



# Materials Forum Volume 38 - 2014 CAMS2014

### PREFACE

#### **Ceramics and Materials**

This volume of Materials Forum represents a unique body of work from researchers and industry practitioners having a common interest in advances in materials science, engineering, technology and the characterisation and performance of materials. The papers are based on the lectures delivered at the "Combined Australian Materials Societies; incorporating Materials Australia and the Australian Ceramic Society (CAMS 2014) Conference" held from Wednesday 26th to Friday 28th of November, in the newly opened Charles Perkins Centre at the University of Sydney 2014. The co-chairs of this conference were Prof. Julie Cairney from University of Sydney and Prof. Charles Sorrell from UNSW Australia.

CAMS 2014 is an exceptional interdisciplinary technical meeting, covering the latest advancements and technological innovation in the field of materials science and engineering. Featuring world-renowned invited speakers, an intensive scientific program with various concurrent streams, and a veritable range of networking events, which informs and engages delegates. The themes of the 2014 CAMS conference were quite diverse, including advances in materials characterisation and steel technology, biomaterials, cements and geopolymers, ferroelectrics, light metals, materials for energy generation, materials simulation and modelling, metal casting and thermomechanical processing, nanostructured and nanoscale materials, particulate packing and flow, raw materials processing and smart building materials. The event was international in scope, and there were speakers from China and Germany as well as Australia. The overarching theme at the conference was a practical industry slant that emphasised the relationships between surface engineered materials and their characterisation and performance when subject to a range of industry based applications.

This collection of the full academic papers that were contributed as part of the conference provide a timely opportunity to illustrate the breadth of this exciting field of materials research and to highlight the advanced nature of its various developments here in Australia. We hope that this volume will further contribute to the development of the discipline, and that it will serve the interests of the wider Australian and international materials community.

All contributions were subject to a stringent and independent process of peer-review. The success of any journal is critically dependant on the efforts of these reviewers, who read the manuscripts on the Editors' behalf and provide the authors with constructive criticism. We would like to take this opportunity to thank both the contributors and the reviewers. This volume of Materials Forum is the result of their hard work.

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### **Aims and Scope**

Materials Forum is published annually and presents critical reviews of recent research in materials science and engineering. These are written by researchers active in the field, reflecting areas of Australian interest and expertise, but are not limited to Australian research. Most importantly, it is expected that articles will, in the first instance, be intelligible to a wide audience of materials scientists and engineers who are not necessarily familiar with the specific field. Reviews will be succinct but authoritative. They may also be extended to include a complex analysis of current theories or present a new interpretation of existing knowledge. In this way, the reviews may also be useful to specialists. All articles are solicited by the Editorial Committee and are independently refereed by two or more assessors.

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### PROSTHETIC ACETABULAR LABRUM IMPLANT

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### **ABSTRACT**

Acetabular labrum is a fibrocartilage tissue that surrounds the hip acetabulum. The presence of labrum influences the biomechanics of the hip joint, to enhance hip stability and as a seal to protect the lubrication of the articulating joint. Tears in the labrum could progress to osteoarthritis, and can occur in both young and elderly patients. Osteoarthritis, which commonly leads to total hip replacement, can be an expensive condition to treat and can diminish quality of life. The prevalence of hip replacement surgery has also been increasing in recent years. Considering the essential role of acetabular labrum, its preservation is important in the treatment of labral tears, either by repair or reconstruction. However, labral repair may also bring the risks of imperfect healing or recurrence of injury, while reconstruction by autograft requires additional surgery and has risks of tissue morbidity.

A synthetic implant could offer an alternative solution for the treatment of labral tears. Various implants have been developed to replace damaged fibrocartilage tissues, thus similar strategies could potentially be applied for labral injury. Additionally, a tissue engineering approach offers further benefits in facilitating healing and regeneration.

The objective of this study is to explore the prospective development of labrum implant to recover the mechanical function of the damaged tissue and to take a role as a scaffold to enhance tissue regeneration. This paper will address literature reports on the role of acetabular labrum, the treatment of labral injuries, and reported fibrocartilage replacements, with a view to developing potential designs and candidate biomaterials for synthetic labrum implants. Ideally, an implant should be able to mimic the structure and mechanical properties of the replaced tissue. From this study, a fabric-based implant could be applied to mimic the fibrous architecture of acetabular labrum. Ultra-High Molecular Weight Polyethylene (UHMWPE) appears to be the promising material for implant macrostructure that provides mechanical strength. Conversely, a nanofibrous polycaprolactone (PCL) could take fit the role of bioresorbable scaffold to facilitate tissue remodelling and regeneration. Additionally, bioactive glass coating offers potential of stimulating interfacial bonding with surrounding tissue, as well as enhancing the process of healing. In summary, this presentation will outline a viable concept for a labrum implant. To the author's knowledge, there are no reports of labrum implants in the literature. Hence, this research represents a novel biomaterials approach to fibrocartilage replacement with potential long term clinical benefits.

### 1 INTRODUCTION

The demand of orthopedic care may rise with increasing life expectation and ageing population. Viewed from economic perspective in the US, the need of orthopedic treatments can be valued as much as US \$849 billion, proportionate to 7.7% of its gross domestic product<sup>1</sup>. Among those treatments, joint-related surgery shows increasing trend, with arthritis is considered as a threatening problem that affect quality of life in the age group of 40 years<sup>2</sup>.

For hip joint, labral tear is a common cause of pain and could lead to osteoarthritis <sup>3-5</sup>. Labral injuries were found to be the common cause of hip pain, as showed by arthroscopic examinations<sup>6</sup>. 436 hip arthroscopies showed that 55% of patients had labral tears<sup>4</sup>, while in other 300 consecutive cases, 90% are associated with labral tears<sup>7</sup>. The prevalence of labral tears is apparently higher in older population, but it may also occur in younger age group <sup>8-9</sup>. 180 volunteers without hip symptoms showed progressive loss in labrum shape, while its shape homogeneity was related with aging <sup>10</sup>. Another observation also found that abnormal form of labrum was more prevailing in older subjects <sup>11</sup>. In the more active population, such as young people and athletes, up to 8.4% of sports injury was related to hip <sup>5</sup>, with 22% of athletes with groin pain had labral lesion <sup>12</sup>.

