厚生労働科学研究研究費補助金 萌芽的先端医療技術推進研究事業 極細ファイバー関節鏡とその付属機器の開発に関する研究 平成14年度~16年度 総合研究報告書

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厚生労働科学研究費補助金 (萌芽的先端医療技術推進研究事業) 総合研究報告書

極細ファイバー関節鏡とその付属機器の開発に関する研究 主任研究者 伊藤 陽一

研究要旨

関節鏡視下手術は、整形外科領域で比較的頻度の多い手術方法である。一般的に、約4mm径の硬性関節鏡が必要であり、一方向刺入のみであるため、関節内での鏡の動きと視野に関して、多くの制限を有する。一方、関節鏡視下手術の際には、関節鏡刺入とは別の場所より、組織切除用等の器具を挿入する必要がある。これらの一連の操作上で煩雑な点は、鏡自体には手術器具がついていない点にある。現在の技術では鏡自体に約4mm径必要であり、鏡に手術器具を付加させると、鏡の径がより増大するため、手術侵襲低下と、関節内での鏡の動きの自由度改善の両方において、鏡の径の低下が必要不可欠である。そこで、本研究においては、関節鏡の径を極限まで細くすることと、関節内での柔軟な動きを得るために、極細ファイバー関節鏡の開発の可能性を検討した。

まず、本研究計画の最初に、既存ペンタックス社製のファイバー内視鏡の使用可能性の検討を行った。現在の硬性関節鏡では、鏡は基本的に外筒により保護されている。その外筒中に、耳鼻科領域で使用中のグラスファイバー内視鏡を挿入して、実際に鏡視が可能かを判断した。検討した内視鏡は、FNL-7RP3、VNL-1130、VNL-1130Rの3機種であった。FNL-7RP3は画像鮮明度に乏しく、VNL-1130はアングル長と有効長が長過ぎると判断出来た。VNL-1130Rは画像鮮明度も許容範囲であり、十分な視野確保も得られた。しかし、前2機種と同様に、ファイバー内視鏡自体が硬性鏡の外筒内を容易に回転してしまうため、鏡視の方向が正確に把握出来ず、手術操作の困難さを認めた。また、アングル基部が関節軟骨間に挟み込まれて損傷を受け、内視鏡の耐圧性に問題を認めた。以上の結果より、耐水性に関しては、既存のファイバー内視鏡で十分と判断出来た。しかし、鏡視方向の正確な把握目的には、外筒とファイバー内視鏡の間のロック機構をつける必要があると判断出来た。さらに、内視鏡の耐圧性に関しては、外筒に保護されている部分には問題は少ないが、外筒外で関節内に露出する部分に関しては、ファイバー内視鏡の必要長の検討と、ファイバー内視鏡の外側被覆している、ゴムの素材の改良が必要であると考えられた。

その結果をもとに、オリジナルファイバー内視鏡(EA-Y1170)と外筒ロック機構を開発した。 開発機器に関して、アングル角度、視野角度、観察深度、グリップ形状、送水流量、彎曲部分 の長さ、外筒ロック機構の固定状況等を検討した。動物実験において、実際に関節鏡視を行 い、実際の鏡視可能性及び内視鏡の操作性等を判断した。関節鏡手術中に、鏡視画像をパーソ ナルコンピューターに取り込み、記録した。さらに、鏡視写真もあわせて記録した。これら は、開発機器と従来の硬性関節鏡の両方で行い、両者の比較検討を行った。画像検討事項とし ては、静止画像の鮮明度、動画画像の鮮明度と画像の振れの有無を中心に行った。

開発機器では、関節鏡操作時に外筒からの還流液の漏出を防ぎ、かつ、関節内に挿入されてアングル角度を自由に変更できる部分の長さ調節が、十分に可能であることが確認できた。また、鏡視画像の動画静止画ともに、実際の臨床利用に問題の無いレベルであることの確認が可能であった。しかし、オリジナルファイバー内視鏡の耐久性と耐圧性には依然として若干の問題がある事と、画像の明るさが不十分である事の問題点があり、極細化にはグラスファイバー内視鏡では限界があると判断できた。

そこで、石英ファイバー内視鏡の開発にも従事した。我々の用いているグラスファイバー内視鏡は、可視光線の透過性に優れた光学ガラス素材を用いた ϕ 50 μ mの光学ガラス製の光ファイバーであった。一方、石英ファイバー内視鏡は、コアに純粋石英を用いており、透過ロスは少なく十分な光量が得られると判断できた。我々は、外径1mm、画素数12000画素で視野角度70度が可能になる石英ファイバー内視鏡をあらたに開発し、極細化への挑戦としては、外径0.4mm、画素数6000画素で視野角度70度が可能になる石英ファイバー内視鏡の開発を行った。石英ファイバー内視鏡において、極細化は可能となったが、グラスファイバー内視鏡のような軟性鏡ではなく直視鏡であるため、鏡先端部分の可動性がなく、柔軟性において劣っていた。よって、日常臨床においては、グラスファイバー内視鏡と、石英ファイバー内視鏡を適宜使い分ける必要があると判断できた。

A. 研究目的

関節鏡検査及び関節鏡視下手術は日常よく 行われている検査方法あるいは手術方法であ る。最も頻繁に行われている関節は膝関節で あるが、最近では肩関節、肘関節、足関節、 手関節等にその範囲は拡大されつつある。ま た、場所により若干異なるが、一般的に、関 節鏡には約3から4mm径の硬性鏡が必要である。 原則として、関節鏡はあくまで一方向刺入の みであり、関節内での鏡の動きに関して、多 くの制限を有する。さらに、解剖学的構造に よって、一方向のみの鏡視しか出来ない場合 があり、関節内構造物の位置関係から死角に なる部分もあり得る。これらの改善のために は、鏡の先端が多方向を向くことが可能であ ったり、より細い径で深部までの進入が可能 であったりすると、現在の鏡視像よりも改善

が期待でき、より低侵襲で十分な病態把握が可能になると思われる。

一方、関節鏡視下手術の際には、関節鏡刺 入とは別の場所よりポータルを作成し、組織 切除用あるいは組織縫合用の器具を関節内に 挿入することによって、鏡視下手術が可能に なる。これらの一連の操作上で煩雑であるこ とは、鏡自体には操作用の器具がついていな い点である。現在の技術では鏡自体に約3から 4mm径必要であり、鏡に手術操作用の器具を 付加させると、鏡の径がより増大するため、 手術侵襲と関節内での鏡の動きの自由度の両 方においてマイナスである。つまり、鏡の径 を小さくすることが必要不可欠である。

