

**Abschlussbericht des**

**Ausschusses Krankenhaus**  
**nach §137c SGB V**

**Methode:**  
**Autologe Chondrozytenimplantation (ACI)**

**Indikationen:**  
**ACI an den Fingergelenken**  
**ACI am Schultergelenk**

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## 1. Einleitung

Die Überprüfung der Autologen Chondrozytenimplantation (ACI), Teilindikation ACI am Fingergelenk zur Behandlung von Gelenkknorpelschäden am Finger gemäß § 137c SGB V im Ausschuss Krankenhaus ist mit Datum vom 05.11.2001 durch die Spitzenverbände der Krankenkassen beantragt worden.

Nach Veröffentlichung des Themas im Bundesanzeiger Nr. 99, Seite 11933 vom 4.06.2002, der Zeitschrift „Das Krankenhaus“ 7/2002, Seite 565 und im Deutschen Ärzteblatt Nr. 99, Heft 27 vom 05.07.2002, Eingang der Stellungnahmen, Recherche und Aufarbeitung der wissenschaftlichen Literatur durch die Geschäftsführung des Ausschusses Krankenhaus ist die Beratung über die Indikation ACI am Fingergelenk in der Sitzung des Ausschusses Krankenhaus vom 26.03.2003 nach vorheriger Vorbereitung im Arbeitsausschuss Methodenbewertung erfolgt. Einzelheiten des Verfahrens sind in den Verfahrensrichtlinien des Ausschusses Krankenhaus (Bundesanzeiger Nr. 77, Seite 8893 vom 24.04.2002) festgelegt. Nach Abschluss der Überprüfung aller beantragter Indikationen der ACI erfolgt ein zusammenfassender Gesamtbericht.

## 2. Grundlagen der Autologen Chondrozytenimplantation

Schäden des Gelenkknorpels zeichnen sich durch eine große Heterogenität aus. Dabei ist die Ätiologie und die Ausdehnung des Knorpelschadens von großer Bedeutung. Unterschieden werden degenerative Knorpelschäden, posttraumatische Knorpelschäden, entzündliche Knorpelschäden, metabolische Knorpelschäden, vaskulär-toxische Knorpelschäden und – als eigene Entität – die Osteochondrosis dissecans. Als allgemein gültige Beschreibung der Ausdehnung des Knorpelschadens ist die Klassifikation der International Cartilage Repair Society allgemein anerkannt. Therapiebedürftig sind nach allgemeinen fachlichen Konsens Knorpelschäden Grad III und IV.

Zur Diagnostik von Gelenkknorpelschäden wird im wesentlichen die Kernspintomographie eingesetzt. Mit Hilfe knorpelspezifischer Sequenzen (*Flash 3-D*) sind gute Darstellungen der knorpeligen Gelenkoberflächen und des subchondralen Knochens möglich. Unabhängig davon haben die Standardröntgenuntersuchung, neben Funktionsaufnahmen (Beinganzaufnahmen, Varus- und Valgusstressaufnahmen etc.), nach wie vor ihren Stellenwert in der Diagnostik von Gelenkschäden. Bei der Therapie von Gelenkknorpelschäden ist die Behandlung von Begleitverletzungen eine *Conditio sine qua non*. Knorpelregenerative Techniken haben insbesondere dann Aussicht auf Erfolg, wenn bestehende Varus- und Valgusdeformitäten, die Integrität des Gelenkes sowie Bandinstabilitäten mit berücksichtigt und ggf. therapiert werden.

Der hyaline Gelenkknorpel zeigt einen einzigartigen strukturellen Aufbau. So wird eine oberflächliche tangential Zone, die etwa 10 bis 20 % des Gesamtvolumens ausmacht, von einer mittleren Zone mit 40 bis 60 % Volumenanteil und einer tiefen Zone mit 30 % Volumenanteil unterschieden. In der oberflächlichen tangentialen Zone sind die Zellen und die Kollagen-II-Fibrillen tangential angeordnet. In der mittleren Zone zeigen die Zellen eine säulenartige Anordnung, die Kollagenfibrillen sind hier scherengitterartig ausgerichtet. In der tiefen Zone erfolgt die Verankerung an die subchondrale Knochenschicht. Die Kollagenfasern sind hier senkrecht angeordnet.