Arthritis may lead to disability, with its figure in developed countries was projected to double in the next 10 years<sup>13</sup>. In hip joint, severe arthritis is commonly treated with total hip replacement. This surgery is expected to increase as much as 200% in US for the next two decades<sup>13</sup>. As one of the most frequently performed orthopaedic surgery, its amount in US reached 250,000 per year and was projected to increase more than two folds in 2030<sup>14</sup>. Meanwhile, the number of its revision surgery was projected to reach 97,000 by 2030, a 137% increase from 2005 volume. In Australia, 2002 financial report showed that 26,689 hip replacements were performed<sup>15</sup>. It was also reported that for the past 10 years, there was 5-10% increase per year in hip and knee replacement surgery, with revision rate was estimated to be 20-24%. This revision surgery affects both patients and hospitals. For patients, it is equivalent to spend more time and cost in hospital and surgical operation<sup>14</sup>. Additionally, the risk of dislocation may also occur. For hospitals, the resource utilization for revision surgery is significantly greater than that of primary surgery, which some cases require more complex and costly techniques <sup>14</sup>.

The number of osteoarthritis is projected to increase, as it also leads to economic concern. Therefore, it is important to anticipate this problem at earlier stage. One of viable options is the treatment of labral tears. In this

case, labrum preservation is considered essential to protect joint cartilage from damage<sup>5, 16-17</sup>. However, there are still risks of imperfect healing or recurrence of injury after labral repair<sup>18-21</sup>. In cases which damaged labrum could not be preserved, this unhealthy tissue needs debridement and substitution using autograft<sup>5, 22-23</sup>. Still, autograft exhibits some limitations, for example limited availability, endangering tissue surrounding the graft source, and compromise in biomechanical properties <sup>23-24</sup>.

A labrum implant is proposed as an alternative approach to enhance labral repair and healing. This device may also serve as synthetic graft for overcoming autograft limitation. Synthetic material offers several advantages, including tailored properties, improved availability, and reproducibility. To date, there is no synthetic labrum replacement has been investigated. With the important role of acetabular labrum, its development is worth to be explored and could also enrich the knowledge in fibrocartilage tissue replacements. This review will elaborate information related to histology and biomechanics of acetabular labrum, and biomaterials for fibrocartilage replacements, to provide a foundation for developing design concept of artificial human acetabular labrum.

## 2 ANATOMY, HISTOLOGY, AND BIOMECHANICAL ROLE OF ACETABULAR LABRUM

Acetabular labrum, or cotyloid ligament, is a fibrocartilage tissue located in the edge of acetabulum, between femur and acetabular rim (figure 1) <sup>17, 25</sup>. Its structure is similar to meniscus, a fibrocartilagenous structure in knee joint <sup>26-27</sup>. The labrum unites with both bony acetabulum and acetabular hyaline cartilage, on the capsular side and articular side, respectively (figure 2) <sup>25</sup>. Labrum structure is circular around the edge of acetabular cup and triangular in cross-section, with its apex forms free edge <sup>26</sup>.

Acetabular labrum is divided into two zones based on its tissue formation, namely articular and capsular side (fig. 1B) <sup>9</sup>. Articular side or internal layer is a region of thin fibrocartilagenous layer with continuous transition to dense connective tissue, which is comprised by type II collagen and chondrocytes. Compressive and shear forces take role in the development of this zone. On the other hand, capsular side or external layer consists of dense connective tissue which contains type I and type III collagen. Formation of this zone is influenced by tensional stress. From its fiber arrangement, labrum appears to have three distinct layers <sup>9, 11</sup>: (1) A network of delicate fibrils corresponds to the articular side; (2) A lamellar layer corresponds to the fibrocartilage layer; and (3) A main portion consists of circumferentiallyarranged collagen fibrils bundles, which corresponds to the external layer and is continuous with the transverse acetabular ligament.

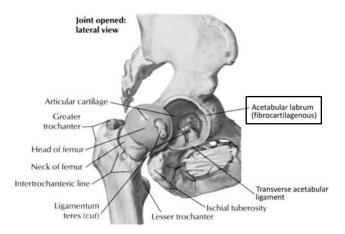


Figure 1. Location of acetabular labrum (boxed) in the hip joint (picture adapted from Netter's Orthopaedics<sup>28</sup>).

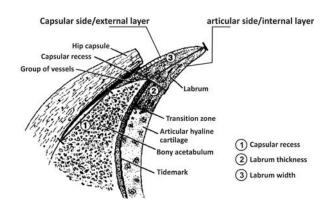


Figure 2. Histologic appearance of human acetabular labrum and its attachment site <sup>25</sup>.

Acetabular labrum is supplied with blood vessel, mainly at the external one-third, while avascular in the inner two-thirds <sup>9</sup>. The vascularity shows similar pattern throughout labrum regions <sup>29</sup>. Blood supply is located in the capsular side, and its circulation is interconnected to whole hip vasculature<sup>9, 17, 25, 30-31</sup>. Vascularity may influence the healing capacity of the labrum, with the vascular side is speculated to have more potential to heal<sup>29</sup>.

The structure of acetabular labrum improves to hip joint stability. 22% of articulating surface and 33% of acetabular cup depth are contributed by the labrum, besides providing a cover for more than half of femoral head <sup>17, 25-26</sup>. Its tensile strength further provides further stability to the hip, while delivering cartilage protection <sup>17, 31</sup>. Structurally, the transverse acetabular ligament hold the circular collagen fibrils of the labrum, providing restriction against motions in acetabulum <sup>9</sup>.

