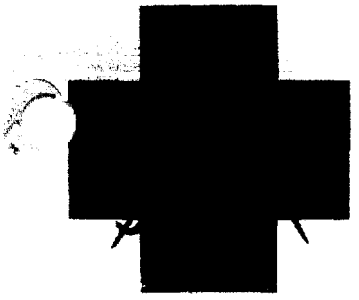

June 8, 1999

John Goode
Food and Drug Administration
CDRH
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Re: Reclassification Petition – Constrained Hip Prosthesis

Dear John:

Enclosed are 7 copies of supplemental information you requested for the petition. The information includes the following:

1. Search engines and criteria used for the bibliography
2. Revised bibliography and copies of two additional articles
3. Summary of **cemented/uncemented** cases and device types (where available)

We are disappointed that we couldn't make the July panel meeting, but we understand. Thank you for informing us about plans for taking the petition to the October 20 panel meeting.

If I can **further** assist you, please feel free to contact me at telephone no. 219-372-15 10, FAX no. 219-372-1790, or E-mail: lonnie.witham@biometmail.com.

Sincerely yours,

Lonnie Witham
OSMA Director

SEARCH ENGINES AND CRITERIA USED FOR BIBLIOGRAPHY

Search Criteria for Bibliography

A literature search was done utilizing WWW.ORTHOGUIDE.COM that includes a Medline Search designed for orthopedics. The keyword search criteria was “constrained, hip”. The date of publication was not specified, so the search was for all articles from 1967 - present. Each document found has a link to further refine the search by clicking (see Related Articles). This was done to search for the articles that included constrained acetabular components. Articles were chosen that contained information on the use of constrained acetabular prostheses, such as those defined in this petition. Articles were excluded that did not report on the usage of constrained acetabular prostheses. References 1 O-18 were chosen in this manner. Please refer to the attached sample screens from the ORTHOGUIDE web page.

References l-9 were chosen for the large number of cases reported. The keyword search criteria was “hip, dislocation”. These references were used to establish an overall dislocation rate following total hip arthroplasty.

Timesaving Medline & Internet Search for Orthopaedics

ORTHOGUIDE.com

Orthopaedic Internet Search	Medline Search Designed for Orthopaedics
Enter Keyword to search Search help ◉ Or ○ And ○ Matchentire phrase	Enter Keyword to search Search help

Categories

Premier Orthopaedic Sites

- **Full Disorder Listing** (MESH1998© NLM)
  Including Arthritis, Back Injuries, Ligament Injuries, Tumors, etc.

- **Specialtic**
  Arthroscopy - Foot And Ankle - Hand - Hip And Knee - Joint Replacement - Pediatrics - Shoulder - Spine - Sports Medicine - Trauma - Tumors

- **Education**
  Board Review - Cases - Classification - Courses - Ethics - Grants - Guidelines - Laboratories - Medication - Research

- **Organizations**
  Associations - Centers - Hospitals - Institutions - Residencies - Societies - Universit t m e n t s

- **Patient Information**
  Arthritis - Avascular Necrosis - Developmental - Disorders - Foot And Ankle - Guides - Hand - Handouts - Hip And Knee - Metabolic - Neuromuscular - Osteoporosis - Pediatrics - Rheumatoid - Shoulder - Spine - Sports Medicine - Support Groups - Trauma - Tumors

- **Management**
  Administration - Ethics - Government - Law

- **Commercial**

- **Disorders**
  Arthritis - Avascular Necrosis - Developmental - Foot And Ankle - Hand - Hip And Knee - Metabolic - Neuromuscular - Osteoporosis - Pediatrics - Rheumatoid - Shoulder - Spine - Sports Medicine - Trauma - Tumors

- **Related Fields**
  Anatomy - Biomechanics - Biomedical - Biostatistics - Disability - Gait Analysis - Infectious Diseases - Kinesiology - Orthotics - Pathology - Physical Theraa - Podiatry - Prosthetics - Radiology - Rheumatology - Sport Science - Workplace

- **Electronic**
  Chatlines - Classified - Forums - General Orthopaedics - Journals - Residencies - Textbooks - Usenet

- **Links**
  Search Engines - Personal - Practice

- **Print**
  Books - Journals - Magazines

- **Misc**
  German - Italian - News - Non English

Timesaving Medline & Internet Search for Orthopaedics

ORTHOGUIDE.com

Searching for keyword(s): constrained, hip

This engine will automatically search the most commonly searched Orthopaedic Related Journals; depending on your keywords, this can significantly reduce the time required to review your search results.

- Choose the journals you like to search (use the control key and your mouse simultaneously to **add** or delete journals),
- You may choose a date of publication (leave blank for **full** search), and other criteria,
- Press Submit,. .
- If you like to add/delete a journal on the list, please **email** us.

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Orthopaedic Journals	**Other Related Journals**
Acta Chir Orthop Traumatol Cech Acta Orthop Belg Acta Orthop Scand Acta Orthop Scand Suppl Aktuelle Probl Chir Orthop Am J Orthop Am J Orthop Surg Am J Sports Med Arch Orthop Trauma Surg Arch Orthop Unfallchir	AJNR Am J Neuroradiol AJR Am J Roentgenol Br J Neurosurg Br J Radiol Br J Radiol Suppl Clin Neurol Neurosurg Clin Neurosurg Clin Radiol Curr Opin Neurol Neurosurg Invest Radiol
Date of Publication	**Limit search to**
Enter the date of publication: . . . . . . Example: **1998/03** will find articles publish in March 1998 Leave blank to search for all articles from **1967-present**	English Language Human Studies Review Articles Only 200 **results displayed per page.**

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112 citations found

Abstract report for the articles selected (default all)

documents on this page through Loansome Doc

Goetz DD, et al. [See Related Articles]
Salvage of total hip instability with a constrained acetabular component.
Clin Orthop. 1998 Oct;(355):171-81.
PMID: 9917602; UI: 99116127.

