



Selective laser fiber welding on woven polymer fabrics for biomedical applications



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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 orthopedic 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.

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

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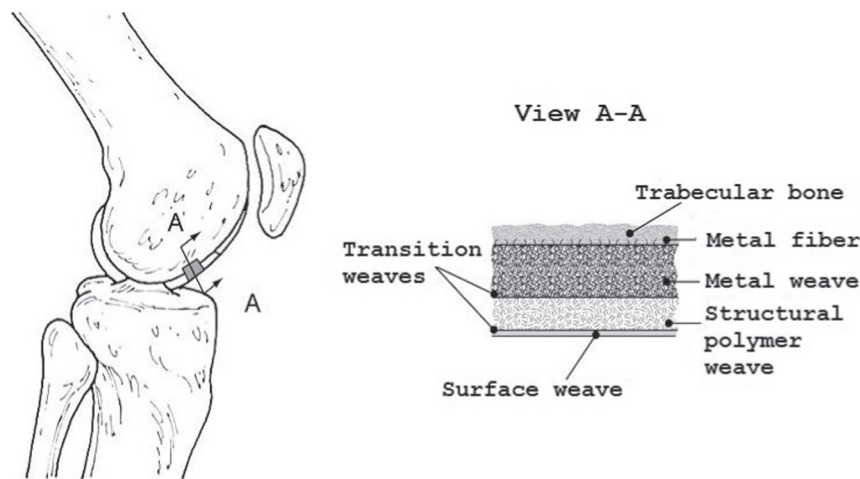


Fig. 1. Schematic illustration of the cartilage repair implant, shown on the knee. Some of the design features that can be incorporated into advanced weaving processes are shown on the right.

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 Fig. 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.

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 orthopedic 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 poly(lactide-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 (UHM WPE) 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 Shikunami 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].

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