Der Gelenkknorpel weist einen Friktionsindex auf, der nur 20 % des Gleitwiderstandes von Eis auf Eis hat. Dies ist nur möglich durch eine einzigartige Architektur der extrazellulären Matrix. Sie besteht zu 65 bis 80 % aus Wasser, 10 bis 20 % Kollagen Typ II, 4 bis 7 % Aggrekan und 1 bis 5 % Zellen. Hinzu kommen als kleinere Komponenten mit einem Volumenanteil von <5% die Proteoglykane, Decorin, Fibromodulin, Kollagen V, VII, IX, X, XI, Link Protein, Hyaluronsäure und Fibronectin. Durch die negativen Ladungen der Proteoglykane wird das Wasser passiv in das extrazelluläre Netzwerk hineingezogen und unter physiologischer Belastung wieder wie ein Schwamm herausgepresst. Durch diesen Mechanismus wird die Versorgung der Chondrozyten mit Nährstoffen aus der Gelenkflüssigkeit sichergestellt. Der Anteil von Chondrozyten am Gelenkknorpel variiert zwischen 1 bis 5 %. Es sind ausdifferenzierte mesenchymale Stammzellen, die weder innerviert noch perfundiert sind. Die Nährstoffversorgung erfolgt per Diffusion durch eine doppelte Membrane (Synoviazellen / Chondrozyten). Der Metabolismus wird über eine anaerobe Glykolyse aufrechterhalten. Die Porengröße der Zellen beträgt 50 Å und ist damit für Proteine mit einer Größe <20 kd permeabel. Die Diffusionszeit beträgt zehn Sekunden bis eine Stunde. Für die Neusynthese einer Kollagenfibrille benötigt eine menschliche Knorpelzelle bis 600 Tage und für Proteoglykane ca. 30 Tage. Zelluläre Reaktionen können durch Zytokine, Wachstumsfaktoren, Hormone, Ladungsveränderungen, Druckveränderungen uvm. ausgelöst werden. Für die Homeostase des Gelenkknorpels ist ein Gleichgewicht der regulatorischen Zytokine notwendig.

Die physiologische Antwort des Organismus auf eine Schädigung des Gelenkknorpels hängt von einer Vielzahl von Faktoren ab. So zeigen Kinder bis zum Abschluss des Wachstums eine erstaunliche Regenerationskapazität. Im Gegensatz dazu weisen Erwachsenen und besonders der ältere Mensch nur noch eine sehr geringe Regenerationsfähigkeit auf. Inwieweit dies zum Beispiel mit dem Abfall der Konzentration mesenchymaler Stammzellen im Organismus in Zusammenhang steht ist noch unklar.

Die herkömmlichen Behandlungsstrategien sind Knochenmark-stimulierende Methoden (Pridie, Microfracture, Abrasionsarthroplastik), bei denen durch Eröffnung des Markraums eine Blutung induziert wird. Dieser „Fibrin Clot“ kann sich in einen Faserknorpel mit reduzierten biomechanischen Eigenschaften umwandeln. Die Beschwerden der Patienten können dadurch für eine begrenzte Zeit gemindert werden. Durch die Transplantation osteochondraler Zylinder kann die Patientensymptomatik nachhaltig verbessert werden. Die Technik ist in ihrer Anwendung durch die Hebedefekte bei der Entnahme der Spenderzylinder deutlich limitiert.

