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Additional Information

Selective laser fiber welding on woven polymer fabrics for biomedical applications

T. Rodts^a, S.R. Schmid^a, M.A. Selles^b, T. Pasang^c, S. Sanchez-Caballero^b

^a*Department of Aerospace and Mechanical Engineering, University of Notre Dame, Notre Dame, IN 46556, USA*

^b*Department of Mechanical and Materials Engineering, Universitat Politècnica de València, 03801 Alcoy, Spain*

^c*Auckland University of Technology, Auckland, New Zealand, NZ*

Abstract

Localized cartilage damage is a common problem for younger patients. This can heal, but often results in a painful condition that requires intervention. A welded-woven three-dimensional polymer fabric has been suggested as a suitable cartilage replacement because such materials closely match the mechanical properties of cartilage. However, such materials fare poorly when evaluated with respect to wear. A microscopic investigation of wear mechanisms showed that it is critical that the fibers not deflect laterally under a normal load. This observation led to the use of a new process for selective laser welding of the surface layers of three-dimensional fabrics in order to improve their wear resistance. Experimental evaluations were made in a pin-on-disc arrangement with a biomimetic loading. All materials used in the studies have previously been used in orthopaedic devices or meet the requirements for United States Pharmacopeial Convention (USP) Class VI biocompatibility approval. The wear rates were significantly reduced and the lifespan of the fabrics was markedly improved due to surface welding, making this a viable option for cartilage replacement in vivo.

Keywords: Laser; Biomaterial; Polymer; Cartilage

1. Introduction

With the great advances in medical care in the past few decades, life expectancies have been considerably increased, but so have expectations in quality of life and that effective health care treatments exist for all maladies. One of the reasons for the realized improvements in quality of life has been the great success of orthopedic implants in the past forty years. Hip, knee, shoulder, spine and other implants have resulted in increased activity and reduced pain for millions of people worldwide. Advances in medical technology have led to a continuing increase in life expectancy, and as the baby boomers continue to age, the number of orthopedic operations is sure to rise in the next twenty years.

Treatment of senior patients is well-established; total joint replacements for the knee and hip as well as shoulder, elbow and ankle, spine fixation devices, and bone fracture fixation devices have been developed and are remarkably successful. Not as much attention has been directed towards younger patients. Certainly, as implant technology has been improved and their useful lives extended, ever younger patients have become candidates for orthopedic implants. However, the community of users is still essentially limited, even though orthopedic ailments are common to middle-aged and younger patients. Too often, people are told to “live with the pain” because treatments do not exist for them, or else surgeons fear the consequences of revision surgery later in the patients’ lives.

Even for seniors, the availability of orthopedic treatments requires a high level of pain before a surgeon will resort to implantation. This is understandable; modern implants work very well, but require painful surgery and rehabilitation. The possibility of premature implant failure is always a concern. Thus there is a real need for a new class of orthopedic implants, which provide less invasive solutions than total joint replacements, are intended for younger or healthier patients, and which are designed for obsolescence with the intention of eventual repair or application of a total joint replacement.

Advances in materials and designs have extended the useful life for total knee replacements (TKRs), so that modern implants are approaching two decades of useful average life. This is a welcome development, since revision of TKRs is more invasive and painful than initial TKRs, and the success rate and expected useful lives are lower. The recognized reluctance to require multiple revisions in a patient drives surgeons to delay first application of TKRs until the patient is either of sufficient age or until their natural joint becomes unbearably painful, as discussed above.

At the same time, life expectancies are increasing, so that a younger patient – which can even include an individual in their 50s or 60s – has no treatment option other than to live with the pain. There is an entire class of individuals that are thought to be too young for TKRs who receive no effective care as a result. In addition, there are very young individuals, in their 20s and 30s, who damage cartilage or their meniscus that cannot currently receive medical treatment. Often, a meniscectomy will be performed, with the realization that the individual will require a TKR, perhaps in as little as a decade or so.

An alternative to a TKR is an implant that effectively provides a new surface to the damaged areas of the femoral condyles and/or tibia compartments. An illustration of a candidate solution is shown in Figure 1, that exploits the material properties and capabilities of three-dimensional weaving. The implant is envisioned as a local correction to damaged cartilage, and as such should be pictured as a slug roughly 10-15 mm in diameter. In this way, it would be surrounded and partially anchored by cartilage.