そこで、本研究においては、関節鏡の径を 極限まで細くすることの挑戦と、鏡視下手術 に必要な器具を関節鏡に付加させて、より安 全な関節鏡視下低侵襲手術方法の確立を目的とする。

現在使用されている内視鏡はグラスファイバーが用いられているため、極細ファイバー関節鏡の開発が必須であろうと考えている。整形外科疾患の中で、変型性関節症を中心とした関節疾患は大多数をしめている。極細ファイバー関節鏡の開発が可能になれば、それらの治療に際して、低侵襲での正確な鏡視下手術が可能になり、患者にとってより安全、安心な医療技術の提供を図ることが可能になり、さらには、入院を必要としない外来手術によって、医療費の軽減にもつながる。

B. 研究方法

日本は内視鏡の分野では独自の発展をし、技術的にもすぐれた製品を開発しており、特にグラスファイバーの進歩は著しい。今回、外科領域や耳鼻科領域において広く使用されているグラスファイバー内視鏡に対して、<I>整形外科領域においての応用の可能性の有無の検討、<II>改良項目の抽出と改良方法の検討を行い、ついで、<III>オリジナルファイバー関節鏡の開発を行った。実際の研究実施においては、(1)現在のグラスファイバー内視鏡の使用の可能性の検討、

(2) グラスファイバー内視鏡の耐水性の獲得、(3) グラスファイバー内視鏡の耐圧性、耐久性の獲得、(4) 関節内での実際の鏡視と可動性の確認、(5) 鏡視画像の評価の順に行った。

本研究計画の最初に、耳鼻科領域において 広く使用されているグラスファイバー内視鏡 に関する、基本的な情報収集を行った。最も 情報交換が容易な手段として、当大学病院の 耳鼻科において、実際に臨床使用されている 機器の特徴、サイズ、利便性およびそれらの 作成機器メーカーの特定を行った。

現在、硬性関節鏡で最も普及しているサイズは4mmの30°斜視鏡である。鏡は基本的には外筒により保護されている。その外筒の中に、外科及び耳鼻科領域で使用中のグラスファイバー内視鏡及び、開発機器であるオリジナルファイバー関節鏡を挿入して、動物実験(羊使用)において、実際に関節鏡視を行い、実際の鏡視可能性及び内視鏡の操作性等を判断した。関節鏡手術中に、鏡視画像をパーソナルコンピューターに取り込み記録し、鏡視写真もあわせて記録した。これらは、ファイバー関節鏡と、従来の硬性関節鏡の両方で行い、両者の比較検討を行った。画像検討事項としては、静止画像の鮮明度、動画画像の鮮明度と画像の振れの有無を中心に行った。

(倫理面への配慮)

研究過程で用いる動物種は羊である。動物 愛護の面で、全身麻酔下で、疼痛の無い状況 下で、清潔操作にて、極細ファイバー関節鏡 を用いた関節鏡視下手術を行った。術後の抗 生物質投与は実際の臨床例と同じく、術後3 日間の点滴静注を行い、感染症の防止に努め た。

C. 研究結果

当大学病院耳鼻科医師に信頼性の高い内視鏡は、ペンタックス社製であったため、同社の内視鏡の使用可能性を検討することにした。最初に検討した内視鏡は、鼻咽喉ファイバースコープ FNL-7RP3 (有効長300mm 直径2.4 mm アングル角度上下130度)であった。関節腔内の鏡視はかろうじて可能であったが、画

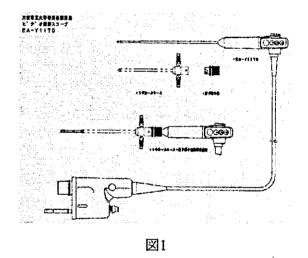
像鮮明度は乏しく、既存の硬性関節鏡に大き く劣っていた。しかし、グラスファイバー内 視鏡の耐水性は十分と判断出来た。そこで、 ファイバー内視鏡の直径をやや大きくして、 臨床使用上で許容可能な画像鮮明度が得られ るかを判断するために、ビデオ鼻咽喉スコー プ VNL-1130 (有効長300mm 直径3.7mm アングル角度上下130度)を次ぎに検討した。 画像鮮明度は若干硬性関節鏡に劣るが、臨床 使用上では、何とか許容範囲内と判断出来た。 しかし、アングル角度130°を得るために約3c mのアングル長を必要とする事と、有効長が30 0mmと必要以上に長い事は、操作を困難にさ せている要因と判断できた。そこで、有効長 の短縮とアングル角度を低下させたアングル 付鼻腔鏡 VNL-1130R (有効長 150mm 直 径3.7mm アングル角度上下90度)を次ぎに検 討した。画像鮮明度は許容範囲であり、十分 な視野確保も得られた。しかし、有効長等の 低下による操作性の向上はあるが、前2機種と 同様に、鏡視の方向が正確に把握出来ず、動 画画像評価において、明らかに画像の振れを 大きく認めた。さらに、本機種の検討中に、 アングル基部が関節軟骨間に挟み込まれて損 傷を受けた。

以上の結果から、硬性鏡外筒併用下で、有 効長150mm、直径3.7mmアングル角度90°の既 存ファイバー内視鏡の使用は可能であった。 また。耐水性は良好であったが、耐圧性に問題を残した。 さらに、硬性鏡外筒内でグラス ファイバー内視鏡が回旋する事と、外筒外部 の内視鏡長が不確定である事で、制御性に問題があった。最後に、現段階では、外筒除去 は困難と判断できた。

そこで、オリジナルファイバー関節鏡の開

発における改善項目として、回旋制御目的のロック機構を完成する事。ついで、マーカー刻印によって、内視鏡長調節を可能にする事。耐圧性、耐久性の向上目的には、硬性部分を含む事を基本に開発を進めた。

オリジナルファイバー関節鏡EA-Y1170の開発を、スミス&ネフュー社とペンタックス社の協力の下に行った。直径3.7mmで、視野角度120°、観察深達度2~30mm、アングル角度90度、硬性部長200mm、刺入部長調節目的に第二彎曲部30mmの追加を基本とした。さらに、EA-Y1170には、外筒との間のロック機構と、内視鏡長調節のためのマーカー刻印を追加した。(図1)