Das Tissue Engineering ist durch die Einführung der Autologen Chondrozyten-transplantation ein weiteres Verfahren der Behandlung von Gelenkknorpelschäden geworden. Bei der ACT werden z.B. im Rahmen einer ACI am Kniegelenk bei einer Arthroskopie eine definierte Knorpelmenge aus einem gesundem unbelasteten Knorpelareal entnommen. Das Gewebe wird unmittelbar in ein mit Medium gefülltes Spezialgefäß überführt. Unter Beachtung einer geschlossenen Kühlkette wird die Knorpelbiopsie in einer speziellen Transportbox zu dem entsprechenden Zelllabor transportiert. Aus der entnommenen Knorpelprobe werden dann, durch ein mechanisches und ein enzymatisches Verfahren, die Knorpelzellen herausgelöst und unter GMP-Bedingungen vermehrt. Für diesen Expansionsprozess sind eine Vielzahl von Validierungsschritten notwendig. Insbesondere muss die Aussaatdichte, verwendete Kulturgefäße, Kulturmedien, Cofaktoren wie Antibiotika und Vitamine, Eiweißtyp und Eiweißkonzentration, pH-Werte, pO<sub>2</sub>, CO<sub>2</sub>, Temperatur, Häufigkeit der Medienwechsel, Zeitpunkt der Passagierung sowie die Kontrolle der Bakterienfreiheit

überprüft werden. Dabei zeigen die von ihrer umgebenden extrazellulären Matrix befreiten Chondrozyten interindividuell eine große Schwankungsbreite ihrer Wachstumspotenz. Entsprechend verändert sich das mikroskopische Aussehen der Zellen von einem runden zu einem eher fibroblastischen Zelltyp. Dieser Prozess der DEDIFFERENZIERUNG zeigt sich auch im Metabolismus. So zeigen dedifferenzierte Knorpelzellen nur noch eine Expression unspezifischer Metaboliten wie Kollagen I und VI. Werden mehr als drei Passagen zum Erreichen der Zielzellzahl benötigt, reduziert sich die Fähigkeit der Zellen sich zu vollwertigen Chondrozyten wieder umzuwandeln. Eine REDIFFERENZIERUNG in vitro wie in vivo ist dann nicht mehr zu erwarten. Das Ziel der Expansion von humanen Chondrozyten ist - unter Optimierung kurzer Kultivierungszeiten - eine ausreichende Anzahl redifferenzierungsfähiger, vitaler und nichtkontaminierter Zellen zu erreichen. Dabei sollte die Redifferenzierungsfähigkeit mikroskopisch und metabolisch durch entsprechende standardisierte Analytik vor Abgabe der Zellen belegt werden. Unter Einhaltung einer geschlossenen Kühlkette werden die Zellen (ca.  $1 \times 10^6$  Zellen /  $\text{cm}^2$  Defekt) dann für die Implantation an die entsprechende Klinik per Kurier abgegeben. Im Rahmen einer zweiten offenen Kniegelenk-Operation werden die vermehrten Chondrozyten unter einen eingenähten Periostlappen injiziert. Sie wachsen dann an dieser bioaktiven Kammer fest und füllen den Defekt mit einem Knorpelregenerat auf. Dieses primäre Regeneratgewebe reift unter mechanischer Stimulation langsam zu einem differenzierten Knorpel aus (6 Wochen bis 18 Monate). Um den Behandlungserfolg zu sichern, sollte eine standardisierte und qualifizierte Nachbehandlung erfolgen.

### **3. ACI an den Fingergelenken**

#### 3.1 Informationsgewinnung

Die Informationsgewinnung des Ausschusses Krankenhaus zielt bei der Vorbereitung des jeweiligen Beratungsthemas auf eine Feststellung des derzeit verfügbaren medizinisch-wissenschaftlichen Wissensstandes einer Methode im Sinne von § 2 Abs. 1 Satz 3 SGB V ab.

Hierzu werden über den Weg der Veröffentlichung aktuelle Stellungnahmen von Sachverständigen aus Wissenschaft und Praxis eingeholt. Über die hiermit gewonnenen Hinweise auf aktuelle wissenschaftliche Veröffentlichungen hinaus, führt der Ausschuss Krankenhaus eine umfassende aktuelle Literaturrecherche durch.