Goetz DD. et al. [See Related Articles]
Salvage of a recurrently dislocating total hip prosthesis with use of a constrained acetabular component. A retrospective analysis of fifty-six cases.
J Bone Joint Surg Am. 1998 Apr;80(4):502-9.
PMID: 9563379; UI: 98222843.

Joshi A. et al. [See Related Articles]
Prognosis of dislocation after total hip arthroplasty.
J Arthroplasty. 1998 Jan;13(1):17-21.
PMID: 9493533; UI: 98 152527.

Anderson MJ. et al. [See Related Articles]
Constrained acetabular components.
J Arthroplasty. 1994 Feb;9(1): 17-23.
PMID: 8163971; UI: 94216866.

Lombardi AV Jr, et al. [See Related Articles]
Preliminary report on the S-ROM constraining acetabular insert: a retrospective clinical experience.
Orthopedics. 199 1 Mar;14(3):297-303.
PMID: 2020628; UI: 91212312.

REVISED BIBLIOGRAPHY &

COPIES OF TWO ADDITIONAL ARTICLES

The revised bibliography (with references 17 & 18 added) replaces pages 170 and 17 1 in the original petition. Copies of the articles are atached.

BIBLIOGRAPHY / PUBLISHED ARTICLES / ABSTRACTS

A. Dislocation Rate

1. Ali Khan, M.A., Brakenbury, P.H., Reynolds, I.S.: Dislocation Following Total Hip Replacement. *Journal of Bone and Joint Surgery (Br)*, 198 1; 63-B(2): 2 14-8

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4. Madley, SM., et al: Charnley Total Hip Arthroplasty with Use of Improved Techniques of Cementing. The Results after a Minimum of Fifteen Years of Follow-up. *Journal of Bone and Joint Surgery*, 1997 January; 79(1): 53-64

5 Morrey, B.F.: Difficult Complications after Hip Joint Replacement. Dislocation. *Clinical Orthopedics*, 1997 November; (344): 179-87

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7. Schulte, K.R., et al: The Outcome of Charnley Total Hip Arthroplasty with Cement After a Minimum of Twenty Year Follow-up. The Results of One Surgeon. *Journal of Bone and Joint Surgery*, 1993 July; 75(7): 96 1-75

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9. Woo, R.Y., Morrey, B.F. : Dislocations after Total Hip Arthroplasty. *Journal of Bone and Joint Surgery*, 1982 December; 64(9): 1295-306

B. Constrained Hin Replacement

10. Anderson, M.J., Murray, W.R., Skinner, H.B.: Constrained Acetabular Components. *Journal of Arthroplasty*, 1994 February, 9(1): 17-23

11. Cameron, H.U. : Use of a Constrained Acetabular Component in Revision Hip Surgery. *Contemporary Orthopaedics*, 199 1 November, 23(5): 48 l-4

12. Fisher, D. A., Kiley, K.: Constrained Acetabular Cup Disassembly. *Journal of Arthroplasty*, 1994 June; 9(3): 325-9

13. Goetz, D. D., Capello, W.N., et al: Salvage of a Recurrently Dislocating Total Hip Prosthesis with Use of a Constrained Acetabular Component. A Retrospective Analysis of Fifty-six *Cases. Journal of Bone and Joint Surgery,* 1998 April; 80(4): 502-9

14. Goetz, D. D., et al: Salvage of Total Hip Instability with a Constrained Acetabular Component, *Clinical Orthopaedics,* 1998 October, (3 55): 17 l-8 1.

15. Kaper, B. P., Bernini, P.M.: Failure of a Constrained Acetabular Prosthesis of a Total Hip Arthroplasty. *Journal of Bone and Joint Surgery*, 1998 April 80(4): 56 1-5

16. Lombardi, A.V., Jr., Mallory, T.H., Kraus, T.J., Vaughn B.K., Preliminary Report on The S-ROM Constraining Acetabular Insert: A Retrospective Clinical Experience. *Orthopedics*, 1991 March, 14(3): 297-303

17. Bryan, J.W., Reeve, R.E. : Dislocation and Fa · lure of an Articulated Total Hip Replacement, A Case Report. *Orthopedics*, August 1986, Vol. 9/No. 8

18. Russin, L.A., Ashok, S., Indications for Use of a Constrained THR Prosthesis. *Orthopaedic Review* Vol.X/No. 1, January 198 1

Dislocation and Failure of an Articulated Total Hip Replacement

A Case Report

William Jay Bryan, MD*
Robert E. Reeve, BS†

Case Report

A 54-year-old woman with primary osteoarthritis of the left hip underwent a cemented, mechanically-articulated total hip replacement 6 years prior to presentation (Fig. 1). She had been a community ambulator until 6 months prior to admission when she began to have progressive, activity-related anterior left hip pain. Three days prior to admission, there was sudden increase in left hip pain and inability to bear weight. Radiographs taken at this time are seen in Figure 2. It was assumed that the vertically-positioned acetabular component had become loose with secondary hip dislocation.