その結果、本開発機器では、関節鏡操作時に外筒からの還流液の漏出を防ぎ、かつ、関節内に挿入されてアングル角度を自由に変更できる部分の長さ調節が、十分に可能であることが確認できた。

オリジナルファイバー関節鏡における実際の関節鏡画像では、良好な解像度が得られ、関節内の十分な評価が可能であった。また、マーカー刻印により内視鏡長調節は円滑に行えた。さらに、アングル角度を関節内にて様々に変化させる事が可能であり、実際、硬性鏡では死角となる、関節包断裂部深部までの

鏡視が可能であった。

しかし、オリジナルファイバー内視鏡の耐 久性と耐圧性には依然として若干の問題があ る事と、画像の明るさが不十分である事の問 題点があり、極細化にはグラスファイバー内 視鏡では限界があると判断できた。

そこで、石英ファイバー内視鏡の開発にも 従事した。我々の用いているグラスファイバー内視鏡は、可視光線の透過性に優れた光学 ガラス素材を用いたφ50μmの光学ガラス製の 光ファイバーであった。一方、石英ファイバー内視鏡は、コアに純粋石英を用いており、 透過ロスは少なく十分な光量が得られると判断できた。我々は、外径1mm、画素数12000画素で視野角度70度が可能になる石英ファイバー内視鏡をあらたに開発し、極細化への挑戦としては、外径0.4mm、画素数6000画素で視野角度70度が可能になる石英ファイバー内視鏡の開発に従事し、石英ファイバー内視鏡において、極細化が可能となった。

D. 考察

今回検討した耳鼻科用ファイバースコープ 全機種において、鏡視の方向が正確に把握出 来なかったのは、ファイバー内視鏡自体が硬 性鏡の外筒内を容易に回転してしまうためと 考えられた。そして、動画画像評価における、 明らかな画像の振れの原因は、ファイバー内 視鏡自体が関節内の灌流液の影響を受けて、 微少振動を起こすためと推測できた。

この問題の解決策として、外筒とファイバー内視鏡の間に、ロック機構をつける必要があると判断出来、そのロック機構の完成により、軟性鏡の鏡視の方向が正確に把握出来る事と、軟性鏡の微少振動を低下させる事が可

能であった。さらに、外筒外部の内視鏡長が 不確定であり、制御性にも問題があったが、 マーカー刻印により内視鏡長調節が円滑に行 える様になった。

開発したオリジナルファイバー関節鏡に関して、画像鮮明度、アングル角度、視野角度、観察深度、グリップ形状、送水流量、彎曲部分の長さ等に関して、臨床使用が十分に可能と判断できた。しかし、オリジナルファイバー内視鏡の耐久性と耐圧性には依然として若干の問題があり、関節内での骨軟骨組織との接触で、損傷をうける可能性があった。また、画像の明るさが不十分である事の問題点もあり、極細化にはグラスファイバー内視鏡では限界があると判断できた。

そこで、今回我々が開発に従事した石英フ ァイバー内視鏡では、コアに純粋石英を用い ており、透過ロスは少なく十分な光量が得ら れた。我々の用いた石英ファイバー内視鏡で は、極細化への挑戦として、外径0.4mm、画素 数6000画素で視野角度70度が可能になった。 これは画期的なことであり、従来の石英ファ イバー内視鏡とは格段に極細化が可能になっ た。開発器機は、非常に柔軟性に富み、耐久 性も優れており十分臨床利用が可能であると 判断できた。石英ファイバー内視鏡において、 極細化は可能となったが、グラスファイバー 内視鏡のような軟性鏡ではなく直視鏡である ため、鏡先端部分の可動性がなく、柔軟性に おいて劣っていた。よって、日常臨床におい ては、グラスファイバー内視鏡と、石英ファ イバー内視鏡を適宜使い分ける必要があると 判断できた。

E. 結論

本研究の結果、オリジナルファイバー関節

鏡の一応の完成が得られた。本医療機器は、 従来の硬性鏡とは異なり、関節内で、その先 端部分を自由に動かす事が可能であり、鏡視 の範囲が格段に広い。視野角度が120度であり、 アングル角度が90度であることから、最大300 度までの範囲を鏡視することが可能である。 これは、従来の硬性鏡の視野範囲とは雲泥の 差であり、日常臨床において、その利用価値 は高いと思われる。また、極細化に関しては、 石英ファイバー内視鏡により達成可能であり、 日常臨床において、その両者の利用価値は高 いと思われる。極細ファイバー関節鏡の開発 において、大きな進歩となり、臨床使用がよ り現実的になると思われる。しかし、手術操 作機能の付加は、現段階で、達成不可能であ り、今後は、ファイバー関節鏡と石英ファイ バー内視鏡の両者の利点を複合した関節鏡の 開発や、手術操作機能を付加した関節鏡の開 発が望まれる。

整形外科疾患の中で、変型性関節症を中心とした関節疾患は大多数をしめている。極細ファイバー関節鏡の開発に伴い、それらの治療に際して、低侵襲での正確な鏡視下手術が可能になり、患者にとってより安全、安心な医療技術の提供を図ることが可能になり、さらには、入院を必要としない外来手術によって、医療費軽減にもつながると期待出来る。

F. 健康危険情報 なし

G. 研究発表

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H. 知的財産権の出願・登録状況 なし

研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Hiromitsu Toyoda, Yo ichi Ito, Kentarou Inu i, Tatsuya Koike, Yos hiki Yamano, Kunio Takaoka	Evaluation of the rotator cu ff tear with Magnetic Reso nance Arthrography	Trans. ORS	49	1164	2003
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EVALUATION OF THE ROTATOR CUFF TEAR WITH MAGNETIC RESONANCE ARTHROGRAPHY

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INTRODUCTION: Rotator cuff tear is one of the common shoulder disorders and surgical repair is very effective for the improvement of shoulder functions. Current surgical technique for rotator cuff tear is an arthroscopical repair or a mini-open repair. Selection of surgical technique should be determined by the appropriate patient's selection based on the pathology of the rotator cuff tear. Magnetic resonance imaging (MRI) has become a useful imaging modality for establishing the diagnosis, confirming or defining pathology and thereby, directing treatment of rotator cuff tears. However, studies in the literature have reported 89% of sensitivity for the evaluation of the rotator cuff tears with MRI and attention has been focused on optimizing scanning protocols to increase accuracy¹⁾. Magnetic resonance arthrography (MRA), which is the intraarticular introduction of dilute gadolinium diethylenetriamine pentaacetic acid (Gd-DTPA) before MR imaging, has been used to significantly improve visualization of the anterior glenoid labrum and rotator cuff lesions2). However, there is little known about the correct comparison between MRI and MRA for the evaluation of the rotator cuff lesions. Computerized image analysis system is reported to be helpful for the accurate evaluation of MR imaging¹⁾. The goal of our study is to elucidate the advantage of the shoulder MRA by comparing the rotator cuff lesions among MRI and MRA and surgical findings with computerized image analysis system.