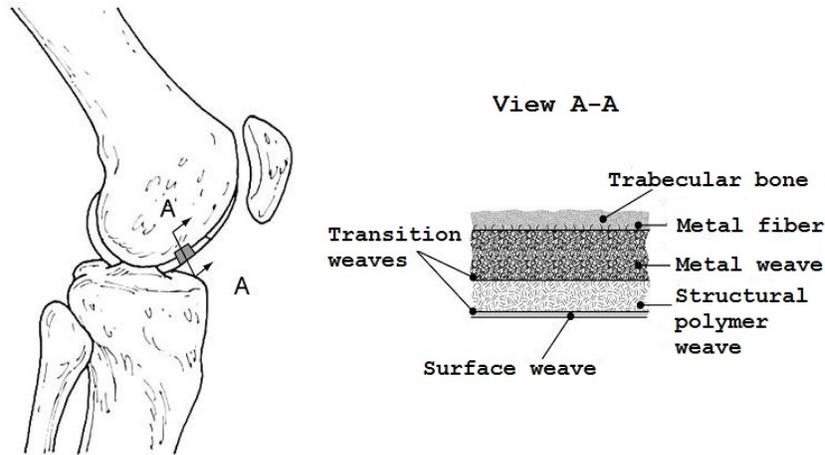


Figure 1: Schematic illustration of the cartilage repair implant, shown on the knee. Some of the design features that can be incorporated into advanced weaving processes are shown on the right.

Some of the features of the spot-cartilage repair implant are:

- The implant requires that the subchondral bone of the femur or tibia be removed, exposing the trabecular bone under the subchondral exterior.
- Adjacent to the trabecular bone is a three-dimensional woven titanium material with numerous loops cut and pulled from the surface. The effect is similar to Velcro™, where the loops grab onto and affix to the porous trabecular bone and locate the implant in the knee. Note that this implant encounters mainly compressive stresses, and is further anchored by surrounding cartilage, so that no significant forces are present to dislodge the implant.
- The broken loops transition to a metal weave with a morphology, stiffness and porosity that facilitates osseointegration or bone ingrowth. Experience with osseointegration suggests that a material with roughly 50-70% porosity and an open-celled structure with cells roughly 0.5 mm in diameter performs well.
- The material then transitions from an osseointegration zone to a structural zone, where polymer and metal weaves are blended to provide a combination of strength and compliance. The use of a polymer structure allows the implant to provide soft elastohydrodynamic lubrication, a significant advantage over TKRs, as discussed later.
- The outside of the material consists of a zone with tribopolymers, perhaps consisting of hydrogel weaves or blends of hydrogels and structural polymers.

2. Woven materials in orthopedics

Fabrics have previously been proposed for orthopaedic uses, both as tissue engineering constructs and as synthetic implants. Braided collagen fabrics were proposed as a canine anterior cruciate ligament (ACL) replacement while knitted collagen fabrics were proposed as a rat abdominal tissue construct [1]. A three-dimensional braided polylactide-co-glycolide (PLAGA) was constructed and assessed for use as a bioresorbable tissue-engineered scaffold for ACL reconstruction [2]. Mechanical properties of the scaffold were documented to be similar to those of a natural ACL as well as showing potential for both tibial and femoral bone ingrowth [2].

Arjmandi et al. [3] studied the friction and wear properties of interpenetrating polymer network alginate-polyacrylamide hydrogels for use in joint implants. They have found that polymer networks (mixed with hydrogels) are focused as the very first attempt to assess them as synthetic cartilage.

Synthetic Achilles tendon replacements were created from braided chitin, poly- ϵ -caprolactone (p-CL) and polylactic acid (PLA) for implantation in rabbits [4]. Both the PLA and hybrid chitin/p-CL tendons exhibited acceptable tissue ingrowth and tensile strength [5]. Woven polyethylene terephthalate (PET) fabrics were used as a scaffold to generate a tissue engineered tendon replacement [5].

A 3D porous pennisetum purpureum (PP)/polylactic acid (PLA) based scaffold was produced and characterized with good properties for construction of implantable tissue-engineered cartilage [6]. Senatov et al. [7] developed a material based on ultra-high molecular weight polyethylene (UHMWPE). They increased the wear-resistance in three different samples, and found that they can be suitable for cartilage replacement as well.