Another significant function of labrum is sealing the hip to protect fluid within the joint. The circumferential structure of its fibers provide restraint against fluid pressure <sup>26</sup>. This sealed fluid prevents consolidation between joints surface <sup>26, 32</sup>. During loading, the fluid distributes and decreases peak loads on the femoral head surface, providing protection for articular cartilage. During motion, it prevents cartilage wear caused by

shear stress in the joint surface because majority of the applied load in the joint is distributed through fluid pressure instead of solid matrix  $^{27}$ . Furthermore, the labrum and the fluid collaborate as a shock absorber, in which the fluid motion and labrum non-linear deformation provide joint compliance  $^{26}$ . Mechanical properties of human acetabular labrum is reported to be  $24.7\pm10.8$  MPa (tensile) and  $31.8\pm16.7$  MPa (compressive)<sup>7</sup>.

### 3 LABRAL TEARS AND CURRENT TREATMENT OF LABRAL TEARS

Labral tear is a detachment of the labrum from the bony acetabulum and suspected as the onset of hip osteoarthritis<sup>3-4, 25</sup>. The tear is classified into two types, namely cam and pincer<sup>17, 25</sup>. Cam type is the detachment of the labrum from articular hyaline cartilage at its transition zone. Pincer type is the tears within the labrum body, which spreads to the labrum surface. Labral damage mostly occurs in anterior region <sup>4, 17, 25</sup>, which has considerably lower tensile and compressive modulus, with attachment that is prone to shear force <sup>7, 17</sup>. Labral damage may also be caused by abnormal morphology of proximal femur and/or acetabulum, that impinges the labrum and is known as femoroacetabular impingement (FAI)<sup>3, 5, 30</sup>.

The tears of acetabular labrum affect biomechanics of hip joint. It could result in nonhomogeneous fluid pressurization and increased contact between articular surface <sup>11</sup>. Furthermore, hip stability might be disrupted, in which femoral head distracts more easily from acetabulum and leading to imbalance, especially during motion <sup>16</sup>.

Labral tears can be treated by either debridement or repair/refixation. Nevertheless, which method resulting in better outcome is remain debatable. Reviews mentioned that labral debridement could relieve hip symptoms but the repair might also provide better clinical result <sup>11, 33</sup>. According to those reviews, there were no studies that proving labral repair was able to successfully restore the tissue structure, permeability, and fluid flow. However, other studies showed that labral repair tended to produce better outcomes 17, 34-35. The role of the labrum in hip stability and cartilage protection lead to consideration that preserving labrum and maintaining its functions are essential<sup>5, 16-17</sup>. To date, labral treatment shifts from debridement toward preservation, correction, and repair<sup>36</sup>. Methods of labral repair have been reported in literatures<sup>5, 30, 34-35, 37</sup>.

In particular cases, the damaged labrum may not be salvaged, such as in severe damage, degeneration, or tissue deficiency, thus a reconstruction is required <sup>23</sup>. For reconstruction, there are suggested indications presented in literatures <sup>5, 23</sup>. Labral reconstruction uses a graft which can be harvested from several sources, for example ligamentum teres <sup>22</sup>, tubularized iliotibial band <sup>5</sup>, and gracilis autograft <sup>23</sup>. This graft should mimic the native labrum and restore its seal function <sup>5, 26-27, 32</sup>. Clinical outcome of labral reconstruction was reported

as a good result <sup>5</sup>. Its techniques have also been described in literatures <sup>5, 23, 37</sup>. Labral reconstruction, along with the debridement and repair, are usually operated arthroscopically <sup>5, 23, 30, 34-35, 37</sup>.

### **4 TISSUE ENGINEERING**

Tissue engineering is an application of engineering and life science to develop biological substitutes that restore, maintain, or improve tissue function  $^{38}$ . It involves the use of scaffold to support tissue ingrowth, by carrying cells and growth factors, while facilitating nutrient and wastes exchange through diffusion. A scaffold should fulfil several requirements  $^{39-41}$ : (1) Three-dimensional porous structure with interconnected pores to facilitate cells growth and flow of nutrients and metabolic waste. Pore size ideally ranges between 100-500  $\mu m;$  (2) Biocompatible with tuneable degradation and resorption rate matching tissue growth; (3) Suitable surface chemistry for cells attachment, proliferation, and differentiation; (4) Mechanical properties equal to the substituted tissue.

Microstructure of the scaffold is important for tissue ingrowth and regeneration. Type of ingrown tissue may be influenced by pore size. Minimum pore diameter of 150 µm induces bone tissue, while size of 200-250 µm stimulates soft tissue development 42. Additionally, structure of a scaffold also influences cells morphology and deposition of matrix extracellular. Cells growth appears to be strongly related to fibre architecture of the scaffold, in which it extends following fibre direction<sup>43</sup>-<sup>45</sup>. It further influences the organization of extracellular matrix deposition and mechanical properties of engineered tissue<sup>44-46</sup>. Furthermore, cells also appear to favour nanostructures more than solid-walled morphology<sup>47-48</sup>. High surface area of nanoscale morphology provides more binding sites for cell attachment<sup>48</sup>. Nanofibrous architecture also resembles structure of soft tissue, such as muscle, tendon, meniscus, and annulus fibrossus 45, 49-50.

Mechanical stimulation also influences cells behaviour and tissue development. Mechanical transduction influences collagen production, in conjunction with nutrition and growth factors <sup>51</sup>. Matrix expression and fibrocartilage formation could be guided by mechanical stimulus, such as tensile/compressive or static/dynamic loading <sup>52</sup>. Furthermore, mechanical forces could determine the differentiation of mesenchymal stem cells into specific cells, including fibrocartilage cells <sup>53</sup>. Mechanical stability of a scaffold also dictates cellular attachment and ingrowth <sup>43, 54</sup>. Additionally, compressive stiffness of a scaffold might influence collagen formation of fibrocartilage, as showed in intervertebral disc <sup>55</sup> and meniscus replacement <sup>56-57</sup>.