MATERIALS AND METHODS: Patients: We retrospectively evaluated MRI and MRA of 14 shoulders in 14 consecutive patients with rotator cuff tears that were surgically treated. There were 8 male and 6 female who had a mean age of 61.4 years. (range, 31-73) MR Imaging: With use of a 1.5 tesla MRI (Siemens Vision 1.5T) spin-echo fatsuppressed T1-weighted images were made with or without injection of 10ml of saline solution and 10ml of radiographically contrast medium (Isovist) containing 1% Gd-DTPA into the glenohumeral joint, Computerized measurements on MR Images: Pathology and size of rotator cuff tears were analyzed with MRI and MRA images. Concerning pathological changes, we classified several types of the edge of torn rotator cuff with MRA images. Concerning rotator cuff tear size, we assessed the following two parameters with both of MRI and MRA images. (1) The maximum transverse size and (2) the maximum longitudinal size of each tear were measured by oblique sagittal images and oblique coronal images respectively with use of image analyzing soft wear (NIH image) (Fig.1). All of the measurements were performed by two of us in a blinded fashion and the average measurements were used as data. We analyzed the correlation of each computerized measurement and each actual measurement during surgical procedures. Statistical analyses were performed using paired t-test. Significance was set at the 5% level

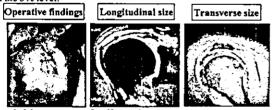


Figure 1: Measurement of cuff tear size

RESULTS: Full thickness rotator cuff tears were recognized in all cases. Sensitivities of full thickness tear on MRI and MRA were 92.9%(13/14) and 100%(14/14) respectively. We could classify five different types of the edge of torn rotator cuff with MRA images and the classifications were as follows: 1) flat end 2) thinning end 3) dull end 4) horizontal tear 5) global tear (Fig.2). Frequencies and mean ages of each classification were as follows: 1) flat end: 28.6%(4/14), 51.8 years old, 2) thinning end: 14.3%(2/14), 70.0 years old, 3) dull end: 28.6%(4/14) 60.3 years old, 4) horizontal tear: 21.4%(3/14), 68.7 years old, 5) global tear: 7.1%(1/14), 66.0 years old. The mean differences of the cuff tear size between MRI findings and surgical findings were -2.6±8.7mm transversely and -12.3±18.6mm longitudinally. (Table 1-Lt) The mean differences of the cuff tear size between MRA findings and surgical

findings were 1.4±4.7mm transversely and -1.7±9.1mm longitudinally. (Table 1-Rt) MRI findings tend to be low estimation both of transversely and longitudinally compared to MRA findings. Both of the maximum transverse and the maximum longitudinal size of the tear are significantly well correlated with surgical findings on MRA compared to MRI. (p<0.05) (r²: 0.834 transversely, 0.739 longitudinally on MRA, r²: 0.273 transversely, 0.004 longitudinally on MRI) (Figure 3)

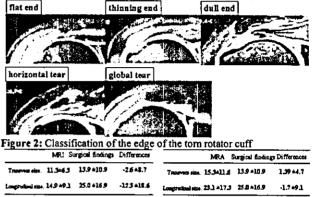


Table 1-Lt: Comparison of MRI and surgical findings and 1-Rt: Comparison of MRA and surgical findings

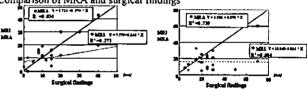


Figure 3-Lt: Correlation of maximum transverse size measured by MRI, MRA and actual size and 3-Rt: Correlation of maximum longitudinal size measured by MRI, MRA and actual size.

DISCUSSION: The most important observation made in this study was that full thickness rotator cuff tear could be accurately visualized, correctly measured and pathologically analyzed with MRA images. In this study rotator cuff tear on MRI are evaluated smaller than those on MRA. This means that the edge of torn rotator cuff was not enough detached to identify in some cases without glenohumeral joint effusion. Because we experienced easier identification of the rotator cuff tear in small number of cases with glenohumeral joint effusion than without it on MRI. In those cases without joint effusion, contrast material could penetrate between glenohumeral joint and subacromial bursa and make a helpful situation for the measurement of tear with MR images. Contrast material could also make a suitable situation to analyze pathological conditions of the tendon and allow us to classify five different types. This is extremely important for the surgical treatment. We could identify the completely similar pathological conditions both on MRA and during surgery. For example, thinning end type showed atrophic changes and dull end type showed hyaline-like degeneration. This means that presurgical predictions of pathological changes and remained rotator cuff function are possible with MRA images. This is crucial for making a plan of rotator cuff repair surgery. Further study is necessary for the investigation of the relationship of our imaging classification and histological changes.

CONCLUSION:MR arthrography is significantly more sensitive to evaluate rotator cuff tear size and pathological condition compared to conventional MRI.

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MODIFIED IMMOBILIZATION AFTER BRISTOW PROCEDURE FOR RECURRENT DISLOCATION OF THE SHOULDER

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INTRODUCTION: Posttraumatic recurrent dislocation of the glenohumeral joint is one of the common shoulder disorders. Many surgical procedures have been performed to treat recurrent dislocation of the shoulder since1960s. The modified Bristow procedure, which was initially described in 1970 by May1), has been thought to be effective in prevention of re-dislocation and has gained popularity over three decades of use. However, studies in the literature have reported about 4% of re-dislocation rate and average motion loss of about 10 degrees of external rotation after the modified Bristow procedure2. There is little known about the challenge to decrease these two major complications after the modified Bristow procedure. Our current strategy is to achieve 0% of re-dislocation rate and to reduce postoperative motion loss of external rotation. We have attempted the modified Bristow procedure with the augmentation by the Bankart repair procedure in order to achieve 0% of re-dislocation rate. We have also attempted modified immobilization in the neutral position with shake-hands' brace postoperatively instead of the conventional immobilization in internal rotation in order to achieve more range of motion of external rotation. The goal of this study was to evaluate the advantage of the modified postoperative immobilization in neutral position after the modified Bristow procedure with special reference to the acquirement of the range of motion of external rotation.