Tri-axial three-dimensional ultra-high molecular weight polyethylene (UHMWPE) fabrics were proposed as synthetic implants for cartilage, meniscus and intervertebral disc replacement [8]. These fabrics exhibited mechanical behavior similar to cartilage and intervertebral discs in compression, torsion and tension. Compressive stiffening similar to natural cartilage was documented [8].

A synthetic three-dimensional artificial disc replacement based on the previous work of Shikinami and Kwarada in 1998 was developed and analyzed with both in vitro and in vivo tests [9]. The replacement is designed to press-fit between cervical vertebral bodies and remain in place with the help of bioresorbable pins that protrude from both sides of the artificial disc. The artificial disc surfaces were coated with hydroxyapatite to promote bonding and bone ingrowth [9]. The artificial discs exhibited good dynamic performance over 105 million cycles of in vitro testing with no wear debris detected [9].

Rodts [10] investigated this system, and evaluated the constrained stiffness of woven materials, demonstrating their suitability for use as a spot cartilage replacement. The main problem with using three-dimensional woven materials for cartilage replacement applications is that their wear performance is lacking.

Wear test results for a polyester, more specifically polyethylene terephthalate (PET) woven material is shown in Figure 2 using a pin-on-disk arrangement.

The wear is initially acceptable, but an increasing wear rate is noticed after around 2.5 million cycles. Careful examination shows that the wear is due to individual fibers being displaced laterally, snagging, and flattening under the normal loads. It became readily apparent that a strategy to prevent lateral fiber motion would have beneficial wear effects.

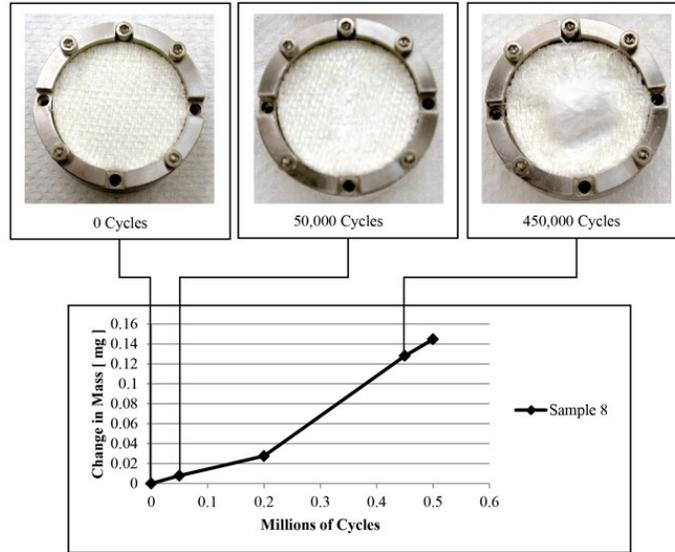


Figure 2: Typical wear results for a conventional woven PET orthogonal woven material. As can be seen, the damage at around 0.5 million cycles is due to fiber pullout and lateral deflection.

3. Selective welding of woven materials

Strength and wear of polymers welds has been investigated by Shi et al. [11, 12], and determined the quality of the welds studying the process of void generation.

Laser transmission welding is sometimes used to weld polymers, but is not useful for fibers because of the laser wavelength and fiber sizes involved. Most polymers are transparent to laser radiation at wavelengths in the range of 1,000 nm [13]. As a result, energy can be transmitted through polymer workpieces with little effect. In order to weld, a component at the desired weld interface must absorb the laser radiation. Laser welding can commence if one or both polymers is transparent so long as an energy absorbing medium is located at their interface. As the energy is absorbed, both the absorbent polymer or medium and the transparent part are heated, melted and bonded through diffusion [14]. Cosson et al. [15] developed a numerical analysis of thermoplastic composites laser welding using ray tracing method. They focused on the energy absorption in the transparent substrate during ray tracing simulation.

Laser welding has been previously demonstrated as a successful joining method for medical implant applications [16, 17]. Titanium and polyimide have been successfully joined using a laser welding technique for use in bioencapsulation devices using near infrared lasers [18]. Stainless steel and polyethylene terephthalate glycol have also been successfully welded together using a Nd:YAG laser [19].