In the operating room, the patient's hip was opened through a lateral approach. Gray reactive synovium, indicative of metal-to-metal wear, filled the hip cavity The acetabular component was not loose but had been cemented in a vertical position. The chrome cobalt constraining ring had abraded the titanium femoral component neck leading to severe structural wear (Fig. 3A, B). The worn inferior edge of the acetabular component is shown in Figure 4. The constraining ring had fatigue fractured, allowing the femoral prosthesis to dislocate from the acetabular component.

The entire prosthesis and all surrounding bone cement were removed. The slotted and fluted femoral component design used in conjunction with pressurized cement technique required splitting of the femoral shaft to remove the femoral component. Cementless acetabular and femoral components were implanted (Fig. 5). 'The patient was discharged without complication and began a partial weight bearing program for 3 months. At 9 months following revision, the patient is pain-free, and uses a cane for walking.

No sequelae from the massive titanium release have been noted.

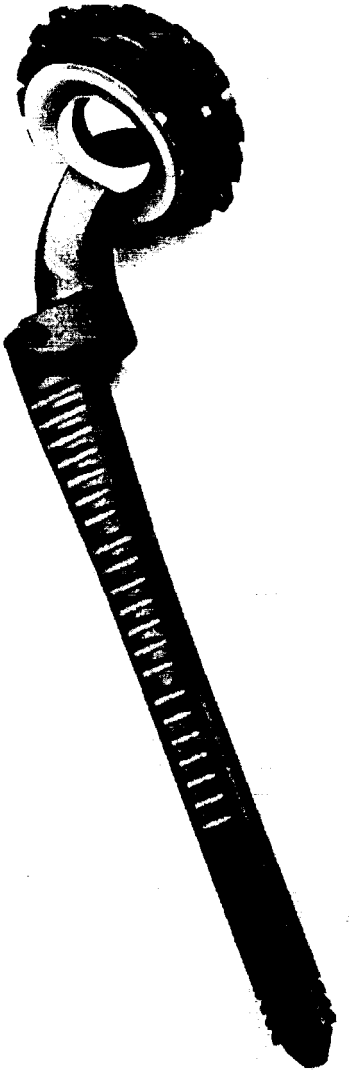

Fig 1: SRN Total Hip Prosthesis featuring a metal-backed polyethylene acetabular socket, a chromecobalt ring which constrains the 28 mm femoral head. The head is welded to a titanium neck and stem which is slotted both laterally to medially (cross slots) and longitudinally (self-broaching flutes).

*Assistant Professor, Orthopedic Surgery, and †Medical Student, Baylor College of Medicine, Houston, Texas.
Reprint requests: Dr. Bryan. Fondren Orthopedic Group. 6560 Fannin #2100, Houston. 7X 77030.

Fig. 2: Radiograph of a dislocated acrylic-cemented articulated SRN Total Hip Prosthesis. The vertical cup position and surrounding radiolucent line gave the impression of component looseness. Note the fragmented constraining ring which has migrated into the soft tissues medial to the femoral component.

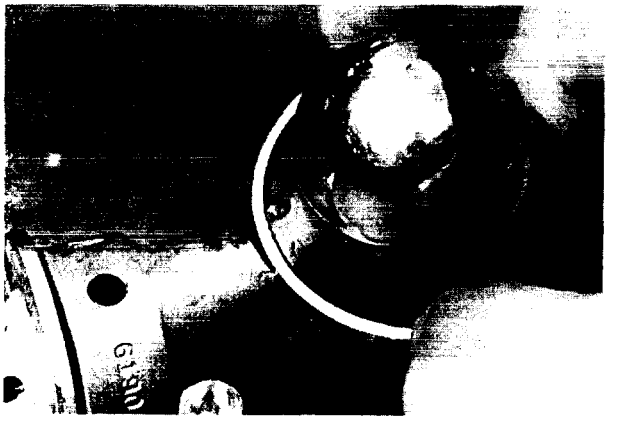

Fig. 3A: Tbe broken chrome-cobalt alloy constraining ring is shown being held in the position thought to have abraded the softer titanium femoral neck.

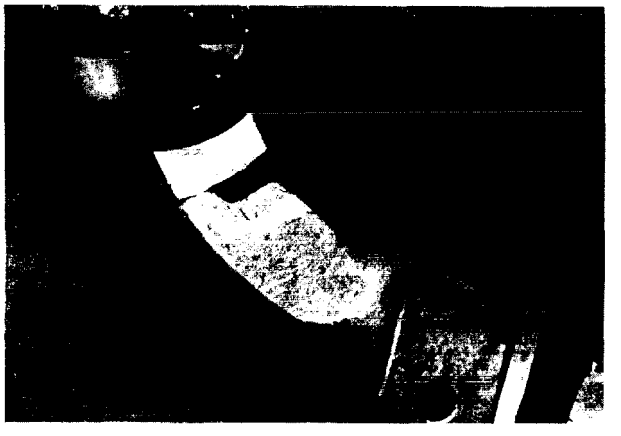

Fig. 3B: Severe structural damage sustained by the femoral prosthesis titanium neck occurred chronically and eventually resulted in fracture of the constraining ring and hip dislocation.

Discussion

Articulated total hip replacement has played a limited role in the orthopedist's approach to hip replacement. Retrospective reviews of articulated total hip systems are few and indicate that this technique should be used in patients who are at high risk for postoperative implant dislocation.[3,4] These include patients with pronounced hip girdle muscle weakness, revision cases where surrounding soft tissue constraints to hip stability are lost, and in elderly and disoriented patients who would not be able to follow the recommended postoperative hip positioning.