Entsprechend wurde eine Recherchestrategie für die Autologe Chondrozytenimplantation erstellt und in folgenden Standarddatenbanken angewendet: The Cochrane Library, MEDLINE, EMBASE, HSTAT, TRIP Database, AWMF-Leitliniendatenbank und bei in der Cochrane Library nicht aufgenommenen HTA-Institutionen. Nachfolgend wurden aus den Ergebnissen die Literaturstellen identifiziert, welche sich mit der Indikation ACI an den Fingergelenken befassen.

Die genaue Recherchestrategie ist in Anlage 5.1 beigelegt.

Die entsprechend aufbereiteten Rechercheergebnisse wurden von einer, durch den Arbeitsausschuss Methodenbewertung eingesetzten Arbeitsgruppe zum Thema ACI geprüft. Basierend auf den Verfahrensabläufen des Ausschusses Krankenhaus wurde diese Liste zunächst gesichtet und die einzelnen Quellen entweder eingeschlossen und klassifiziert oder aber ausgeschlossen, wobei ein Ausschlussgrund angegeben wurde. Eine Auswertung von Tierstudien erfolgte nicht, da die Übertragbarkeit solcher Ergebnisse auf den Menschen und damit in das Versorgungssystem als limitiert anzusehen ist.

Die gefundenen Literaturstellen zum Thema Fingergelenk sind unter Punkt 3.3 beigelegt.

Im nächsten Schritt wurden dann die HTA-Berichte, systematischen Reviews und Leitlinien identifiziert und bewertet. Anschließend wurde die Bewertung auf Primärstudien zunächst der Evidenzklasse I (RCT) und anschließend auf niedrigeren Evidenzstufen ausgeweitet. Aus den vorliegenden Literaturstellen konnten keine Hinweise für den Einsatz der ACI im Bereich der Fingergelenke gefunden werden.

#### 3.2 Entscheidungsfindung und –begründung

Basis der Entscheidungsfindung bildet die Fragestellung, die sich aus den gesetzlichen Vorgaben des § 137c Abs. 1 SGB V ergibt: Erfüllt die Autologe Chondrozytenimplantation an den Fingergelenken – auch im Vergleich zu bereits zu Lasten der gesetzlichen Krankenversicherung erbrachten Methoden – die Kriterien ausreichend, zweckmäßig und wirtschaftlich unter Berücksichtigung des allgemein anerkannten Standes der medizinischen Erkenntnisse?

Im vorbeschriebenen Ablauf der Informationsgewinnung konnten keine HTA Berichte, systematischen Reviews oder Leitlinien zu der Indikation ACI an den Fingergelenken identifiziert werden.

Ebenfalls fehlt es gänzlich an Primärstudien der Evidenzklassen I und IIa-c. Erkenntnisse der Evidenzklasse III, die den Nutzen bei der untersuchten Indikation belegen, liegen dem Ausschuss nicht vor.

Insbesondere ergab auch die Auswertung der eingegangenen Stellungnahmen keine Hinweise auf die Anwendung der ACI an den Fingergelenken.

Basierend auf dieser Situation, dass es derzeit keine medizinisch- wissenschaftliche Literatur zum Thema ACI an den Fingergelenken gibt, kommt der Ausschuss Krankenhaus zu der Auffassung, dass es sich bei der Methode der Autologen Chondrozytenimplantation an den Fingergelenken derzeit nicht um eine Methode handelt, die den Kriterien des § 137c SGB V gerecht wird.

#### **Fazit der Bewertung**

Der Ausschuss Krankenhaus kommt zu der Entscheidung, dass die Methode der Autologen Chondrozytenimplantation an den Fingergelenken derzeit nicht den Kriterien des § 137c SGB V (ausreichend, zweckmäßig, wirtschaftlich) entspricht und ist damit nicht Leistung im Rahmen der gesetzlichen Krankenversicherung.

