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Biomechanical performance of a collagen meniscus implant with regard to suture material and irrigation fluid

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ABSTRACT

Background: The role of meniscus scaffolds remains controversial as failure rates remain high. The aim of this study was to evaluate the pullout strength of different suture materials used for fixation of the Collagen Meniscus Implant (CMI) regarding different suture materials, and type or temperature of irrigation fluid.

Methods: One-hundred and twelve specimens were utilized with horizontal sutures and mounted to a dedicated test device. Loads were applied perpendicular to the CMI, until failure. Two differing suture materials – polydioxanone (PDS) and non-absorbable, braided polyester sutures (NABP) – were evaluated. Additionally, two common irrigation fluids – lactated Ringer's and electrolyte-free, hypotonic Mannitol–Sorbitol solution – were evaluated. Specimens were further evaluated according to different temperatures of the irrigation fluid. Half of the constructs were tested at room temperature (20 °C) and half were evaluated at near-core body temperature (37 °C).

Results: PDS sutures showed a significantly higher load-to-failure compared to NABP sutures ($P = 0.0008$). Regarding the type of irrigation fluid, the electrolyte-free Mannitol–Sorbitol solution showed a significantly higher load-to-failure compared to the overall Ringer group (P b 0.0001). This was equivalent for both the PDS ($P = 0.015$) and for the NABP sutures (P b 0.0001). The temperature of the irrigation fluid did not significantly influence load-to-failure.

Conclusions: PDS sutures and electrolyte-free Mannitol–Sorbitol irrigation fluid provided the best biomechanical properties regarding load-to-failure testing. This study underlines the potential to improve construct stability for the CMI by alteration of the suture material and the type of irrigation fluid, which should be considered whenever scaffold fixation is conducted.

1. Introduction

The functional importance of the meniscus is widely acknowledged [1]. Once injured, the meniscus undergoes structural changes which impair its biological and biomechanical properties [2]. Consequently, not every meniscal tear can be repaired and partial or subtotal meniscectomy is often inevitable. Notably, resection of meniscal tissue has been found to increase peak

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forces across the adjacent cartilage, thus predisposing for degenerative changes of the knee joint [3,4]. For this reason, clinical and experimental studies have been conducted to find a safe substitute for these symptomatic meniscal defects.

Meniscal scaffolds have gained interest, as they are believed to decrease post-meniscectomy pain and improve joint kinematics. These scaffolds are designed to substitute partial meniscal defects. The Collagen Meniscal Implant (CMI) serves as a biodegradable collagen template for subsequent cellular ingrowth of new meniscus-like tissue [5,6]. It consists of purified type-1-collagen of bovine Achilles tendons, enriched with glycosaminoglycans. Clinical reports on medium- to long-term follow-up after implantation of the CMI seem promising, even though a relative paucity exists regarding the biomechanical behavior [7–11]. Due to the highly porous surface of the scaffolds – which is mandatory for the differentiation and proliferation of fibrocartilaginous cells – proper fixation can be difficult to achieve, as the sutures tend to cut through the implant. As a consequence, most reported complications are due to the suture material rather than the meniscal scaffold [12]. This is especially inherent when the implant is moistened by the irrigation fluid during arthroscopy.

The purpose of the current study was to elucidate the best-case scenario for the implantation of a meniscal scaffold. We hypothesized that the maximum load-to-failure is significantly influenced by the suture material, and by the type or temperature of the irrigation fluid used during implantation of the CMI.

2. Methods

One-hundred and twelve Collagen Meniscal Implants (CMI®, Ivy Sports Medicine, Graefelfing, Germany) were used for this study. The scaffolds were sectioned radially, creating specimens of 15 mm width.

Meniscal height was determined to place the suture loop in the middle of the scaffold, leaving a five millimeter distance between the suture loop and five millimeters to each side. Traditional horizontal sutures were placed in an outside-in fashion using a 20-gauge needle (Figure 1).

For biomechanical testing, the scaffold was mounted to a dedicated custom-made test device (Charité Core Facility – Centrum wissenschaftliche Werkstaetten; Figure 2), which was connected to the testing machine (Electro Force LM1 Test Bench, Bose Corporation, Framingham, MA, USA). The loads were applied perpendicular to the implant, in order to simulate the load distribution during fixation of the implant. Tensile loads were acquired using a 225 N load cell with an accuracy of $\pm 0.25\%$ full scale.

2.1. Suture material

For suture materials, a polydioxanone (PDS) suture II size 0 (Ethicon Inc., Summerville, NJ, USA) and an Ultrabraid size 0 non-absorbable, braided polyester suture (NABP), which is used in the Ultra Fast-Fix device (Smith and Nephew, Andover, MA, USA), were evaluated. Each suture was deployed in a horizontal fashion parallel to the length of the scaffold and the free ends of the sutures were pretensioned. Notably, the test setup reflects a best-case scenario due to the direct visualization of suture placement.

2.2. Type of irrigation fluid

In order to determine whether the choice of irrigation fluid (two common irrigation fluids) affects load to failure, the test chambers of the testing device were either filled with lactated Ringer's (Fresenius, Bad Homburg, Germany) or Purisole® (Fresenius, Bad Homburg, Germany) solution. Purisole® is an electrolyte-free and hypotonic Mannitol–Sorbitol solution commonly used for endoscopic and arthroscopic procedures.

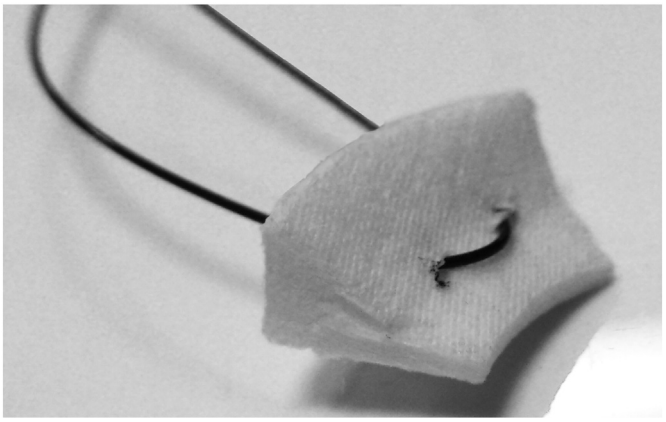

Figure 1. The Collagen Meniscal Implant CMI was sectioned radially, creating specimens of 15 mm width. Traditional horizontal sutures were placed in an outside-in fashion using, in this specimen, a polydioxanone suture.

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