To our knowledge this is the first case of an articulated total hip replacement which failed due to fatigue fracture of the constraining ring with eventual hip dislocation. This model of total hip replacement (SRN Total Hip Prosthesis) features a titanium-backed, ultra-high molecular weight polyethylene acetabular component. A chrome cobalt constraining ring secures the 28 mm head within the acetabular socket. The femoral head cannot dislocate with the constraining ring intact. Tne femoral component head is welded to a tivanium (Ti 6AL 4V) neck and stem which has numerous surface irregularities said to be present for bony ingrowth (although the product brochure describes cement fixation).

While the surgeon might have felt that the articulated nature of this prosthesis allows more liberty in acetabular

Fig. 4: The inferior edge of the acetabular cup is worn from contact against the femoral component.

cup placement, such was not the case. Chronic impingement of the constraining ring against the femoral component neck surface eventually resulted in its fatigue fracture and hip dislocation. Femoral prosthesis fracture is a recognized phenomenon with a seemingly minor crack or scratch able to initiate catastrophic failure.[1,2] In this case, severe structural wear of the femoral component required replacement. This was unfortunate; in this case the femoral component was not mechanically loose or malpositioned. A cementless implant system was chosen since cement pressurization techniques were lost with splitting of the femoral shaft. Early clinical success, while encouraging, requires longer follow up before conclusions can be made.

A rather profound reaction to the abraded polyethylene and femoral component titanium was seen. Tissue reaction to titanium and its alloys led to the formation of a fibrous tissue capsule formed of granulation tissue containing macrophages and foreign body giant cells.[5] The histological sections of resected tissue in this case showed no evidence of metaplasia or neoplasm.

A unique case of total hip failure has been presented. Surgeons contemplating the use of an articulated total hip system should be aware of this complication if component malpositioning occurs,

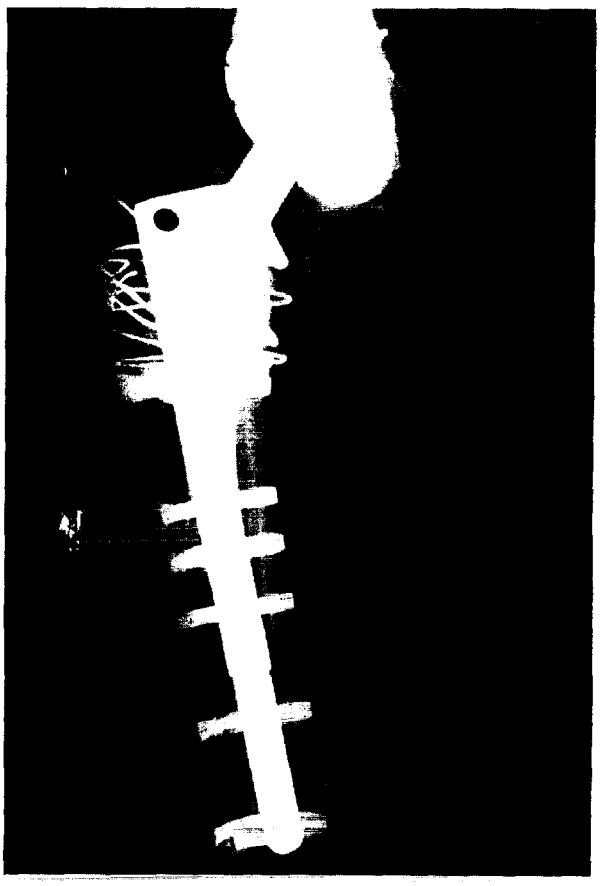

Fig. 5: Radiograph of postoperative revision to a cementless system featuring a metal backed screw in acetabular component and porous metal femoral component. Several Parnhan bands were necessary along with bone graft to reconstitute the proximal femur which was surgically split.

References

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4. Russin LA, Sonni A: Indications for the use of a constrained THR prosthesis. *Orthopedic Review* 1981; 10:81-84.
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Indications for the Use of a Constrained THR Prosthesis

Lester A. Russin, MD and Ashok Sonni, MBBS***

This paper describes the insertion of a Russin-Sivash constrained total hip prosthesis in the right hip of a 56-year-old woman with a ?7-par history of multiple hip prosthesis failures. Constrained prostheses such as rhe Russin-Sivash are not overly popular in the United States. but are used extensively in the Soviet Union and Eastern Europe. This case is presented to illustrate the indications for use of a constrained prosthesis.

Case Report

The patient sustained a fracture of the neck of the right femur when she was struck by a car in 1950. The pins used in June 1950 to repair the fracture went through the femoral head and penetrated the acetabulum (Fig 1A). The fracture began to collapse, causing pain. The pins were removed in December 1930. Subsequently the femoral head dislocated. The fracture failed to unite and infection set in (Fig. 1B).

To combat the infection, a Girdlestone pro cedure was performed *in* February 1951 (Fig 1C). After the infection was eliminated, a Judet prosthesis was installed. The Judet prosthesis failed in March 1953, and was replaced with a Minneapolis metal prosthesis.

*Dr. Russin is Emeritus Chairman, Department o f Orthopaedics and Rehabilitation, Mount Sinai Medical Center, Miami Beach, Florida.

**Dr. Sonni is a Resident in Orthopaedic Surgery, Department of Orthopaedics and Rehabilitation, Mount Sinai Medical Center, Miami Beach. Florida.