A solution for the laser radiation energy absorption in polymers is the use of a material, or toner, coating the fiber or impregnated within the fiber. The toner is designed to absorb the laser energy and cause heating, allowing welding to take place on a fiber scale. A commercially available biocompatible toner, Clearweld[®], was used in this research. The Clearweld[®] material can be used in coating or impregnation form. The Clearweld[®] coating is designed for wavelengths between 940 and 1000 nm.

A typical orthogonal weave is shown in Figure 3. One can readily imagine a woven material that has some fibers, say the binding fibers, infiltrated by Clearweld[®] as the fibers are spun. These fibers would be heated by the laser, while other fibers would be unaffected, allowing selective lasing of fibers. This was the strategy used to restrain lateral deflection of fibers during wear testing.

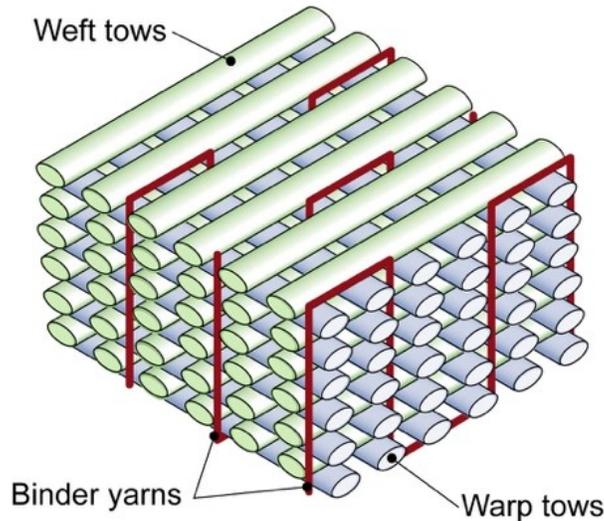


Figure 3: Orthogonal weave, showing weft and warp tow directions and binder yarn. No oblique weaves are considered in this paper.

As its name suggests, the Clearweld[®] material allows for a completely clear weld interface. The Clearweld[®] material is consumed as it absorbs the energy of the incident laser beam. As a result, once the weld is completed at a certain depth, the laser radiation passes through the weld zone and to subsequent lay-

ers. It is possible to produce graded material structures in this manner, since the location of Clearweld®-containing fibers is controllable during the weaving process.

The approach allows for all fibers to be treated after weaving by dissolving the toner in a carrier, infiltrating the woven material, and then evaporating the carrier fluid. This coating approach was used in this research, using acetone as a carrier fluid.

Welding of fibers was investigated to determine the proper laser power and exposure; insufficient exposure led to no welding or a weak joint, while excessive exposure led to fiber damage (Figure 4). With proper laser settings, consistently good welds could be produced in the fibers. Rodts [10] gives details on the lasing study, including a design of experiments approach to determine optimum laser parameters.