Tissue engineering strategy has been applied in fibrocartilage repair and replacement. Development of scaffolds for engineering fibrocartilage tissue, such as meniscus, intervertebral disc, and anterior cruciate ligament, have been widely explored and reviewed<sup>58-59</sup>. Generally, these scaffolds were comprised by

degradable polymer, either natural or synthetic, or its combination. Autologous cells or mesenchymal stem cells might then be seeded in this platform. Engineered tissue could be developed in in-vitro environment, by addition of growth factors or mechanical stimulation using bioreactor. Since many factors should be involved in designing scaffold for tissue engineering, selection and optimization of the biomaterial is important.

### **5 POLYMERIC BIOMATERIALS**

Selection of biomaterial determines the performance of biomedical device. With the wide range of material types and applications, this study will be limited to polymers studied as fibrocartilage replacement. Fibrocartilage is a transitional tissue which has structural and functional properties between those of fibrous connective tissue and hyaline cartilage <sup>60</sup>. This tissue includes labrum, spinal disc, meniscus, tendon, and ligament <sup>58, 61</sup>.

### 5.1. Non-degradable Polymeric Biomaterials

Prostheses for fibrocartilage are commonly fabricated using inert, non-degradable materials. This family of material offers mechanical and chemical stability to support patient quick recovery, but may hinder tissue remodelling <sup>62</sup>. Several non-degradable materials that have been extensively explored as fibrocartilage prostheses are PTFE (polytetrafluoroethylene), PET (polytethylene terephthalate), PU (polyurethane), and UHMWPE (ultra high molecular weight polyethylene).

Polytetrafluoroethylene is one of fluorocarbon polymers and generally polycrystalline. It has inert and hydrophobic properties, thus widely used as vascular graft, facial implant, and artificial tendon <sup>63</sup>. As fibrocartilage replacement, potential use of PTFE has been explored for meniscus <sup>57,64-67</sup> and ligament <sup>68-70</sup>. As meniscus replacement, a standalone PTFE exhibited similar compliance with normal tissue, but was incapable to resist deformation and wear <sup>66</sup>. Material coatings were proposed to improve its performance, but it still showed unfavourable results, both in biomechanics and biocompatibility <sup>57,64-65</sup>. In terms of ligament prostheses, PTFE has been used clinically, well known as Gore-Tex <sup>68-69</sup>. This device had high initial strength, which was three times stronger than human anterior cruciate ligament (ACL), but then performed poorly in long term period <sup>68-70</sup>.

Polyethylene terephthalate is a member of polyester family and generally has semicrystalline structure. This polyester is commonly used as nonresorbable suture and vascular grafts <sup>63</sup>. As fibrocartilage replacement, PET has been studied as meniscus substitute in rabbit <sup>65-67</sup> and used clinically as ligament replacement <sup>62, 68-71</sup>. Generally, this material produced good initial mechanical strength, but performed poorly in long term.

Polyurethane has broad polymer classification. Its structure consisted of hard & soft segments, with varying glass temperature & structural property <sup>63</sup>. The

type of PU is influenced by its soft segment that incorporate ester, ether, or carbonate linkage, resulting in several variants, namely polyesterurethane, polyetherurethanes (PEU), and polycarbonateurethane (PCU), respectively <sup>72</sup>. In biomedical applications, PU was utilized as bearing materials & soft tissue reconstruction <sup>63</sup>. In the area of fibrocartilage, PU was studied as meniscus replacement in various approaches, including coating for another polymer <sup>73</sup>, standalone implant with various soft segment <sup>55-56, 74-75</sup>, or as matrix <sup>75-76</sup>. Those studies showed that PU had mechanical weakness when it was used as an individual material.

Among members of polyethylene family, UHMWPE is the most widely used and studied material <sup>63</sup>. It offers toughness, wear resistance, and load bearing ability, thus has been broadly used as acetabular cup in total joint replacement, with in-vivo survival rates of up to 90% in 20 years <sup>63</sup>. The potential use of UHMWPE as fibrocartilage prostheses has also been explored, particularly as meniscus and artificial intervertebral disc<sup>77-82</sup>. Those studies reported that the devices exhibited similar mechanical behavior with the substituted tissue. Furthermore, UHMWPE also demonstrated durability and mechanical stability when it was tested as artificial intervertebral disc<sup>77-81</sup>. Its clinical application as ACL prostheses delivered similar results, where UHMWPE fibers demonstrated fatigue and abrasion resistant 62.

Mechanical properties of those non-degradable polymers are presented in table 1, while elastic modulus of the labrum and those materials are mapped in figure 3. Additionally, the mechanical and biological performance of several fibrocartilage implants from invivo and clinical reports are summarized in table 2.

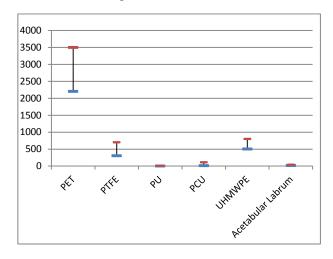


Figure 3. Elastic Modulus of several synthetic polymers and acetabular labrum  $^7$ .

Table 1. Mechanical properties of non-degradable polymers for fibrocartilage replacement

Mechanical Properties	Unit	PE	HD PE*	UHMW PE*	PT FE	PET	PU	PCU**
Bulk modulus	GPa	0.8-2.2	-	-	1-2	3-4.9	1.5-2	-
Tensile strength	MPa	30-40	22-31	39-48	15-40	42-80	28-40	23.4- 60.2
Elongation at break	%	130- /500	10-1200	350-525	250-550	50-300	600-720	633-840
Young's Modulus	GPa	0.45-1.3	0.4-40	0.5-0.8	0.3-0.7	2.2-3.5	0.0018- 0.009	8-109
Elastic limit	MPa	20-30	26-33	21-28	15-30	50-72	28-40	-
Endurance limit	MPa	13-19.6	-	-	9-18	30-43.2	21-30	-
Fracture Toughness	Mpa.m <sup>1/2</sup>	2.2-4	-	-	2.5-3	1.2-2	0.1-0.4	-
Hardness	Mpa	60-90	-	-	27-90	97-210	50-120	-
Compressive strength	Mpa	30-40	-	-	30-60	65-90	33-50	-
Poisson's ratio		0.4-0.42	0.40	0.46	0.44- 0.47	0.38- 0.43	0.47- 0.49	-
Shear modulus	GPa	0.18- 0.46	-	-	0.11- 0.24	0.83-1.1	0.0008- 0.003	-