MATERIALS AND METHODS: Patients: We evaluated 15 shoulders in 15 consecutive patients with traumatic anterior dislocation of the shoulders. There were 11 male and 4 female who had a mean age of 28.7 years (range, 21 to 40 years). Average postoperative follow up was 28 months (range, 8 to 50 months). All the patients were overhand athletes of contact sports. They had recurrent anterior shoulder dislocations and the number of previous dislocations was between 3 and 15 (average 7). Patients with a glenoid fracture and those without a Bankart lesion were excluded from this study.

Operative treatment: Repairable anteroinferior glenohumeral ligament and middle glenohumeral ligament were confirmed to be remained arthroscopically in all cases. The modified Bristow procedures without the Bankart repair procedures were performed in 10 cases. The modified Bristow procedures with the augmentation by the Bankart repair procedures were performed in 5 cases. (Fig.1)



Figure 1: Bankart-Bristow procedure

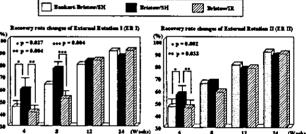
0 to 2 weeks: Immobilization for all day
2 to 3 weeks: Immobilization at night
3 to 4 weeks: Assisted active shoulder elevation
exercise in neutral position
From 4 weeks: Active external rotation exercise
Table-1: Postoperative rehabilitation program

Group	Surgery Pestoperation	
BB-SH	Bankari-Bristow	Neutral rotation
B-SH	Bristow	Neutral rotation
B-IR	Bristow	Internal rotation
Table	of three groups	

Postoperative immobilization: Five shoulders in 10 cases in which the modified Bristow procedures were performed had been immobilized in the position of internal rotation. Other 5 shoulders in 10 cases in which the modified Bristow procedures were performed and all the 5 shoulders in which the modified Bristow procedures with the Bankart repair procedures were performed had been immobilized in the modified position of neutral rotation with shake-hands' brace. Postoperative physical therapy was followed in the same manner. (Table 1) All the 15 shoulders were divided into three groups according to the differences of surgical procedures and postoperative immobilization. (Table 2)

Measurements of range of motion: The motion of external rotation of the shoulder in 0 degree of abduction (ER I) and the motion of external rotation of the shoulder in 90 degrees of abduction (ER II) were measured respectively at 4, 8, 12 and 24 weeks postoperatively. All the measurements were performed by two of us in a blinded fashion and the averages were used as data. Recovery rates (ratio between the motion of operatively treated shoulder and the motion of healthy shoulder) were evaluated respectively. Statistical analyses were performed using unpaired t-test. Significance was set at the 5% level.

RESULTS: Reliability of the Methodology: The coefficient of variation for the methodology precision was within 4.7 degrees of the range of motion and 4.9 % of recovery rate. Recovery rate changes of ER I: Recovery rates were gradually increased postoperatively in all three groups. The recovery rates of Bristow/SH group at 4 and 8 weeks were significantly higher compared to Bristow/IR group. (p=0.004, p=0.004 respectively) The recovery rate of Bankart-Bristow/SH group at 4 weeks was significantly lower compared to Bristow/SH group. However, there was not a significant difference between these two groups at 8 weeks and there were not significant differences among three groups after 12 weeks postoperatively. (Fig. 2 left) Recovery rate changes of ER II: Recovery rates were gradually increased postoperatively in the same manner observed in the changes of ER 1. The recovery rates of Bristow/SH group at 4 weeks were significantly higher compared to Bankart-Bristow/SH group and Bristow/IR group. (p=0.002, p=0.033 respectively) However, there were not significant differences among three groups after 8 weeks postoperatively. (Fig. 2 right) - 111



Briston/SH

Figure 2: Recovery rate changes of ER I and ER II

DISCUSSION: The most important observation made in this study was that early acquirements of the motion of external rotation were recognized in the groups immobilized in the neutral position with shakehands' brace postoperatively. This means that the conventional immobilization in internal rotation induce to stiffen anterior capsuloligamentous complex of the glenohumeral joint and the subscapularis tendon. Stiffness of these anterior components may occasionally cause severe postoperative stiff shoulder and decrease of sport activities of the athletes. In other words, postoperative immobilization in the neutral position might be useful for the prompt recovery to the high-level sport activities of the operatively treated overhand athletes. All 15 shoulders have not been re-dislocated during our follow up period. The advantage of the modified Bristow procedure with the augmentation by the Bankart repair was not yet confirmed in this study. However, recent literature reported that labral coaptation at the Bankart lesion is affected in the neutral position compared with the coaptation achieved with the conventional position of internal rotation3). The subscapularis tendon becomes tight and thereby closes anterior joint cavity, bringing the repaired anterior labroligamentous complex to the glenoid rim in the neutral position. Modified immobilization of the neutral position after the modified Bristow with the Bankart repair procedure might be reasonable for the enhancement of the healing process of the repaired labroligamentous lesion.

CONCLUSION: Modified immobilization of the neutral position induces early acquirements of the motion of external rotation after the Bristow procedures and it might be useful for the prompt recovery to the high-level sport activities of the operatively treated overhand athletes.

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ADVANTAGE OF NAVIGATION SYSTEM FOR SHOULDER ARTHROSCOPY

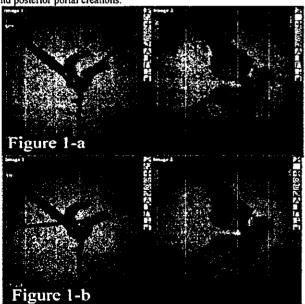
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INTRODUCTION:

In the past decade, the practice of shoulder arthroscopy achieved the status in the orthopaedic armamentarium of a well accepted, if not essential, adjunct for the diagnosis and management of simple and complex shoulder problems. Consequently, the need to develop the requisite skills to perform basic diagnostic shoulder arthroscopy and, in many cases, arthroscopic surgical reconstruction has become more important than ever for any orthopaedic surgeon whose practice includes caring for patients with shoulder problem.