The stem of the Minneapolis metal prosthesis fr :tured in August 1972 causing pain in the hip (Fig. 1D). It was replaced with a Tronzo total hip prosthesis (Fig 2A). Several months later the femoral shaft fractured at the distal end of the femur, below the prosthesis. This fracture healed uneventfully, but lacer a recurrence of pain signaled loosening of the Tronzo prosthesis itself. It was removed in January 1974 and a Bechrol total hip prosthesis inserted.

The Bechtol prosthesis was prone to recurrent dislocations and subluxations (Fig 2B). In an attempt to prevent them, a lateral transfer of the greater trochanter was performed in October 1974. However the dislocations continued. The patient was referred to us in August 1977.

On examination, the right hip revealed flexion to 80° with pain, abduction to 45° and adducrion to 30°. When the hip *was* placed in 15° external rotation, the prosthesis appeared to subluxate; reduction occurred when the hip was placed back into internal rotation. Also noted was an 8.9 cm shortening of the right lower extremity. Admission x-rays revealed marked osteopenia of the femur with lucency around the distal portion of the prosthesis within the shaft of the femur. suggesting that the prosthesis had become loose. A decision was made to remove the Bechtol prosthesis and substitute a Russin-Sivash constrained total hip prosthesis.

Surgery was performed on August 23, 1977.

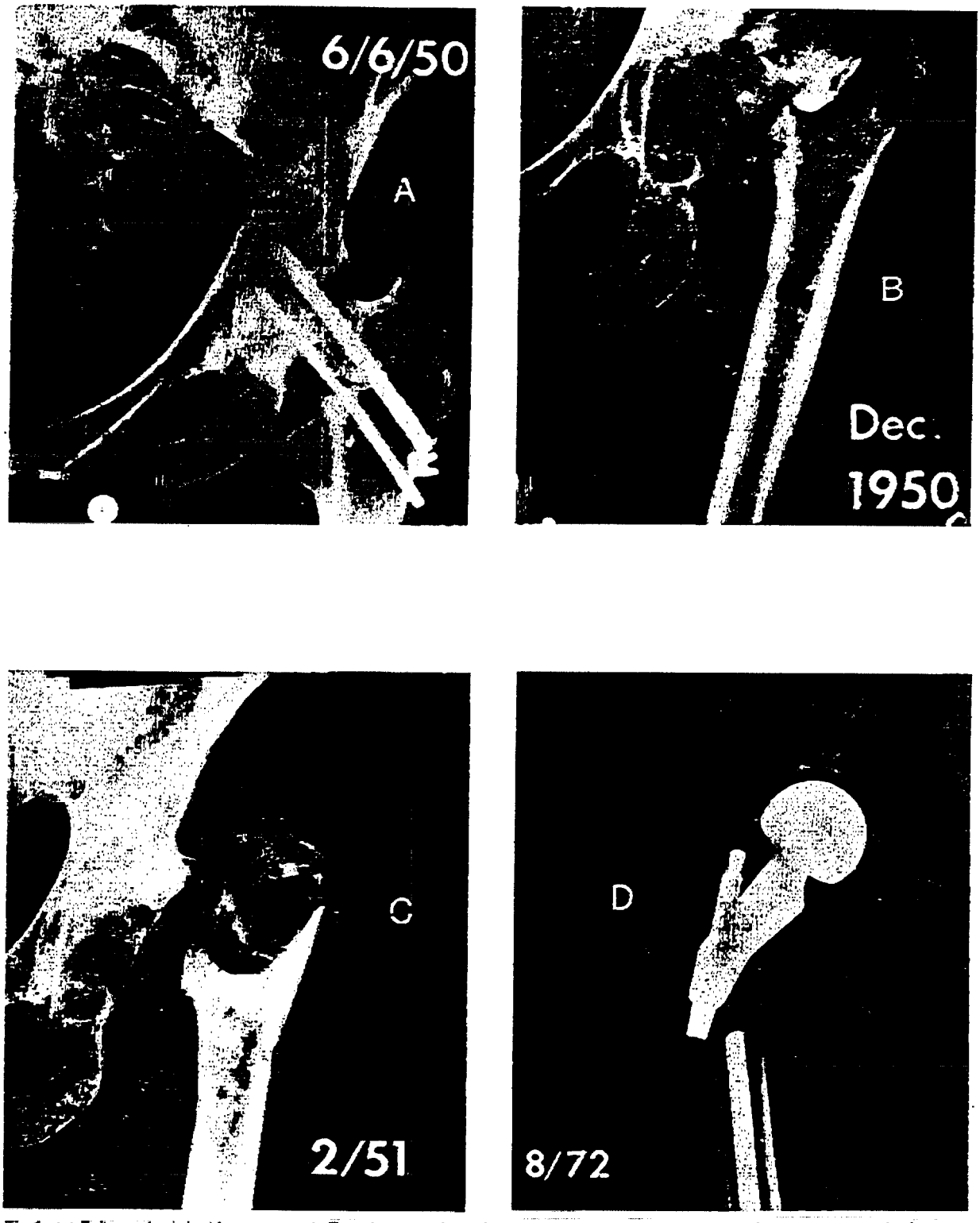

Fig 1. *(A) Failure of original fracture repair. The pins went through the femoral head and penetrated the acetabulum. The fracture started to collapse, causing Pain. June, 1950. (B) Dislocation of femoral head following removal of pins. The fracture failed to unite and infection set in. December, 1950. (C) Girdlestone procedure performed to combat infection. February, 1951. (D) Stem fracture of Minneapolis metal prosthesis, causing pain in the hip. August, 1972.*

The Bechcol prosthesis and associarcd old cement were removed. the femoral shaft and acetabulum prepared to receive the new prosthesis, and the Russin-Sivash consmined total hip prosthesis inserted and cemented in place with methyl methacrylate.

