sutures do not need to be removed after surgical procedure, this may help reduce the patient's pain avoiding suture removal [4,5]. At the early stages of biodegradable sutures, catgut [6], collagen [7], Polyglycolic Acid (PGA) [8,9], poly (p-dioxanone (PDS), and Poly (Lacticco-Glycolic Acid (PGLA) [10] have been widely studied due to their excellent biocompatibility. The main component of catgut sutures is collagen derived from animal intestine by a complex preparation process, which is then treated with chromium salt solution to become a chromic gut, which can resist the digestion of various enzymes in the body and extend the absorption time to over 90 days. The polypeptide structure of the collagen molecule can degrade under the effect of lysozymes. In 1970, Postlethwait et al. [11] introduced the first synthetic absorbable PGA suture [11], which is absorbed by hydrolysis *in vivo*. The difference between this PGA suture and the catgut suture is the PGA degradation mechanism. Although cellular enzymes can accelerate the breakdown of the PGA suture, this suture induces milder local inflammatory reactions and more complete absorptivity than the catgut suture [12]. PGLA suture was first marketed in 1974 as a copolymer of glycolic acid that contains 90:10 units of glycolic acid per lactic acid respectively. PGLA suture requires a multi-strand preparation, which has the characteristics of fast absorption and protection. The fastest absorption in absorbable PGLA sutures have the disadvantages of decreasing the tension by 50% from 5 to 6 days after the surgery, and also the effective wound support time was from 10 to 14 days. Each PGLA fiber is coated separately, eliminating the rough edges of the suture in order to tow the tissue and cause minimal damage and resulting in a smooth knot and wound support that can be extended from28 to 35 days. In comparison, both PGLA and PGA sutures may incite a faint inflammatory reaction, but these reactions are less severe than those induced by catgut. PDS is the only absorbable suture that provides wound support up to 6 weeks, as it could support a wound that was 56 days old and was completely absorbed by the body within 180 days after surgery. In 1980, PDS sutures were first introduced, and their mono filament structures differed from the braided structures of PGA and PGLA. PDS required a significantly longer timing for strength retention and thorough absorption than both PGA and PGLA [13]. PDS evokes an inflammatory response that is less acute than the catgut and PGLA sutures [14]. However, the suture's preparation methods are complex, and the price of raw materials is relatively high.

Cellulose is a renewable natural polymer, and it has been widely used in various fields for more than 100 years. Cellulose is a polysaccharide with crystalline structure, and it is abundant primarily in wood biomass [15]. Due to its biocompatibility, Oxidized Regenerated Cellulose (ORC) is widely used in the biomedical field for constructing adhesion barriers, absorbable hemostats or scaffolds for tissue engineering which advantage is the lower cost, wide raw material sources and simple preparation method. Recently, it has been mainly used in hemostasis due to its broad-spectrum antimicrobial properties [16]. Through oxidation with nitrogen tetroxide (N_2O_4), cellulose can produce ORC [17]. Nitrogen dioxide (NO_2) is the most suitable oxidant for this product because oxidation with NO_2 does not affect the secondary hydroxyl groups of cellulose, thus avoiding secondary reactions. In this case, satisfactory mechanical properties of the oxidized cellulose are maintained, allowing the material's use for creating a biomedical device.

Fabrics made of oxidized cellulose are used for surgical applications because they are bioresorbable and hemostatic. The first industrial process of the oxidation of cellulose involved gaseous nitrogen dioxide, which was disseminated across layers of fabrics [18]. However, this process was later abandoned due to the strenuousness of handling a gas (especially when its atmospheric condensation point is 21 °C, as it is the case for NO_2) and the difficulty of mastering the exothermicity of the reaction in a gaseous system under industrial conditions [19]. As a result, nitroxyl radicals, including 2,2,6,6- tetramethylpyperidine-1-oxyl (TEMPO), that are water-soluble, and stable have been widely investigated while studying catalytic and selective oxidations of polysaccharides' primary hydroxl groups under aqueous conditions [20]. Due to its good hemostatic property, biodegradability and non-toxicity, ORC, as a derivative of cellulose, has made beneficial clinical effects on the medical field [21,22].