The first step in performing the arthroscopic evaluation of the glenohumeral joint is to insert the posterior cannula. Choose the insertion point after palpating the posterior shoulder anatomy and balloting the humeral head. The exact position and direction to insert the posterior cannula cannot be measured from the surface anatomy; it must be determined after considering the thickness of the soft tissues around the shoulder and the size of the bony anatomy. The second step is to create the anterior portal. The anterior portal is necessary to complete the diagnostic examination of the joint by palpating the anatomy and surgical reconstruction. There are two major anterior portals named a high anterior-superior portal for superior labrum anterior to posterior (SLAP) lesion repair, and an anterior mid-glenoid portal for anterior capsular reconstruction. Both of these anterior and posterior portal creations are essential basic techniques for shoulder arthroscopy. However it is extremely difficult for beginners to accomplish them correctly. If these two portals are created in the wrong position and direction, it makes shoulder arthroscopy to become more difficult as well as to increase the risk of nerve and vessel injuries around the shoulder joint.

Recently, navigation and computer assisted placement techniques have been developed in the field of hip, knee and spine surgeries. ^(1), 2), 3) It is reported and it helped surgical procedures to become more accurate and safe. However, there is not well known about the usefulness of navigation system for shoulder surgery. It is important to evaluate the possibility to use the navigation system for the development of shoulder arthroscopy. The aim of this study is to elucidate the advantage of the navigation system for shoulder arthroscopy with reference to the anterior and posterior portal creations.

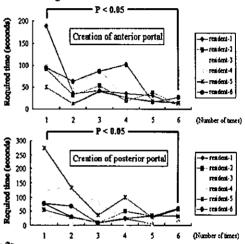


<Figure 1-a and 1-b>

Shoulder navigation radiographic images of antero-posterior glenohumeral view and scapula-Y view demonstrating the anterior model portals (Fig. 1-a) and posterior model portals (Fig. 1-b).

MATERIALS AND METHODS:

Anatomically reproduced shoulder model bones including clavicle, scapula and humerus were used in this study. Six orthopaedic residents without any experiences of shoulder arthrocopy tried to create anterior and posterior portals in the model bones under the navigation control. Our navigation system was a Fluoro. Nav. Application (Medtronic Sofamor Danek, Co., Ltd. Version 2.4.1) and presented two radiographic images of antero-posterior gleno-humeral view and scapula-Y view. (Fig. 1-a and 1-b) Both images demonstrated the model portals created at the ideal location and the arthroscopic obturator handled by an each resident. The time for the model portal and the arthroscopic obturator could overlap to each other was measured as a required time. Each resident tried to create both portals six times. Frequency dependent changes of each required time were evaluated. Statistical analyses were performed using an ANOVA. Significance was set at the 5% level.



<Figure 2>
Required time changes for creation of anterior and posterior portals
RESULTS:

The required time decreased with frequency to create both anterior and posterior portals. (Fig. 2) Average required time for the creation of anterior portal was 92.2 seconds at the first time and decreased to 15.5 seconds at the last time. Average required time for the creation of posterior portal was 107.0 seconds at the first time and decreased to 32.3 seconds at the last time. The required time for both of the portals at the last time was significantly decreased than the first time. (P <0.05) DISCUSSIONS:

The shoulder navigation system used in this study is a passive navigation system, which provides the surgeon with additional information prior to and during the surgical procedure. Our data showed that navigation system could dramatically assist the beginners ascend the steep learning curve for the creations of both anterior and posterior portals in shoulder arthroscopy. Under the navigation control, all the residents could create anterior portal within 30 seconds and posterior portal within 70 seconds. It might help experienced shoulder surgeons as well as beginners to insert anchors for arthroscopic shoulder reconstruction surgeries.

Computer assisted surgery may allow surgeons to be more precise and minimally invasive, in addition to being an excellent research tool. Therefore, future studies have to focus on integrating, arthroscopy, 3-D image-enhanced computer navigation, and virtual kinematics, as well as to increase precision in surgical technique.

CONCLUSION:

Shoulder navigation system could dramatically assist the beginners ascend the steep learning curve for the acquirement of the basic shoulder arthroscopy techniques.

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PROLIFERATIVE CHARACTERIZATION IN ROTATOR CUFF TENDONOPATHY

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INTRODUCTION:

The rotator cuff tendon is the primary dynamic stabilizer of the shoulder joint and is placed under significant stress during overhead activities. Rupture of the rotator cuff tendon results in significant pain and difficulty with overhead activities. In clinical practice, a ruptured rotator cuff tendon rarely heals without surgical reposition. The causes of failure in the natural healing process of ruptured rotator cuff tendon are not well determined. Degenerative changes have been reported to be in the tendon matrix of ruptured rotator cuff tendon and this might be one of the causes of failure. ¹⁾ However, regenerative process has been unknown in the rotator cuff tendonopathy.

Cell proliferation is an important component of tissue morphogenesis and regeneration as well as in the maintenance of homeostasis in many adult tissue. It is a physiological process contributing to the control of natural tissue healing. To understand the mechanism of tendon cell proliferation eventually leads to stimulate the natural healing potential of the ruptured rotator cuff tendon. However, the involvement of proliferation in tendon regeneration has not been evaluated. The aim of this study is to examine the proliferative activity of the tendon cells in rotator cuff tendonopathy.

MATERIALS AND METHODS:

Tissue collection: 17 supraspinatus rotator cuff tendon samples were collected from patients with full thickness rotator cuff tears undergoing shoulder surgeries. The mean age of the rotator cuff ruptured patients was 62.1 years (age range 50 -74 years). The samples consisted of the 3mm length of edges of torn supraspinatus tendon excised prior to surgical reattachment. The rotator cuff repair surgery was performed with mini-open method. The size of the tear was recorded during surgical procedure.

Tendon cell proliferation: Tendon cell proliferation was assessed by immunolocalization of proliferative cell nuclear antigen (PCNA). PCNA has been documented to be useful for studying cell proliferation and we followed the protocol based on the method reported previously by Hall et al. ¹⁾

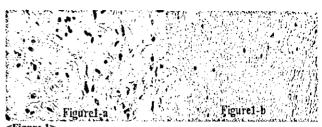
Quantification of tendon cell proliferation: Computerized histomorphometric measurements of the proliferative index (PCNA positive cell number / total cell number x 100 in each examined area) were performed with a MAC scope semiautomatic Image-analysis system (Mitani corporation, JAPAN). We examined two different area consisted of the distal area and the proximal area in each sample. The distal area was located within distal Imm length from the torn edge and the proximal area was located within proximal 1mm length in each sample. Both of these two areas were randomly chosen. Each examination was repeated twice separated by two of us to ensure reproducibility and an average measurement was analysed. Statistical analyses were performed using one factor ANOVA. Significance was set at the 5% level.