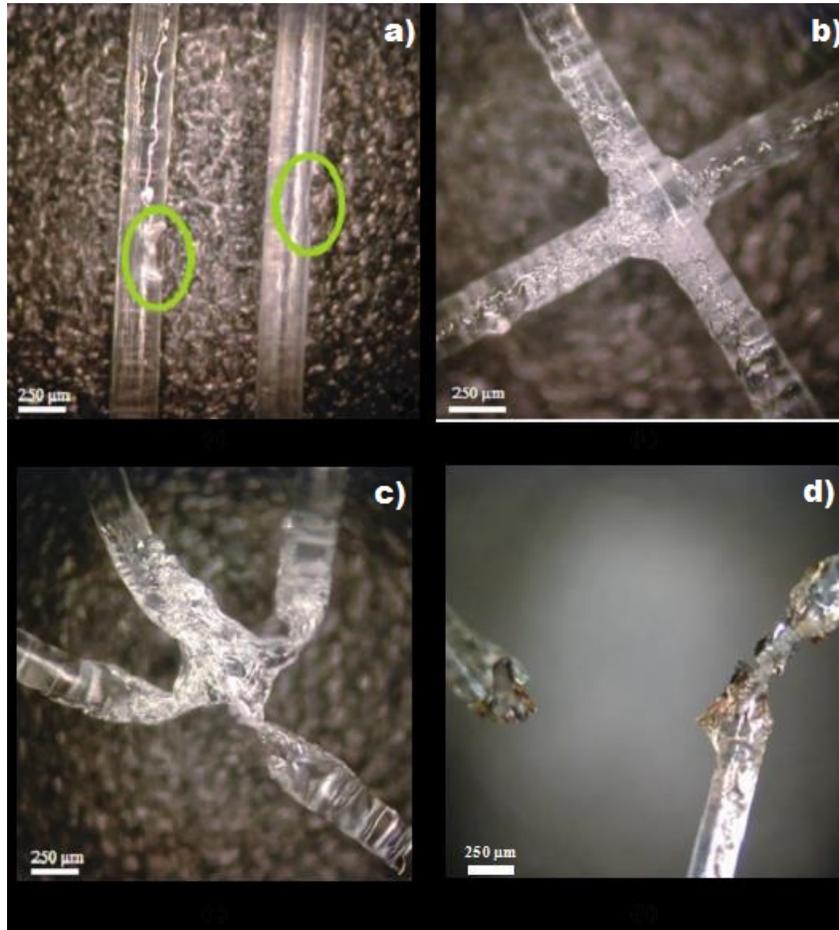


Figure 4: Examples of fiber-fiber welding with a toner. (a) insufficient laser power, leading to poor adhesion; (b) strong weld; (c) and (d) fiber damage resulting in poor weld strength.

4. Wear testing

A six-station pin-on-flat wear tester (Orthopod, Advanced Mechanical Technology, Inc., Watertown, MA, USA) was used for the wear study. A load-velocity profile was developed that mimics the human gait cycle [20].

The 2-phase profile design mimics the stance phase of gait, with a slower velocity and a heavier load, and the swing phase, with faster velocity and a lighter load. The test used a 0.785 seconds (1.27 Hz) cycle [20]. As numerous studies have reported knee simulator tests of tibial inserts that operate at frequencies of 1-2 Hz [21–24], this cycle is appropriate.

Polymer fabric samples and a cobalt chrome pin (tip radius of 12.7 mm) comprised the tribopair. Pins were weighed 3 times before each testing interval.

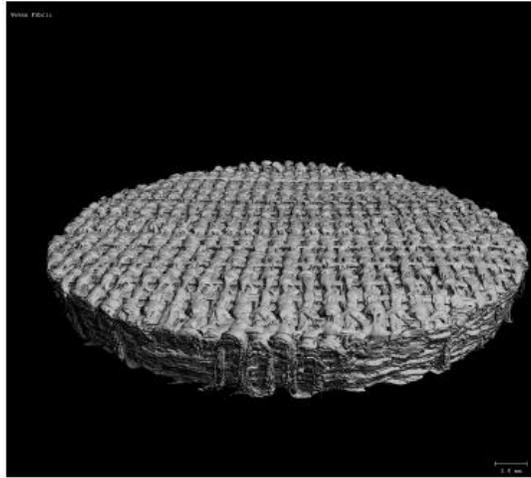
Table 1: Fabrics studied in pin-on-disc wear testings.

Fabric	Material	Description
SN 3786	PET	200 Denier orthogonal weave 18 y-direction ends High density in picks
SN 3787	PET	200 Denier orthogonal weave 18 y-direction ends Low density in picks
SN 3825	UHMWPE	200 Denier orthogonal weave 24 y-direction ends 2 layers dyneema 220 dTex 5 harness satin finish added to protect stitching

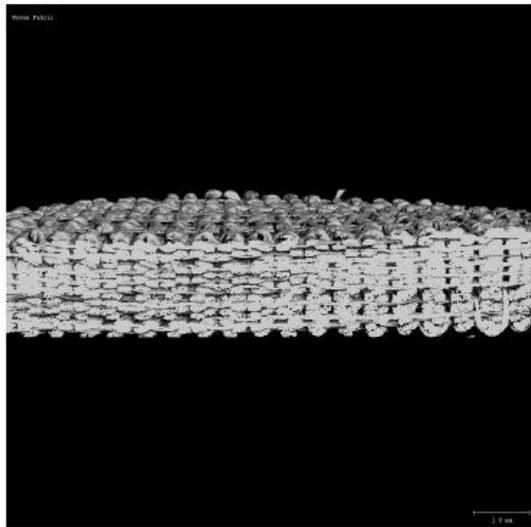
Within all the testing intervals, each pin’s surface roughness was measured by a NewView 7000 Series Optical Profiler (Zygo Corporation, Middlefield, CT, USA).