The ORC is contributing greatly to the adhesion barrier field because products with ORC (Intercede; Ethicon, Somerville, NJ) have been effective in preventing postoperative adhesions in abdominal surgical procedures [23]. INTERCEED®, a form of ORC, is a knitted fabric that has shown success in healing wounds to prevent postsurgical adhesions [24]. When the ORC is surgically implanted *in vivo*, it forms a bio absorbable physical barrier between adjacent tissues. During this process, the ORC endures gradual mechanical changes: first hydrating, then swelling into a gel-like material, and eventually dissolving and disappearing from the site of implantation. Such controlled degradation is essential for scaffolds in tissue engineering applications [25,26], and the process is equally important for absorbable sutures [2,27-30]. The objective of this study was to optimize the novel formulation of braided RC suture materials that involve TEMPO-mediated oxidation. The carboxyl content was controlled by different times of oxidation. The physical properties of TORC, including straight-pull tensile, knot pull tensile strength, diameter, and *in vitro* degradation property were obtained. The U.S. Pharmacopeia required the knot-pull tensile strength to be measured for all samples. This study aimed to investigate the clinical applications of novel braided TORC suture materials.

ATR-FTIR characterization

The ATR-FTIR spectra of the RC suture with different oxidation times have been determined. The peak has been observed at 3400 and 2890cm^{-1} and has been due to the stretching vibration of O\\H, and the asymmetrical and symmetrical stretching vibration of -CH_2. The absorption at 1653cm^{-1} was contributed to the bending vibration of the absorbed H_2O, and the absorption around 1049cm^{-1} was due to the stretching vibration of C-O-C. Furthermore, there is a new characteristic absorption appearance at 1749cm^{-1} which was caused to the CO of carboxyl group. Thus, it could be direct inferenced that the RC had been oxidized TORC with a certain amount of carboxyl group content [31,32].

Carboxyl content of TORC sutures analysis

In materials for bioabsorbable sutures, the carboxyl content is an important performance index of the oxidized regenerated cellulose that must be between 4 and 12.5% [33]. The carboxyl content increases with longer oxidation time, also it increases at a greater rate during the initial period of the oxidation reaction, and when the oxidation reaction reaches a certain degree, the growth of carboxyl content becomes slower. This is due to the existence of a crystalline region and an amorphous region in regenerated cellulose. During the initial stage of the reaction, the oxidant can rapidly penetrate into the amorphous region, and the reaction mainly occurs in the amorphous region and the surface of the crystalline region. A large number of primary hydroxyl groups is present during this stage, thus the oxidation reaction occurs fast, and so does the growth of carboxyl content. Once the primary hydroxyls in the amorphous region were completely oxidized, the reaction mainly occurred on the surface of the crystalline region and inside the amorphous region. Because the cellulose molecular chain in the crystalline region was closely arranged, it was difficult for the reaction medium to destroy the crystalline structure of cellulose. In this case, there is a small number of primary hydroxyls, and as a result both the reaction and the growth of carboxyl content occur slowly. Considering the performance of the product in terms of saving energy, the best oxidation duration was 45min.

XRD characterization

It has been confirmed that a certain amount of carboxylate groups was formed in the TORC suture. However, the crystal structure of cellulose I, the crystallinity indices, and the crystal sizes of RC remained unchanged after the oxidation different times [20,34,35]. These results show that the formed carboxylate groups by TEMPO-mediated oxidation, without change internal cellulose crystallites, were selectively present on cellulose microfibril surfaces.

Suture's weight and diameter characterization

The changes in weight (n=5) and diameter (n=10) of the RC sutures with different oxidized times have been determined. For all the test groups, the total weights and diameters continued to decrease with the increase of oxidized time, but the weight value began to stabilize when the oxidized time exceeded 45min. The results showed that some mass loss was caused by the oxidation reaction.