RESULTS:

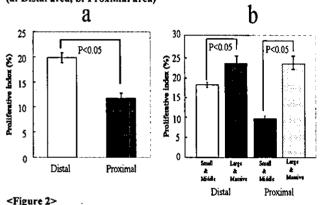
We could detect proliferating tendon cells in our rotator cuff tendon samples by immunohistochemical analysis of PCNA. (Fig. 1)

Relationship between tendon cell location and proliferation: The proliferative index for the distal area was 19.8 %, whereas the proliferative index for the proximal area was 11.8 %. The tendon cells in the distal area were significantly more proliferating compared to the tendon cells in the proximal area. (P<0.05) (Fig. 2-a)

Relationship between rotator cuff tear size and proliferation: Our 10 samples were subdivided into small and middle size tear group and 7 samples were subdivided into large and massive size tear group according to the classification of Cofield et al. 3) The proliferative index in the distal area for large and massive size tear group was significantly higher compared to the small and middle size tear group. (17.8 % and 23.0 % respectively) (P<0.05) The proliferative index in the proximal area for large and massive size tear group was significantly higher compared to the small and middle size tear group. (23.2 % and 9.3 % respectively) (P<0.05) (Fig.2-b)



Representative immunohitochemical analysis of PCNA (x100)
(a: Distal area, b: Proximal area)



(a) Relationship between tendon cell location and proliferation
(b) Relationship between rotator cuff tear size and proliferation

DISCUSSIONS:

The results of this study revealed two important observations. First, the proliferative capacity of the tendon cell is remained after the tendon has been ruptured. Second, the proliferative activity of the tendon cell is related to the location in the torn tendon and the size of the tear. These observations have potentially important implications regarding tendon healing and tendon repair. In both cases, the quantity of tendon tissue formed is important. The quantity relates to the number of tendon cells, which is determined by cell proliferation. Therefore, an understanding of how we might increase cell proliferation during tendon healing or repair is important. The data in this study suggest a possible way to stimulate cell proliferation by directly stimulating tendon cell with intrinsic proliferative capacity. Our data indicate that the tendon cells in the distal area have more proliferative activity than the proximal area as well. This fact is very reasonable for the repair principles, in which detached distal tendon end should be stimulated to proliferate, repositioned to the bone and prepared to regenerate bone tendon interface. The tendon cells with intrinsic proliferative activities can be stimulated to proliferate with mitogenic growth factors such as basic FGF, a potent mitogen for tendon cells. 4) This study provides us the opportunity to treat partial thickness rotator cuff tear by stimulating tendon cells' intrinsic proliferative activities as well as possible improvement of the rotator cuff repair surgeries.

CONCLUSION:

The proliferative activity of the tendon cell is remained after the rotator cuff tear. It is strongly related to the location of the torn tendon and the tear size. This will contribute to our understanding of the enhancement of the healing potential of untreated and surgically treated rotator cuff tendons.

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QUANTITATIVE ASSESSMENT OF ROTATOR CUFF MUSCLES WITH MAGNETIC RESONANCE IMAGING -COMPARISON BETWEEN TEAR SIZE AND MUSCLE ATROPHY-

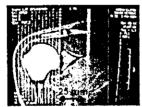
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INTRODUCTION:

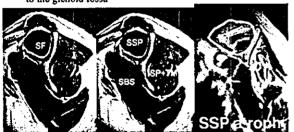
Surgical repair of the rotator cuff tears is effective for improvement of shoulder function. Several factors influence the decision to perform surgery, including the extent of tearing and the underlying pathology of the rotator cuff muscles. Atrophy of rotator cuff muscles as the underlying pathology is an important factor influencing the outcome of rotator cuff repair. Accurate evaluation of the muscular volume is essential for good shoulder reconstruction, though it is quite difficult to measure. Magnetic Resonance (MR) images were reported to be useful for muscular volume assessment as well as rotator cuff tear size evaluations. ^{13, 23, 35} However, factors influencing atrophy of rotator cuff muscles are not well known and the relationship between the muscular volume and the rotator cuff tear size is not well determined. The aim of this study is to evaluate the comparison between these two parameters with MR images.

MATERIALS AND METHODS:

We retrospectively evaluated MR images of 38 shoulders in 38 patients with surgically treated full thickness supraspinatus tendon tears. Subjects included 20 men and 18 women, with a mean age of 60.8 years (Range, 31 to 77). All full-thickness tear sizes were measured transversely and longitudinally with a ruler at surgery. 12 shoulders in 12 people without rotator cuff tear were used as control. Their mean age was 29.3 years old. (Range, 18 to 40) The MR images were scanned into a personal computer and analysed by image-analysing software (NIH Image). Muscle volume was evaluated with oblique sagittal images in the 25 mm medial plane parallel to the glenoid fossa (Fig. 1). Standardized crosssectional areas (Each rotator cuff muscle area divided by the area of the supraspinatus fossa (SF)) were measured as an indicator of the muscular volume according to the method of Zanetti et al (Fig.2). ¹⁾ Supraspinatus (SSP/SF), Infraspinatus and Teres minor (ISP+TM/SF) and Subscapularis (SBS/SF) were measured respectively. We compared these measurements between in the rotator cuff tear group and in the control group. We also analysed correlation between these measurements and tear sizes: longitudinal and transverse sizes. Statistical analyses were performed using one-factor ANOVA. Statistical analysis of correlation was performed using the Fisher's protected least significant difference (Fisher's PLSD). Significance was set at the 5% level.



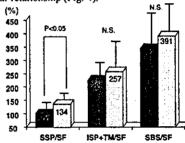
<Figure 1> Oblique sagittal images in the 25 mm medial plane parallel to the glenoid fossa



<Figure 2> Muscular volume measurements with MRI and typical image of SSP atrophy

RESULTS

SSP/SF, ISP+TM/SF and SBS/TM in the control group were 134 ± 41 , 257 ± 103 , 391 ± 137 (%) respectively. The measurements in the rotator cuff tear group were 100 ± 29 , 226 ± 80 , 345 ± 128 (%) respectively and SSP/SF was significantly decreased compared to the control. There were not significant differences on ISP + TM / SF and SBS/SF in two groups (Fig. 3). SSP/SF in the rotator cuff tear group was inversely proportional to the longitudinal tear size (r=-0.377) and the transverse tear size (r=-0.452) in a linear relationship (Fig. 4).