The patient's postoperative course was rela-

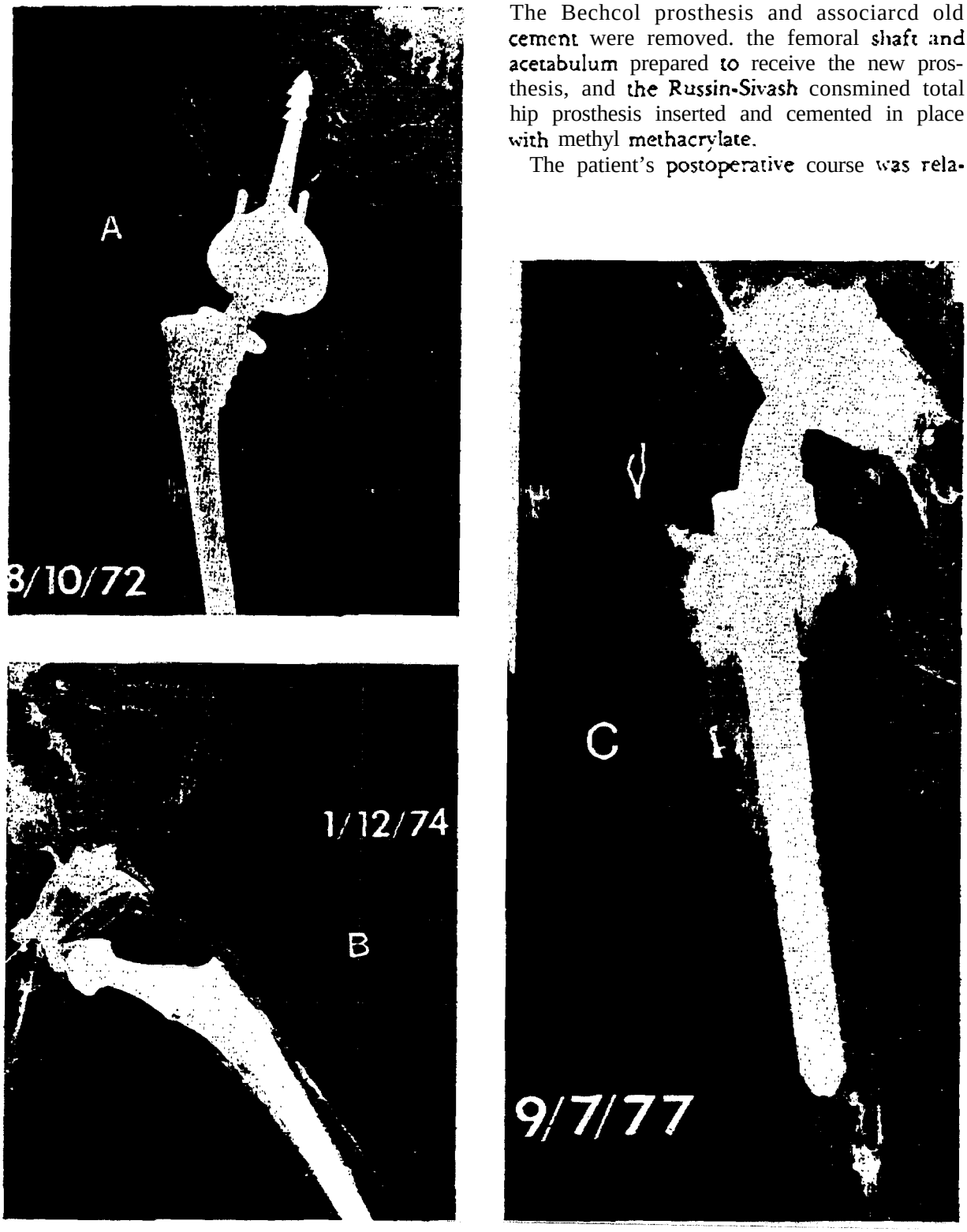

Fig 2. (A) Tronzo total hip prosthesis inserted to replace Minneapolis metal prosthesis. August, 1972. (B) Bechtol total hip prosthesis in dislocated state. Dislocations and *subluxations occurred repeatedly* with *the Bechtol prosthesis. January. 1974 (C) Russin-Sivash constrained total hip prosthesis 15 days after insertion. September. 7977.*

tively uneventful. She was allowed out of bed *in* a chair on the third postoperadve da);. Gait training with partial weightbearing on the right hip began on the seventh postoperative day. She soon became ambulatory with the aid of crutches. Stitches were removed 12 days post-operatively, and the patient was discharged 16 days postoperatively. Postoperative x-rays (Fig 2C) showed good placement of the prosthesis.

Following insertion of the Russin-Sivash constrained total hip prosthesis, the patient has remained painfree and enjoys unlimited ambulation with the aid of a cane. The right hip flexes LO 60°, abducts to 50°, and adducts to 50°. It is capable of 70° external rotation and *10°* internal rotation. Because the patient's right leg remains 8.9 cm shorter than her left. her right shoe was provided with a 5.1 cm lift on.the heel and a 3.8 cm lift on the sole.