Tensile strength, knot-pull tensile strength and friction coefficient of RC and TORC suture analysis

The knot-pull tensile strength of all the tested sutures demonstrated values higher than 10.0 N for all TORC sutures, exceeding the required strength by the USP 37 [29]. However, the knot-pull tensile strength values decreased significantly with longer oxidation times. Moreover, when analyzing the decrease of suture diameters, the intensity of the knot-pull tensile strength was calculated by a conversion because the intensity values of all sample declined, and the intensity values of the TORC-90 suture showed a particularly large decrease compared to RC and other TORC sutures.

With the extension of oxidation time, the breaking strength of the material decreased gradually. On the other hand, more primary hydroxyls were transformed into carboxyl during the oxidation reaction. Since the volume of carboxyl is larger than that of hydroxyl, the hydrogen bond between cellulose molecular chains was gradually broken with an increase in oxidation time, thus increasing the distance between molecular chains. As a result, inter-molecular attraction was reduced, thereby decreasing the monofilament strength. On the other hand, the macromolecular chain broke, resulting in the decrease of material monofilament strength. Another possible cause of this phenomenon is that during the oxidation reaction, the originally smooth surface of the regenerated cellulose monofilament may have gradually etched until the etching degree became more severe with the extension of oxidation duration, thereby increasing local stress concentration and leading to the decrease of material monofilament strength [36]. Capstan experiment procedure for friction characterization of surgical sutures is has been determined. After TEMPO-mediated oxidation treatment, TORC sutures have the lower friction coefficient than the RC suture. Adding oxidation time showed a negative impact on friction performance of TORC sutures, but there is no continuity to worse of the friction performance. This can be due to the TEMPO mediated oxidation only on the fiber surface and the oriented structure of the fiber is not destroyed too much.

Evaluation of *in vitro* degradation

One of the properties of the viscose fiber is that it has a high flexibility and extensibility, therefore, the slight decrease in extensibility after oxidation should not compromise the application of the fibers. The knot-pull tensile strength of the sutures before and after physiological saline impregnation at different days was also evaluated because this is a deterministic component in surgical sutures. The flexibility of the suture was down slightly after the physiological saline impregnation, as evident from the data obtained. The knot-pull tensile strength of all TORC sutures is relatively lower than RC suture. The reason for this difference may be the etching that occurred during the oxidation process. It has been shown that After 14 days of incubation period, the RC suture showed a dry weight loss of 2.11% and tensile strength loss of 61.5%.

The oxidation suture showed a dry weight loses of 3.05%, 3.01%, 3.17%, 4.21%, 4.83% and knot-pull tensile strength losses of 60%, 70%, 66.6%, 55.5%, 60% to TORC-15, TORC-30, TORC-45, TORC-60 and TORC-90, respectively. After TEMPO oxidation, RC structures of primarily hydroxyl turn into carboxyl and lead to increases in molecular chain spacing and the reduction in molecular inter-atomic forces. As a result, water can easily enter the inner region of the fiber and the fiber may easily swell during hydrolysis, causing the fiber to break. In consequence, TORC sutures were divided into short fibers and dissolved in a saline solution. However, if the content of carboxyl group is low, such as TORC-15 and TORC-30, numerous hydroxyl groups still remain in the fiber structures, and the hydrogen bond between them prevents the material from swelling completely. The results show that the TORC-45 suture after 28 days of incubation period achieved stable mechanical properties, with a knot-pull tensile strength of 2±0.3N which meets the required strength mandated by the United States Pharmacopeia (USP) [29].

Conclusion

This research studied physical and handling characteristics of novel oxidized regenerated cellulose braided sutures, using knot-pull and straight-pull tensile strengths. Through TEMPO-mediated oxidation, the TORC medical suture with controlled carboxyl content was obtained. We demonstrated that the braided TORC medical sutures exhibit ideal knot-pull tensile strength. In general, TORC-45 showed relatively stable knot security and ease in knot sliding. The quantitative test results indicated that TEMPO-mediated oxidation significantly influenced the physical and handling characteristics. Moreover, during the *in vitro* hydrolysis, TORC-45 showed satisfactory physical and handling characteristics. Future studies will be conducted to analyze the fineness ratio of the shell and core strands during braiding to decrease the occurrence of weak links and enhance the knot-pull tensile strength in TORC sutures.

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