The woven materials considered are summarized in Table 1.

Before each test, the control samples and fabric assemblies were cleaned (ASTM F2025-06). A stream of deionized water rinsed samples before they were placed in the test apparatus and submerged in deionized water. Containers were sealed and laid inside an ultrasonic bath for 5 minutes. Samples were removed and re-rinsed with a stream of deionized water before being returned right-side up to the plastic containers, which were filled with deionized water and finally sealed. Samples were processed as follows: sonicated for 15 minutes and re-rinsed in a stream of deionized water; exposed to a jet of lab air to remove most water; placed inside a vacuum oven (40°C, from 75% to 85% vacuum, minimum 10 h); removed and left to cool for 1 h to room temperature; weighed 3 times and recorded. Photographs were taken of the dry samples within each wear test interval. Samples were then scanned by microcomputed tomography in a SCANCO Medical μ CT 80 (Brüttisellen, Switzerland). High-resolution scans of the fabric were taken at a current of 177 μ A, 45 kVp, with a voxel 10 μ m size. 3D reconstructions were done to confirm uniform surface welding and that the subsurface fabric was preserved (Figure 5).



(a)



(b)

Figure 5: 3D MicroCT reconstruction of successful surface welding of SN 3786.

Assemblies were fitted on the Ortho-POD six-station disc and lowered on the Ortho-POD chassis. Pins were also lowered to be clamped in place before balancing load cells. The Ortho-POD's controller software programmed the number of cycles per interval. The test began and was left to run until it ended. One control sample of each tested fabric type underwent static loading in 20

mL of deionized water throughout the pin-on-disc wear test. The gravimetric data acquired from the load-soak control samples were employed to account for any hygroscopic effects (Figure 6).



Figure 6: Fabric assemblies installed in Ortho-POD.

Figure 7 compares the wear test results of the same material and weave as in Figure 2. The welded specimen had surface layers welded, but a substrate that was unaffected. The welded materials shown exhibits a dramatically lower wear rate for the first two million cycles, but transitions to a wear rate more typical of the untreated material as the welded surface layers are worn away. However, as can be seen, the selective welding of the three-dimensional woven material led to a significant increase in life.

Table 2: Comparison of virgin and welded wear rates.

Fabric	Virgin	Welded	
	Wear Rate (mg/10 ⁶ cycles)	Welded Surface Wear Rate (mg/10 ⁶ cycles)	Sub-surface Wear Rate (mg/10 ⁶ cycles)
SN 3786	230.3	9.550	39.72
SN 3787	142.3	8.788	83.77
SN 3825	6.032	0.4516	—

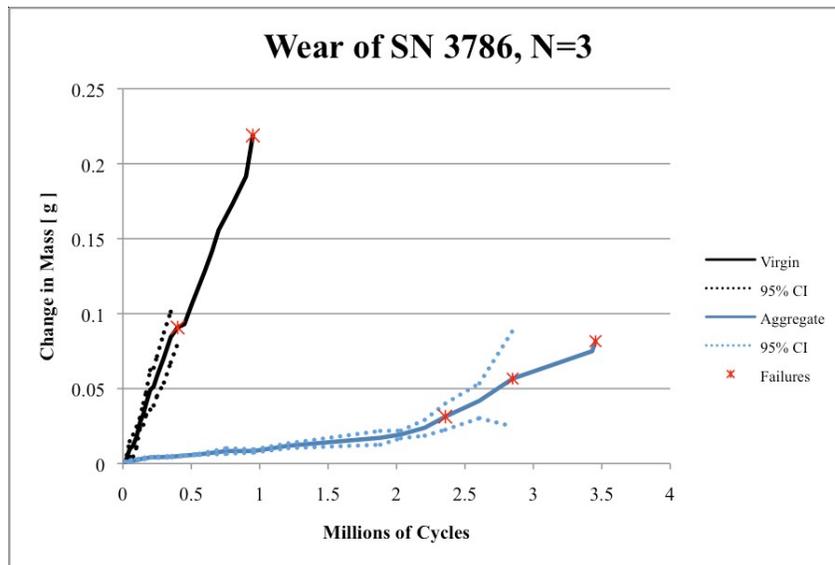


Figure 7: Representative results from wear tests comparing original and welded material. The material is described in Table 1, using three repetitions (N=3).