Discussion

The patient described above underwent multiple procedures for repair of her right hip over a 27-year period. The review of her history, examination, and x-rays prior to the 1977 surgery cook into account the kinesiological features. the previous shortening of her right leg, muscle loss, and loss of strength in *the* remaining hip ,muscles (especially the abductors), potential technical difficulties resulting from the loss of landmarks, and rhc patient's worry over the prospect of future dislocations. These considerations all led us to conclude that only a constrained total hip prosthesis would be suitable in this instance.

Our previous experience with two adult cerebral palsied patients and one patient with arthrosis of the hip and associated Parkinson's disease has only verified and reinforced our opinion as co the efficacy of the constrained total hip prosthesis in this type of condition.

Summary

A case report illustrates the indications for use of a constrained total hip prosthesis. The patient had experienced several previous hip prosthesis failures. Among the indications for insertion of a constrained total hip prosthesis were kinesiological features, previous shortening of the right leg, loss of musculature, and loss of strength in remaining musculature in the hip region. Following insertion of a Russin-Sivash constrained total hip prosthesis in 1977, the patient has remained painfree and enjoys unlimited ambulation with the aid of a cane.

Clinical Use of Hyperbaric Oxygen Conference in June

The Sixth Annual Conference on the Clinical Application of Hyperberic Oxygen will be held June IO-12 at the Memorial Hospital Medical Center of the University of California, Long Beach, Calif.

Currently accepted uses of hyperbaric *oxygen will* be discussed in plenary sessions at the clinically oriented conference. This will include the presentation of original papers, workshops. sound slides and scientific exhibits.

For further information contact G. B. Hart, MD, Director, Baromedical Department, Memorial Hospital Medical Center, 2801 Atlantic Avenue, Long Beach, California 90801.

SUMMARY OF CEMENTED / UNCEMENTED PROCEDURES

DEVICE TYPES

The information in these summaries is limited by availability.

NUMBER of CEMENTED & UNCEMENTED PROCEDURES

FROM PUBLISHED ARTICLES

	ACETABULAR CUPS		FEMORAL STEMS	
	Cemented	Uncemented	Cemented	Uncemented
REF. #10	2	19	<21 Undetermined>	
REF. #11		1	< 1 Undetermined>	
REF. #12		2	1	1
REF. #13		36	33	5
REF. #14	12	89	92	9
REF. #15		2		2
REF. #16		57	<57 Undetermined>	
REF. #17		1		1
REF. #18	1			
TOTAL	15	207	127	18
			79 undetermined	

FROM BIOMET RINGLOC STUDY

	ACETABULAR CUPS		FEMORAL STEMS	
	Cemented	Uncemented	Cemented	Uncemented
TOTAL	22	60	37	33
	<72 Underemined>		<84 Undetermined>	

RECLASSIFICATION PETITION – CONSTRAINED HIP

Summary of Devices and Fixation Methods

REFERENCE

10. Anderson, M.J., Murray, W.R, Skinner, H.B.: Constrained Acetabular Components. *Journal of Arthroplasty*, **1994 February, 9(1): 17-23**

Number of Cases: 22 consecutive (1 tumor case excluded leaving 2 1)
Acetabular Description:
Polyethylene liner: S-ROM Constrained Acetabular Liner
Metal shell: Porous-coated Arthopor (Joint Medical Products Corporation)

Previous procedure
Acetabular Cups in Place
13 uncemented porous coated cups
5 **cemented** metal-backed cups
2 cemented all-polyethylene cups
1 bipolar cup

Constrained procedure (8 cases required liner change only)
Acetabular metal shell
19 uncemented porous-coated Arthopor shells
2 cemented Arthopor II shells
Acetabular liner
22 S-ROM constrained acetabular liners

Note: Femoral components were not identified other than the femoral head size of the 18 previous THA dislocation patients: 6 cases with 26mm, 11 cases with 32mm, and 1 case with a bipolar.

REFERENCE

11. Cameron, H.U.: Use of a Constrained Acetabular Component in Revision Hip Surgery. *Contemporary Orthopaedics*, **1991 November, 23(5): 481-4**

Number of Cases: 1 case history (stated that 6 cases were performed over 4 years)
Acetabular Description:
Polyethylene liner: S-ROM Constrained Acetabular Liner
Metal shell: S-ROM porous-coated metal shell

Previous procedure: Girdlestone (7 years old procedure)
Acetabular Cup in Place: none

Constrained procedure
Acetabular metal shell and liner: Uncemented porous-coated S-ROM shell & liner

REFERENCE

12. **Fisher, D. A., Kiley, K.: Constrained Acetabular Cup Disassembly. *Journal of Arthroplasty*, 1994 June; 9(3): 325-9**

Number of Cases: 2 case reports
Acetabular Description:
Polyethylene liner: S-ROM Constrained Acetabular Liner
Metal shell: S-ROM porous-coated Supercup

Previous procedure
Acetabular Cups in Place
2 uncemented porous-coated S-ROM Supercups (most recent previous procedure)
Femoral Stems in Place
1 **cemented #3** Precision Stem (Howmedica) **w/allograft** and 2 **AO** plates
1 uncemented unknown **w/28mm** head

Constrained procedure
Acetabular metal shell
1 **uncemented 60mm** Arthopor II
1 **uncemented** 61mm porous-coated S-ROM Supercup
Acetabular liner
2 S-ROM Constrained Acetabular Liners (1 32mm & 1 28mm)

REFERENCE

13. **Goetz, D. D., Capello, W.N., et al: Salvage of a Recurrently Dislocating Total Hip Prosthesis with Use of a Constrained Acetabular Component. A Retrospective Analysis of Fifty-six Cases. *Journal of Bone and Joint Surgery*, 1998 April; 80(4): 502-9**

Number of Cases: 56 consecutive (1 lost to follow-up)
Note: Of the 56 consecutive cases 10 constrained cups were implanted **with cement** and 40 were implanted **without cement. 8 uncemented** cups were liner replacements only. 38 patients were living at latest follow-up and 16 had died of unrelated causes.