<sup>\*</sup>Data is obtained from Kurtz (2009) 84

Table 2. Performance of several non-degradable polymers as fibrocartilage replacement

No	Non-degradable	Performance
	Polymers	
01	PTFE	Showed high tensile strength but low elasticity <sup>68, 71</sup>
		Showed fibers or structural breakage and instability <sup>62, 64, 68, 70</sup>
		• Induced fibrous tissue formation or encapsulation <sup>62, 68</sup>
		Had inferior healing capacity, compared to polyester <sup>62</sup>
		• Risk of complication in distant site (PTFE particles deposits in lymphonode) 70
02	PET	Showed fibres or structural breakage and instability <sup>62, 69-70, 86</sup>
		• Induced fibrous tissue formation or encapsulation 62, 68, 86-87
		Induced chronic inflammatory response <sup>62,70</sup>
03	UHMWPE	• Showed wear and abrasion resistant <sup>62, 77-81</sup> .
		• Showed flexural and rotational fatigue resistant <sup>62, 77-81</sup> .
		• Induced fibrous tissue formation or encapsulation <sup>62, 66, 77-81</sup> .
		Induced chronic inflammation and synovitis <sup>62</sup>
04	Carbon fibre	Showed early fibres rupture due to poor resistance to torsional force 70
		• There was carbon deposits in the liver <sup>70</sup>
		Induced inflammation and synovitis <sup>70</sup>
05	Polyurethane	Induced fibrocartilagenous tissue formation <sup>56, 74, 88-89</sup>
		• Showed structural fragmentation <sup>56, 89</sup> .
		• Could cause cartilage damage <sup>56, 74, 76, 89</sup> .

### 5.2. Biodegradable Polymers

Biodegradable scaffold is considered important in tissue engineering. It should provide temporary strength to support tissue ingrowth, while degrading in suitable rate with tissue regeneration. Biodegradable polymers can be either naturally derived or synthetically made. Both offer different potentials and challenges. Natural polymers, for example collagen, silk, and chitosan, come from renewable sources and available abundantly in nature <sup>90</sup>. Most of them has hydrophilic properties <sup>40</sup>. However, natural polymers are usually lack of reproducibility, resulting in variations in different sources and production batches <sup>90-91</sup>. On the other hand,

synthetic polymers offer more predictable and reproducible properties, as well as advantage in tailoring and optimizing its characteristics  $^{41, 90, 92}$ . Nevertheless, its acidic degradation and resorption may cause inflammatory reaction, while solvents use d may also be toxic  $^{39, 90}$ 

Natural-derived biodegradable materials, for example collagen and silk, have been studied for application in fibrocartilage tissue engineering. Collagen has been applied clinically as partial meniscus replacement, known as CMI (Collagen Meniscus Implant) <sup>93</sup>. This device demonstrated mixed clinical results of both favourable and concerning outcomes <sup>67, 93-95</sup>. Several

<sup>\*\*</sup> Data is obtained from Spirkova (2011), with the material is in the form of sheets 85

reports showed a biocompatibility of this device, as well as the capability to support tissue development similar to meniscus<sup>93-94</sup>. However, CMI also exhibited structural instability, for example rapid shrinkage and fragmentation, besides unimproved clinical score in long term observation<sup>93</sup>. Other concerns regarding collagen use are related to immune response, pathogen transmission, and control of its properties<sup>41, 91</sup>.

Another natural substance that offers many potential advantages for tissue engineering is silk. The benefits offered includes menchanical strength, environmental stability, biocompatibility, and even genetic control 91, 96. Nevertheless, removal of sericin, a protein content in silk, becomes an issue, since it may cause hypersensitivity and affect biocompatibility.

From an opposite side, synthetic biodegradable polymers also have advantages to offer, that leads to its development as fibrocartilage replacement. Biodegradable polyesters appear to be the most explored synthetic materials in tissue engineering and have been already approved by FDA 41, 43, 99. These polyesters include polylactic acid (PLA), polyglycolic acid (PGA), polycaprolactone (PCL), and their copolymers. Comparison of properties and applications from these polyesters has been reviewed in several papers<sup>39, 41, 99-100</sup>. Their thermal and mechanical properties are presented in table 3, while table 4 summarizes degradation properties and medical applications. These aliphatic polyesters have been being studied as scaffold material for fibrous tissue engineering, such as ligament 42, 54, 91, 101-102, meniscus 44, 3, and intervertebral disc <sup>45-46, 104</sup>. Overview of their performance is summarized in table 5.

### 6. BIOACTIVE GLASS

Fibrocartilages, including acetabular labrum, are connected to both hard and soft tissue. Attachment to surrounding tissue is an important consideration when designing a medical device. Bioactive glass offers

potential ability to bond with both of those tissues, thus provide advantages for the development of labrum prosthetic. Bioglass is a bioactive material which is both osteoproductive 105. osteoconductive and Osteoconductivity is related to bone growth and bonding, while osteoproductivity is associated with genetic stimulation for osteoblast cell cycles<sup>24, 105-107</sup>. The first developed composition is 45S5 Bioglass, which has formula of 45% SiO<sub>2</sub>, 24.5% CaO, 24.5% Na<sub>2</sub>O, and 6% P<sub>2</sub>O<sub>5</sub>. It has been used clinically, for example as ossicular prostheses, bone graft, and dental applications <sup>105, 108</sup>. Besides the ability to stimulate strong interfacial bone bonding, bioglass offers several potential properties that may be beneficial for developing biomedical product, including soft tissue bonding <sup>24, 105, 109</sup>, angiogenic stimulation <sup>108, 110</sup>, and antibacterial property <sup>105, 108</sup>.