For the materials listed in Table 1, the measured wear rate coefficients are summarized in Table 2. A distinction is made between the initial wear rate on the welded-woven materials and the wear rate that occurs at a first transition to higher wear rates as the surface is worn away. Not reported is a satin weave PET polymer, which performed poorly under all wear conditions. It was also seen that the satin fabric would not weld well, because of the loose nature of surface fibers.

The behavior of welding at individual fiber-fiber contact sites was investigated. The quality of the welds was characterized by applying a load to one of the two mating fibers. The load was then transferred through the weld zone to the

second mating fiber, thus testing the weld strength (Figure 8).

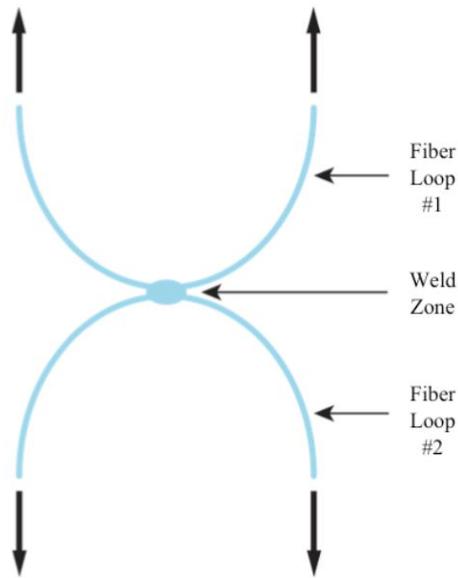


Figure 8: Schematic of weld strength test.

Prior to testing, each of the two fibers was bent away from the weld zone to create a loop. Clamping the two fiber ends completed the loop. The fiber that was originally the top fiber in the welding setup was hung from a cantilever and the entire welded assembly of two fibers was allowed to hang under its own weight plus the lead split shot that was used to clamp the fibers into loops. Deadweight was added to a plastic sample bag suspended from the bottom fiber at a rate of approximately 1.6 g per second until the weld ruptured. At this point the mass of the deadweight was recorded.

72 Clearweld®-coated, PET fiber pairings were processed with the near infrared laser under no tension. Of the 72 samples processed, 82% demonstrated a weld of some varying degree.

Without conducting weld strength tests, it was clear that the strength of the weld in 13 samples was 0 MPa. The mean weld strength of the 59 eligible samples is shown in Table 3.

5. Conclusions

A three-dimensional fabric with laser-welded reinforcements was proposed as a synthetic, minimally invasive articular cartilage replacement. The laser welding process using the Clearweld® Material System was investigated with a study of fiber-to-fiber welding and subsequent determination of the joining weld

Table 3: Weld strengths of tested welds.

Category	N. of samples	Weld strength (MPa)
No weld	8	0
Welded fibers	47	57.29
Weld with polymer degradation	12	28.32
Severed fibers	5	0

strengths. The laser welding procedure was then adapted to add surface welds to previously manufactured three-dimensional woven fabrics. The fabrics were investigated with confined compression and pin-on-disc wear studies to illustrate the benefits of the welded-woven concept.

Surface welding was attempted on three fabrics to create welded versions of each type. The fabrics again welded uniformly with good repeatability. The fabrics were subject to wear testing with cobalt chrome pins in a lubricating bath of deionized water.

The welded-woven orthogonal fabrics outperformed the non-welded versions of the orthogonal fabrics. The wear rates were reduced by greater than 90% through nearly two million cycles; whereas the non-welded orthogonal fabrics failed by the one-millionth cycle. The reduction in wear rate is attributed to the reinforced surface that is both damage-resistant and damage-tolerant. Any damage that does occur is limited to the wear profile and does not migrate outwards until final failure in which the pin wears through the full thickness of the sample. Lateral displacement of fibers, and associated snagging and rupture, was avoided with the welded surface.

With the outstanding pin-on-disc wear studies, an implant design is proposed here that would incorporate features of several of the tested fabrics.

A robust manufacturing method has been developed and demonstrated for improving and tailoring three-dimensional fabrics. A new class of material, the welded-woven fabric, has been created for the first time. An initial application was investigated, though many other potential uses and applications exist in the medical device industry.

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