Acetabular Description:
Polyethylene liner: Omnifit Constrained Liner (Osteonics)
Metal shell: Osteonics Metal Acetabular Shell

Previous procedure
Acetabular Cups in Place
7 Girdlestone (no implant)
2 Arthrodesis (no implant)
47 unknown (various types)
Femoral Stems in Place
40 well fixed femoral stems of various types (33 **cemented, 7 uncemented)**

Constrained Procedure

Acetabular metal shell & liner

38 Living Patients

27 uncemented new Omnifit shell & constrained liner

7 uncemented old shell and new Omnifit constrained liner

1 **cemented** new Omnifit constrained liner directly (no metal shell)

2 uncemented old shell & new Omnifit liner cemented into shell

1 lost to follow-up

Femoral Stems

38 Living Patients

9 **cemented** new femoral stems (type unknown)

24 cemented old well-fixed femoral stems (left in place)

5 uncemented old well-fixed femoral stems (left in place)

Note: No new stems were implanted without cement.

REFERENCE

14. Goetz, D. D., et al: Salvage of Total Hip Instability with a Constrained Acetabular Component, *Clinical Orthopaedics*, 1998 October, (355): 171-81.

Number of Cases: 101 (in 98 patients)

Acetabular Description:

Polyethylene liner: Omnifit Constrained Acetabular Bearing Insert (Osteonics)

Metal shell: Osteonics standard profile metal acetabular shell

Previous procedure

Acetabular Cups in Place

9 well-fixed Osteonics **uncemented** metal shells (left in place)

remainder unknown

Constrained procedure

Acetabular metal shells & liners

6 new Osteonics liners **cemented** into old shells (types unknown)

6 new Osteonics liners assembled into **cemented** new Osteonics metal shells

9 new Osteonics liners assembled into old **uncemented** Osteonics shells

80 new Osteonics liners assembled into new **uncemented** Osteonics shells

Femoral stems

39 cemented stems left in place (types unknown)

8 uncemented stems left in place (types unknown)

53 cemented new stems (types unknown)

1 **uncemeuted** new stem (type unknown)

REFERENCE

15. Kaper, B. P., Bernini, P.M.: Failure of a Constrained Acetabular Prosthesis of a Total Hip Arthroplasty. *Journal of Bone and Joint Surgery*, 1998 April 80(4): 561-5

Number of Cases: 2 case histories are detailed (from a total of 4 failures of 12 cases)

Acetabular Description:

Polyethylene liner: S-ROM Constrained Acetabular Liner

Metal shell: S-ROM porous-coated shell

Previous procedure

Acetabular Cups in Place

2 uncemented S-ROM porous-coated constrained acetabular cups

Femoral Stems in Place

1 **uncemented** SRN Femoral Component (Joint Medical Products Corp.)

1 **uncemented** Porous Coated Anatomic **(PCA)** femoral stem

Constrained procedure (latest of multiple revisions - 2 case histories)

Acetabular metal shell

2 uncemented S-ROM porous-coated metal shells

Acetabular liner

2 S-ROM Constrained Acetabular Liners

Femoral stems

2 uncemented (1 retained SRN and 1 retained PCA)

REFERENCE

16. Lombardi, A.V., Jr., Mallory, T.H., Kraus, T.J., Vaughn, B.K., Preliminary Report on The S-ROM Constraining Acetabular Insert: A Retrospective Clinical Experience. *Orthopedics*, 1991 March, 14(3): 297-303

Number of cases: 57 cases (55 patients)

Acetabular Description:

Polyethylene liner: S-ROM Constrained Acetabular Insert

Metal shell: S-ROM Porous-Coated Supercup

Previous procedure

Acetabular Cups in Place

unknown

Femoral Stems in Place

Unknown

Note: The article reports the primary diagnoses only, and that there were 5 1 revision cases and 6 primary cases performed with the constrained S-ROM cup.

Constrained procedure
Acetabular metal shell
57 uncemented S-ROM Porous-Coated Supercups
Acetabular liner
57 S-ROM Constrained Acetabular Inserts

REFERENCE

17. Bryan, J.W., Reeve, RE.: Dislocation and Failure of an Articulated Total Hip Replacement, A Case Report. *Orthopedics*, August 1986, Vol. 9/No. 8

Number of cases: 1 case (case history)
Acetabular Description:
Polyethylene liner: SRN mechanically articulated polyethylene socket
Metal shell: SRN metal shell

Previous procedure
Acetabular Cup and Femoral Stem in Place
1 **cemented** SRN Constrained Total Hip Prosthesis

Revision Procedure
Acetabular Cup and Femoral Stem Used
1 **uncemented** metal backed screw-in acetabular component (unknown type)
1 **uucemented** porous-coated femoral component (unknown type)

REFERENCE

18. Russin, L.A., Ashok, S., Indications for Use of a Constrained THR Prosthesis. *Orthopaedic Review* Vol.X/No.1, January 1981

Number of Cases: 1 case (case report)
Previous procedure: cemented Bechtol prosthesis
Constrained Procedure: cemented Russin-Sivash Constrained Total Hip Prosthesis