Among those advantages, the brittleness of bioactive glass limits its clinical usage to non-load-bearing device <sup>105, 108</sup>. Coating is one of applications of the bioglass regarding to its high bioactivity, to promote bonding between the implanted device and host tissue <sup>105, 108, 111</sup>. The ability to bond with soft tissue also opens prospective use in soft tissue reconstruction and engineering. Several studies have explored this potential and demonstrated promising results, such as promoting implant-soft tissue integration, supporting vascularization, and controlling degradation rate <sup>112-115</sup>. Furthermore, bioactive glasses could also influence chondrogenesis <sup>116-119</sup>.

The benefit of bioglass on soft tissue engineering and reconstruction depends on its amount and composition, thus needs optimization. If the SiO<sub>2</sub> composition exceeds 52% weight, the bioglass will only form bone bonding<sup>105</sup>. For soft tissue engineering application, the addition of Co<sup>2+</sup>, Mg<sup>2+</sup>, Zn<sup>2+</sup>, or their combination into glass composition has been proposed. This enhanced composition could delay apatite formation, which was desirable for this purpose<sup>120</sup>. However, high quantity of bioglass might halt fibroblast proliferation, thus only

Table 3. Properties of biodegradable polyesters 97-98

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Polymers	Mw	Tg	Tm	Tensile	Tensile	Elonga	tion (%)				
		(°C)	(°C)	Strength	Modulus	Yield	Break				
				(MPa)	(MPa)						
PGA	50,000	35	201	647	6,500	N/A	N/A				
PLLA	50,000	54	170	28	1,200	3.7	6.0				
PLLA	100,000	58	159	50	2,700	2.6	3.3				
PLLA	300,000	59	178	48	3,000	1.8	2.0				
PDLLA	107,000	51	N/A	29	1,900	4.0	5.0				
PCL	44,000	-62	57	16	400	7.0	80				

Table 4. Degradation properties and medical application of biodegradable polyesters <sup>39</sup>

Polymers	Degradation process	Mechanical lost (month)	Mass loss (month)	Applications
PLLA	Bulk erosion	9-12	36-48	Orthopaedics, oral, and maxillofacial surgery
PDLLA	Bulk erosion	1-2	5-6	-
PGA	Bulk erosion	0.5-1	3-4	Orthopaedic surgery
PCL	Bulk and surface erosion	9-12	24-36	Drug Delivery

Table 5. In-vitro performance of biodegradable polymers

No	Biodegradable Materials	Performance
01	Collagen	• Induced tissue remodelling <sup>93</sup> .
		Showed rapid shrinkage <sup>93</sup> and lack of mechanical properties <sup>121</sup>
02	Silk <sup>96</sup>	Had extraordinary mechanical properties.
		Sericin may cause problem related to hypersensitivity.
03	PLLA	Attracted cells adhesion and promote cell spreading and proliferation 54
		• Showed mechanical integrity during culturing period <sup>54, 91, 101</sup> .
		• Nanofibrous structure provided uniform cell morphology and ECM deposition <sup>104</sup> .
04	PLGA	UV sterilization resulted in surface roughness 54
		Showed rapid degradation <sup>91, 101</sup> .
		Braided structure promoted cells adhesion and proliferation <sup>54</sup> .
05	PGA	Induced less optimal cellular response 54
		PLA coating promoted ECM deposition <sup>46</sup> .
07	PCL	• Ultrafine fibrous structure provided cells attachment, maintained cells phenotype, and induced matrix secretion along fibres direction 44-45, 121.
		Promoted ECM deposition similar to natural fibrocartilage 44-45.
		Had weaker mechanical properties compared to natural fibrocartilage 44.

relatively small amount of bioglass addition could enhance soft tissue ingrowth 112-113.

Another potential benefit of bioglass is its ability to enhance angiogenesis, a process related to blood vessels formation. Vascularization is important for nutrient supply, in supporting tissue healing. Bioglass coating could induce the formation of blood vessels, by stimulating the release of VEGF and other angiogenic growth factors <sup>112, 115</sup>.

In cartilage engineering, the growth of chondrocytes and formation of neocartilage could be facilitated by bioactive glasses<sup>116-119</sup>. Bioglass formed bonding with subchondral bone and induced formation of hyaline-like cartilage with earlier chondrogenesis compared to hydroxyapatite <sup>116</sup>. Another study showed substrate of 45S5 bioglass provided suitable environment for chondrocyte attachment, proliferation, and homogenous distribution <sup>118</sup>. This study then suggested that the glass substrate was able to influence chondrocytes to retain their phenotype feature. Moreover, addition of 45S5 bioglass could improve hydrophilicity of hydrophobic material, thus increasing cell migration and adhesion <sup>119</sup>.

Scaffold degradation might also be tuned by the addition of bioactive glass. Bioglass took role as a barrier that controlled the polymer degradation rate <sup>114</sup>. According to those studies, the glass layer released alkali and created pH buffer on polymer surface, leading to small pH changes and decreased the degradation rate. Subsequently, structural reliability of the polymeric substrate could be improved <sup>114</sup>. Furthermore, acidic degradation of degradable polyesters could be controlled to lessen inflammatory response <sup>122</sup>.

Materials used for fibrocartilage replacement were mostly inert, such as PET, PTFE, PU, or PE. This type of material induces formation of non-adherent fibrous capsule, rather than stable adhesion of implant and host tissue <sup>108, 123</sup>. Consequently, the implant could loosen and it leads to clinical failure <sup>123</sup>. Implant stabilization could be improved by addition of bioactive material to

provide biological bonding with surrounding bone tissue <sup>65, 79, 108</sup>. The coating of ligament replacement using 58S5 bioglass demonstrated that the coated implants induced more new bone formation and higher expression of VEGF and BMP-2 compared to the uncoated samples<sup>115</sup>. The coating of AWGC (Apatite-Wollastonite Glass Ceramic) on artificial intervertebral disc also showed direct bonding between bone and AWGC <sup>79</sup>.