■ Cuff tear □ Control

<Figure 3>Comparison between rotator cuff tear group and control
group

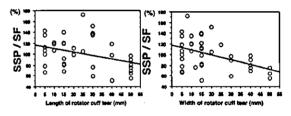


Figure 4-1 Figure 4-2

<Fig.4-1>Correlation between SSP/SF and length of rotator cuff tear $Y = -0.646 \ X + 117.114$, $r = -0.377 \ (P < 0.05)$

<Fig.4-2>Correlation between SSP/SF and width of rotator cuff tear $Y = -0/902 \ X + 118,129$, $r = -0.452 \ (P < 0.05)$

DISCUSSIONS:

Several authors reported about the MR images evaluation of the muscular volume with rotator cuff tears. Tingart et al. reported a significant correlation between MRI and water displacement measurements in shoulder cadaver model and methodological reliability of this measurement. ³⁾ Zanetti et al. reported cross-sectional areas by MRI could discriminate patient with different stages of rotator cuff tears from asymptomatic subjects. Shimizu et al. reported atrophy of the rotator cuff muscles depends on the site of the tears. ³⁾ However, to the best of our knowledge, this paper is the first to show the significant correlation between muscular atrophy and transverse rotator cuff tear size. Our data indicates that surgical repair, particularly of large rotator cuff tears, should be performed before excessive transverse rotator cuff tearing and muscle atrophy is established.

CONCLUSION:

Shoulder muscular atrophy was more correlated to the transverse rotator cuff tear size compared to the longitudinal tear size.

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EVALUATION OF ROTATOR CUFF TEAR SIZE WITH SHOULDER ARTHROGRAPHY

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INTRODUCTION:

Shoulder arthrography was first introduced by Codman in 1934 and graphically demonstrates the integrity, shape and capacity of the glenohumeral joint. It is a valuable diagnostic tool and it can yield an extremely high level of accuracy in diagnosing full thickness rotator cuff tear, adhesive capsulitis, capsular rupture, deformities of the articular cartilages, synovial disorders and abnormalities of the long head of the biceps. Deven small partial tears on the humeral side of the rotator cuff are easily detected as well.

Current Magnetic resonance Imaging (MRI) can assist in establishing the diagnosis of shoulder disorders including rotator cuff tears. However, MRI cannot confirm the final diagnosis of full thickness rotator cuff tear. On the other hand, the accuracy in the diagnosis of full thickness rotator cuff tear by shoulder arthrography has been well established when leakage of contrast material injected into the shoulder joint is seen in the subacromial space. Other significance of the shoulder arthrography in rotator cuff disease is not well known. Furthermore, there is little known about the evaluation of the rotator cuff tear size by shoulder arthrography. The aim of this study is to elucidate the value of shoulder arthrography in assessing the precise size of rotator cuff tear.

MATERIALS AND METHODS:

We retrospectively evaluated shoulder arthrography of 52 shoulders in 47 consecutive patients with full thickness rotator cuff tears that were surgically treated. There were 26 male and 21 female who had a mean age of 60.4 years. (Range, 32-74) We performed shoulder arthrography by contrast material infusion into the glenohumeral joint with a needle guided at the centre of the joint under fluoroscopic control. Minimum volume of the contrast material leakage into the subacromial space from glenohumeral joint was measured as leakage volume. (Fig. 1) Combined range of motion of external and internal rotation of the shoulder in 90 degrees of abduction was also measured under general anesthesia as rotational range of motion. Concerning rotator cuff tear sizes, we assessed the maximum longitudinal size (L), the maximum transverse size (T) and the defect area (A) of each tear during surgical procedures. We analyzed the correlation of each parameter. Statistical analyses were performed using paired t-test. Significance was set at the 5% level



Needle injection Before leakage

At leakage to SAB

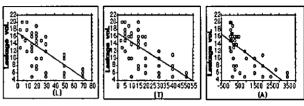
After leakage

<Figure 1>
Leakage volume measurement during shoulder arthrography

RESULTS:

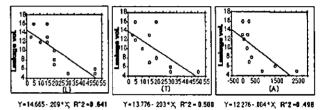
In all data, the longitudinal size, the transverse size and the defect area were inversely proportional to the leakage volume in a linear relationship. ($r^2 = 0.471$, 0.457 and 0.449 respectively) (Fig. 2) In the stiff shoulder group, 12 shoulders recognized below 120 degrees in rotational range of motion, the three parameters of the rotator cuff tear size were inversely proportional to the leakage volume in the same manner. ($r^2 = 0.641$, 0.500 and 0.498 respectively) (Fig. 2) In the notstiff shoulder group, 40 shoulders recognized above 120 degrees in rotational range of motion, same correlations were observed. ($r^2 = 0.578$, 0.515 and 0.530 respectively) (Fig. 2) Classification of the shoulder stiffness helped to enhance the correlation between the leakage volume and the rotator cuff tear size significantly. (P<0.05)

in all data

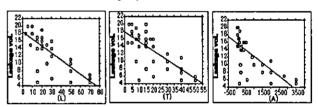


Y=17.141-.1754X, R12=0.471 Y=18.015-.2354X, R12=0.457 Y=14.889-.0034X, R12=0.449

In the stiff shoulder group



In the not-stiff shoulder group



Y-1848-188*X R*2-0.578 Y-17.841-25*X R*2-0.515 Y-15825-004*X R*2-0.530
<Figure 2>

Relationship between leakage volume and longitudinal size (L), transverse size (T) and the defect area (A) in all data and subdivided groups

DISCUSSIONS:

Generally, the size of the rotator cuff tear became larger; the amount of the leakage volume became smaller. Correlation between the longitudinal size and the leakage volume is highest among three parameters. This observation have potentially important implications regarding the mechanism of the leakage from glenohumeral joint into the subacromial space in full thickness rotator cuff tear. Shoulder joint is started to be filled with the contrast material from the center of the glenohumeral joint and progressed from medial to lateral space. In the stiff shoulder group, the narrow joint space may induce the small leakage volume even in the small size of tear. On the other hand, in the not-stiff shoulder group, enough joint space may induce much leakage volume even in the large size of tear. We could recognize that shoulder arthrography is very useful for the evaluation of the shoulder stiffness and the rotator cuff tear size.

CONCLUSION:

We can speculate the rotator cuff tear size by measuring the leakage volume during shoulder arthrography without MRI examination.

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