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## **4. ACI am Schultergelenk**

### 4.1 Informationsgewinnung

Die Informationsgewinnung des Ausschusses Krankenhaus zielt bei der Vorbereitung des jeweiligen Beratungsthemas auf eine Feststellung des derzeit verfügbaren medizinisch-wissenschaftlichen Wissensstandes einer Methode im Sinne von § 2 Abs. 1 Satz 3 SGB V ab.

Hierzu werden über den Weg der Veröffentlichung aktuelle Stellungnahmen von Sachverständigen aus Wissenschaft und Praxis eingeholt. Über die hiermit gewonnen Hinweise auf aktuelle wissenschaftliche Veröffentlichungen hinaus führt der Ausschuss Krankenhaus eine umfassende aktuelle Literaturrecherche durch.

Entsprechend wurde eine Recherchestrategie für die Autologe Chondrozytenimplantation erstellt und in folgenden Standarddatenbanken angewendet: The Cochrane Library, MEDLINE, EMBASE, HSTAT, TRIP Database, AWMF-Leitliniendatenbank und bei in der Cochrane Library nicht aufgenommenen HTA-Institutionen. Nachfolgend wurden aus den Ergebnissen die Literaturstellen identifiziert, welche sich mit der Indikation ACI an den Schultergelenken befassen.

Die genaue Recherchestrategie ist in Anlage 5.1 beigefügt.

Die entsprechend aufbereiteten Rechercheergebnisse wurden von einer, durch den Arbeitsausschuss Methodenbewertung eingesetzten Arbeitsgruppe zum Thema ACI geprüft. Basierend auf den Verfahrensabläufen des Ausschusses Krankenhaus wurde diese Liste zunächst gesichtet und die einzelnen Quellen entweder eingeschlossen und klassifiziert oder aber ausgeschlossen, wobei ein Ausschlussgrund angegeben wurde. Eine Auswertung von Tierstudien erfolgte nicht, da die Übertragbarkeit solcher Ergebnisse auf den Menschen und damit in das Versorgungssystem als limitiert anzusehen ist.

Im nächsten Schritt wurden dann die HTA-Berichte, systematischen Reviews und Leitlinien identifiziert und bewertet. Anschließend wurde die Bewertung auf Primärstudien zunächst der Evidenzklasse I (RCT) und anschließend auf niedrigeren Evidenzstufen ausgeweitet. Es konnten keine Literaturhinweise für den Einsatz der ACI im Bereich des Schultergelenkes gefunden werden.

#### 4.2 Entscheidungsfindung und –begründung

Basis der Entscheidungsfindung bildet die Fragestellung, die sich aus den gesetzlichen Vorgaben des § 137c Abs. 1 SGB V ergibt: Erfüllt die Autologe Chondrozytenimplantation am Schultergelenk – auch im Vergleich zu bereits zu Lasten der gesetzlichen Krankenversicherung erbrachten Methoden – die Kriterien ausreichend, zweckmäßig und wirtschaftlich unter Berücksichtigung des allgemein anerkannten Standes der medizinischen Erkenntnisse?

Im vorbeschriebenen Ablauf der Informationsgewinnung konnten keine HTA-Berichte, systematischen Reviews oder Leitlinien zu der Indikation ACI an der Schulter identifiziert werden.

Ebenfalls fehlt es gänzlich an Primärstudien der Evidenzklassen I und IIa-c. Erkenntnisse der Evidenzklasse III, die den Nutzen bei der untersuchten Indikation belegen, liegen dem Ausschuss nicht vor.

Insbesondere ergab auch die Auswertung der eingegangenen Stellungnahmen keine Hinweise auf die Anwendung der ACI am Schultergelenk.

Basierend auf dieser Situation, dass es derzeit keine medizinisch-wissenschaftliche Literatur zum Thema ACI am Schultergelenk gibt, kommt der Ausschuss Krankenhaus zu der Auffassung, dass es sich bei der Methode der Autologen Chondrozytenimplantation am Schultergelenk derzeit nicht um eine Methode handelt, die den Kriterien des § 137c SGB V gerecht wird.