### 7 FIBROUS SCAFFOLD FOR ACETABULAR LABRUM IMPLANT

Fibrocartilage possesses fibrous structure, which its arrangement depends on the tissue <sup>60</sup>. According to the theory of causal histogenesis, tissue structure is directly related to the applied stress, with collagen fibrils are always oriented in the direction of the greatest tension<sup>9</sup>. Structure of acetabular labrum consists of collagen fibers, which its main portion arranged circumferentially<sup>9</sup>. Therefore, to mimic the function of native tissue, fibrous structure could be advantageous in the design of labrum implant.

Fabrics and textile are potential for fabrication of highly porous scaffold required for tissue engineering <sup>39, 96, 124</sup>. Textile technology has been applied in various biomedical applications <sup>124</sup>. The fabric can be in the form of knitted, braided, woven, or non-woven structure, which every structure delivers different microstructure and mechanical properties <sup>96, 124</sup>. Several scaffolds and implants for fibrocartilage also employed this fabrics structure, including those for ACL <sup>42, 54, 59, 62, 96</sup> and intervertebral disc replacement <sup>77-81, 124</sup>.

Scaffold with nanoscale structures draws interests in tissue engineering studies. It could potentially mimic the architecture of natural tissue, thus provide favourable environment for cells attachment<sup>45, 48-50</sup>. Nanofiber approach has been used in the scaffolds for fibrocartilage tissue engineering have been developed

using nanofibrous structures, for example those for meniscus  $^{44,\,103}$  and intervertebral disc  $^{45,\,104}$ .

To fabricate these ultrafine fibers, electrospinning provides a relatively simple and versatile approach. Generally, this process uses high electric potential to transform polymer solution into fibres with diameter from 3 nm to 5 µm<sup>125-127</sup>. Various processing parameters and techniques, along with their effects on fibers morphology has been reviewed in a literature 125-126. Fiber arrangement could also be tailored using rotating drum or mandrel collector<sup>44, 103, 126</sup>. However, electrospinning produces densely arranged fibres, thus it may be lack of porosity. Therefore, several strategies should be employed to create a desirable porous structure. Those approaches include leaching, ice crystals collector, wet electrospinning, laser/UV irradiation, microfibers-nanofibers combination, and control of electronic fields distribution <sup>128</sup>.

Regarding the fibrous structure of acetabular labrum, fabrics-based design could be potentially employed as the labrum implant. The implant may consist of fabric composite, which a non-degradable fabric combined with degradable polyester fibers. The degradable part comprises electrospun fibers network that performs as temporary scaffold for tissue regeneration. On the other hand, the non-degradable fabric will provide mechanical support during tissue remodelling and healing process. Furthermore, bioactive glass coating can be added to promote interfacial bonding to the adjacent tissue, as well as improving healing process. For further consideration, the implant should also be suitable for arthroscopic.

For the implant macrostrucutre, UHMWPE fabric appears to be the promising material due to its mechanical strength and stability. Studies on device for intervertebral disc and ACL replacement showed fatigue and abrasion resistant of UHMWPE 78, 80-81, 129. Used as ligament prostheses, this polyethylene exhibited both rotational and flexural fatigue resistant, as showed by limited wear and axial split if compared to those from PTFE and PET. Additionally, it may overcome poor shear strength and wear resistant of carbon fibre, as well as water absorbance of Kevlar<sup>130</sup>. Due its mechanical strength and biocompatibility, UHMWPE fabric has been applied clinically, for example as ACL replacement and dental applications<sup>62, 131</sup>. Nevertheless, its inert nature would not induce tissue response, thus addition of bioactive substance is required to form tissue bonding. Hydrophobicity is also another issue, particularly for interfacial adhesion in composite material <sup>130, 132</sup>.

For the degradable section of the device, PCL nanofibers appear to be suitable candidate, due to its tissue compatibility and mechanical flexibility. It is a biocompatible material and already FDA-approved <sup>39, 43</sup>. For tissue replacement that require elasticity, such as fibrocartilage, PCL appears to have compliance and flexibility, besides structural stability toward hydrolysis, to support cell propagation and interaction with the

matrix in physiological environment<sup>43</sup>. However, its mechanical strength is weak compared to PLLA, although it remains elastic and even is used to cover the brittleness of PLLA<sup>121, 133</sup>. Degradation rate of PCL is relatively slower compared to other degradabale polyesters (table 2), which may be enough to support the labrum recovery. In clinical setting, it has broadly utilized mainly for drug-delivery<sup>39, 90</sup>. PCL has been developed for fibrocartilage tissue engineering application for meniscus and intervertebral disc, having reach as far as preclinical stage<sup>58, 134</sup>. Its further potentials are also still being explored, including those for meniscus <sup>44, 103, 135</sup>, vertebral disc <sup>45</sup>, cartilage <sup>136-137</sup>, and musculoskletal tissue <sup>121</sup>.

As a starting point of the development process, design requirements need to be identified. Those factors could be derived from the purpose or objective of the prostheses, complemented with risk of failure analysis. In this case of prosthetic labrum, the purposes are developed from abovementioned studies of acetabular labrum function and its disorders, supplemented with the concept of tissue engineering scaffold. Meanwhile, risk of failure analysis is useful to anticipate potential problems, and it will be discussed in the next section. The relationship matrix between the implant purpose and failure risk to the design requirement is presented in a table 6. Design requirement is a list of measurable factors to assess the product quality. From this list, several material candidates are compared and taken into consideration for material selection (table 7). The approach of the implant for labrum recovery is illustrated in figure 4.