#### **Fazit der Bewertung**

Der Ausschuss Krankenhaus kommt zu der Entscheidung, dass die Methode der Autologen Chondrozytenimplantation am Schultergelenk derzeit nicht den Kriterien des § 137c SGB V (ausreichend, zweckmäßig, wirtschaftlich) entspricht und ist damit nicht Leistung im Rahmen der gesetzlichen Krankenversicherung.

## **5. Anlagen**

### 5.1: Suchstrategie „Autologe Chondrozytenimplantation“

#### **Recherchierte Datenbanken**

The Cochrane Library (einschl. NHS Datenbanken)

HSTAT

ISTAHC Database

TRIP Database

MEDLINE

EMBASE

BIOSIS

Current Contents

CCMed

AWMF

#### **Recherchierte Institutionen**

FDA

GAO

NIH

Medicare

## Allgemeine Recherchen (indikationenunspezifisch)

### Datenbank: The Cochrane Library

Recherchezeitraum: keine Restriktionen

Datum der Recherche: 20.06.2002

Suchschritt	Suchtext	Anzahl der gefundenen Dokumente
#1	autologous chondrocyte transplantation	6
#2	CHONDROCYTES single term (MeSH)	6
#3	TRANSPLANTATION AUTOLOGOUS single term (MeSH)	462
#4	TISSUE TRANSPLANTATION single term (MeSH)	8
#5	chondrocyte* AND transplant* AND autologous	7
#6	#3 OR #4	469
#7	#6 AND chondrocyte*	2
#8	#1 OR #5 OR #7	7
#9	cartilage AND (transplantat* OR implantat*)	19
#10	#8 NOT #9	13

Die in der Cochrane Library identifizierten 13 Dokumente entfallen wie folgt auf die Teildatenbanken:

- **The Cochrane Database of Systematic Reviews** ..... 1
- **Database of Abstracts of Reviews of Effectiveness** ..... 1
- **The Cochrane Controlled Trials Register (CENTRAL/CCTR)** ..... 11
- **The Cochrane Database of Methodology Reviews** ..... 0
- **The Cochrane Methodology Register (CMR)** ..... 0
- **About the Cochrane Collaboration** ..... 3
- **Health technology assessment database (HTA)** ..... 4
- **NHS Economic evaluation database (NHS EED)** ..... 0

**Datenbank: MEDLINE (PubMed)**

Recherchezeitraum: 1998-2002

Datum der Recherche: 20.06.2002

Suchschritt	Suchtext	Anzahl der gefundenen Dokumente
#1	Search "Tissue Transplantation"[MESH] OR "Transplantation, Autologous"[MESH] OR "Transplantation"[MESH]	219.164
#2	Search "cell transplantation"[MESH]	16.021
#3	Search "Chondrocytes"[MESH]	1.815
#4	Search #1 OR #2	219.164
#5	Search #3 AND #4	140
#6	Search "Cartilage"[MESH]	40.874
#7	Search #3 OR #6	41.646
#8	Search #4 AND #7	2.945
#9	Search chondrocyt* AND (transplantat* OR implant*)	792
#10	Search #9 OR #8 OR #5	792
#11	Search #10 Field: All Fields, Limits: Publication Date from 1998 to 2002, Human	221

In allen übrigen Datenbanken wurde – je nach Möglichkeit - eine Freitextsuche mit den Suchbegriffen " chondrocyt\*" und „cartilag\*" durchgeführt.



## 5.2 Gesamtliteraturliste ACI

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Autologous chondrocyte implantation. Clinical privilege white paper (62); p.1-8 /20010719/. Journal Article.
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Meniscus transplantation--consensus declaration. Scandinavian journal of medicine & science in sports; VOL: 9 (3); p.131-3 /199906/. Consensus Development Conference; Editorial; Review.
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Resection of metaphyseal and epiphyseal neoplasms: the use of the patella for osteo-articular reconstruction. Italian journal of orthopaedics and traumatology; VOL: 1 (1); p.23-37 /197504/. Journal Article.
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