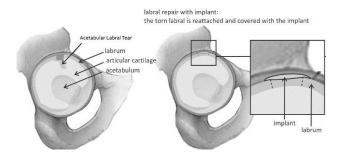


Figure 4. Application of the labrum prostheses in the hip joint

### 8 RISK OF FAILURE FOR ACETABULAR LABRUM PROSTHESES

In the process of the design and development, several challenges need to be identified. In the case of labrum prostheses, failures from clinically used fibrocartilage replacements are taken into consideration, to anticipate potential problems. Those risks are related to both tissue response and intrinsic failure of the implant.

Table 6. User needs, Risks of failure, and design requirements.

Design Requirements	Bioactive, bond with hard and soft tissue 9, 17, 25-26	Stimulate vascularization 9, 25, 30-31.	Compatible tensile strength and stiffness with labrum	Wear resistance	Fatigue resistance	Porosity and interconnected pores <sup>39, 56, 62, 73-74, 88</sup>	Biocompatible 39	Bioresorbable <sup>39</sup>	Suitable surface properties 39	Labral autograft size	Nanofibrous morphology 9, 43, 121	Anchor and suture system <sup>23, 138</sup>
Needs												
Maintain sealing function <sup>26-27, 32</sup>			•									
Maintain stabilization function <sup>17, 27, 31</sup>			•									
Promote tissue regeneration <sup>9</sup>						•	•	•	•		•	
Provide healing potential 9, 30-31		•										
Insertion by arthroscopy <sup>23</sup>										•		
Support anchoring and suturing <sup>5, 23, 37</sup> for implant attachment <sup>64, 76, 80</sup>			•							•		•
Risks												
Tissue penetrates only external layer 44, 62, 68-70						•						
structural breakage <sup>56, 62, 64, 89</sup>	•		•		•							
abrasion and erosion <sup>62, 64, 86</sup>				•								
Fibrous scar tissue formation <sup>62, 69-70, 77-80</sup>								•	•		•	
Inflammation <sup>62, 64, 86</sup>							•	•				
Mechanical incompatibility with natural tissue			•									
Dislocation <sup>64, 73</sup>	•		•		•							•
Damaging surrounding tissue <sup>56, 73-74, 76, 89</sup> or degeneration <sup>68-70</sup>	•			•	•		•					•
Lack of nutrient diffusion <sup>45</sup>						•						

Design and materials of implanted device might affect tissue response, which could lead to complications. It is desirable that an implant could fully integrate with host tissue. However, in many cases of fibrocartilage implant, tissue penetrated only external layer 44, 62, 68-70. Instead of promoting tissue remodelling, an implant could also induce fibrous scar tissue formation 62, 69-70, 77-80. This scar consists of randomly oriented collagen fibres that incapable to resist mechanical loads as normal tissue. Moreover, damage on surrounding tissue or degeneration could occur 56, 68-70, 73-74, 76, 89.

Failures might emerge from structural weakness of a medical device. Structural breakage could be initiated by continuous loading and tissue infiltration<sup>56, 62, 64, 89</sup>. In

several devices, abrasion and erosion were observed mainly in load bearing area<sup>62, 64, 86</sup>. Additionally, dislocation could occur, which was related to the lack of implant attachment to the surrounding tissue<sup>64, 73</sup>. Another challenge is related to the deficiency of nutrient diffusion throughout the implant, which might halt tissue penetration<sup>45</sup>.

### 9 SUMMARY AND FUTURE DIRECTION

There is an increasing awareness of the importance of acetabular labrum in biomechanics of hip joint. Moreover, labral damage has been indicated as the

Table 7. Material Selections

					Materi	al Selec	tion			
	Carbon Fiber	PTFE	PET	UHMWPE	Polyurethane	Collagen	PLLA	PGA	PCL	Bioglass
Design Requirement										
Bioactive, bond with hard and soft tissue	-	-	-	-	-	***	-	-	-	***
Stimulate vascularization	-	-	-	-	-	-	-	-	-	**
Compatible tensile strength and stiffness with labrum	*	**	*	**	***	*	**	*	**	-
Wear resistance	*	*	**	***	*	*	*	*	*	-
Fatigue resistance	*	*	**	***	*	*	*	*	*	-
Porosity and interconnected pores	-	-	-	-	-	-	-	-	-	-
Biocompatible	*	*	**	**	**	***	***	***	***	***
Bioresorbable	*	*	*	*	*	***	***	**	***	***
surface properties for cell adhesion	*	*	*	*	*	***	***	**	***	***
labral autograft size	-	i	ı	-	-	-	-	-	-	-
nanofibrous morphology	*	*	*	*	*	***	***	***	***	***
Anchor and suture system	ı	1	-	-	-	-	-	-	-	-

<sup>\*\*\*</sup> good, \*\* average, \* poor, - not the intended use

References: Carbon fibres <sup>70</sup>, PTFE (polytetrafluoroethylene) <sup>62, 64, 68, 70-71</sup>, PET (polyethylene terephtalate) <sup>62, 68-70, 86-87</sup>, UHMWPE (Ultra High Molecular Weight Polyethylene) <sup>62, 66, 77-81</sup>, collagen <sup>93, 121</sup>, PLLA (poly-L-lactid Acid) <sup>54, 91, 101</sup>, <sup>104</sup>, PGA (polyglicolic acid) <sup>46, 54</sup>, PCL (polycaprolactone) <sup>44-45, 121</sup>, Bioglass <sup>24, 105, 109, 123</sup>.

onset of osteoarthritis. With clinical complications and economic burden of osteoarthritis treatment, such as total hip replacement, preserving the function of the labrum is considered important. However, there are several risks after acetabular labrum treatment, including imperfect healing or reoccurrence of injury that may hinder patients' return to their daily activities. Therefore, labrum prosthesis is proposed as an alternative solution for the treatment of labral injury.

For the development of labrum prosthesis, several strategies need to be addressed. After the design requirements are identified and material candidates are selected, specific value need to be determined, along with the testing methods to validate the design and assess the product quality. Furthermore, fabrication methods and its parameters need to be optimized. During the process, inputs from clinician and manufacture practitioners should also be included, in the effort to realize an applicable design. With the proper design and development approach, a potential benefits for clinical setting could be achieved.

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